United States
Consumer Product Safety Commission

This document has been electronically approved and signed.

Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: January 11, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
Mary A. House, Attorney, Regulatory Affairs

SUBJECT: Notice of Proposed Rulemaking: Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

---

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: February 01, 2023

To implement Reese's Law (Pub. L. No. 117-171; 15 U.S.C. § 2056e), the Office of the General Counsel is forwarding for the Commission's consideration a staff briefing package recommending publication in the *Federal Register* of the attached draft proposed rule to establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries.

To eliminate or adequately reduce the risk of serious injury or death from ingestion of button cell or coin batteries by children 6 years old and younger, the draft proposed rule includes performance requirements for battery compartments of consumer products that contain button cell or coin batteries. The draft proposed rule also requires warning labels on the packaging of button cell or coin batteries, and the packaging, battery compartments, and instructions or manuals that accompany consumer products that contain button cell or coin batteries.

Pursuant to section 27(e) of the Consumer Product Safety Act (15 U.S.C. § 2076(e)), the draft proposed rule further requires manufacturers and importers of button cell or coin batteries, and of consumer products containing button cell or coin batteries, to provide consumers, at the point of sale, both online and in-stores, with performance and technical data related to the safety of button cell or coin batteries.

Please indicate your vote on the following options:

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission

I. Approve publication of the attached notice in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

II. Approve publication of the attached notice in the *Federal Register*, with the specified changes.

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the attached notice in the *Federal Register*.

_____ _____
(Signature) (Date)

IV. Take other action specified below.

_____

_____

_____

_____

_____ _____
(Signature) (Date)

Attachment: Notice of Proposed Rulemaking: Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1263

[CPSC Docket No. 2023-XXXX]

Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: As required by Reese's Law, Pub. L. No. 117-171, to eliminate or adequately reduce the risk of injury from ingestion of button cell or coin batteries by children 6 years old and younger, the U.S. Consumer Product Safety Commission (CPSC or Commission) proposes a rule to establish performance requirements for battery compartments on consumer products that contain, or are designed to use, one or more button cell or coin batteries. The proposed rule also requires warning labels on the packaging of button cell or coin batteries, as well as on the packaging, battery compartments, and accompanying instructions and manuals of consumer products containing button cell or coin batteries. In addition to implementing Reese's Law, the proposed rule requires manufacturers and importers of button cell or coin batteries, and consumer products containing such batteries, to notify consumers of performance and technical data related to the safety of such batteries at the point of sale, both online and in stores. Consumer products subject to the rule must be tested and certified as compliant with the rule.

DATES: Submit comments by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the testing and certification, and the marking, labeling, and instructional literature requirements of the proposed mandatory standard, should be directed to the Office of Information and Regulatory Affairs, the

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Office of Management and Budget, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

You may submit all other comments, identified by Docket No. CPSC–2023–XXXX, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: https://www.regulations.gov. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (e-mail), except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may e-mail them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: https://www.regulations.gov. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: https://www.regulations.gov, and insert the docket number, CPSC–2023–XXXX, into the "Search" box, and follow the prompts.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

FOR FURTHER INFORMATION CONTACT: For further information contact: Daniel Taxier, Project Manager, Division of Mechanical and Combustion Engineering, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; (301) 987-2211, or by e-mail to: dtaxier@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority[1]

A. Explanation of Reese's Law

President Biden signed Reese's Law, Pub. L. No. 117-171, into law on August 16, 2022. 15 U.S.C. 2056e. The purpose of Reese's Law is to protect children 6 years old and younger against hazards associated with the ingestion of button cell or coin batteries. Based on a review of the medical literature, CPSC incident data, and data from the National Capital Poison Center (NCPC), an ingestion hazard is associated with swallowing or inserting a button cell or coin battery that becomes lodged (impacted) in the body (typically in the esophagus but potentially in the airways or gastrointestinal tract), which can cause death or serious injury through choking, generation of hazardous chemicals, leaking of hazardous chemicals, electrical burns, pressure necrosis (tissue damage), or other means. *See* Tab B of Staff's NPR Briefing Package.[2]

Although this proposed rule is primarily intended to address hazards associated with oral ingestion of button cell or coin batteries by children 6 years old or younger, the performance and labeling requirements in the rule will likely also reduce insertion of these batteries in the nose. The data on button cell or coin batteries demonstrate that insertions of batteries into the nose can be aspirated into the trachea and become an ingestion that lodges in the esophagus. This scenario

[1] On [insert date], the Commission voted (x-x) to publish this notice of proposed rulemaking.
[2] The information in this proposed rule is based on information and analysis provided in the January 11, 2023, Staff Briefing Package: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's NPR Briefing Package), available at: [insert link].

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

presents the same hazard as an oral ingestion of a button cell or coin battery. Accordingly, the proposed labeling requirements include warnings regarding ingestion and insertion.

To address ingestion of button cell or coin batteries, section 2(a) of Reese's Law requires the Commission to publish a final consumer product safety standard for button cell or coin batteries, and consumer products containing button cell or coin batteries, not later than 1 year after the date of enactment, meaning by August 16, 2023. 15 U.S.C. 2056e(a). A "button cell or coin battery" is broadly defined in section 5 of Reese's Law as "(A) a single cell battery with a diameter greater than the height of the battery; or (B) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard."[3] Thus, the definition of an in-scope product does not depend on the battery chemistry, but rather the shape of the battery (which contributes to the ingestion-related risk) and, as stated in part (B), whether the battery otherwise is associated with an ingestion hazard, which is consistent with the stated purpose in section 2(a)(1) of Reese's Law. 15 U.S.C. 2056e(a)(1).

This proposed rule focuses on addressing button cell and coin batteries under part (A) of the definition because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type or degree of ingestion hazard as button cell or coin batteries. Cylindrical batteries can pose a choking hazard, and CPSC is aware that consumers have ingested cylindrical batteries. However, the medical literature shows that injury or death due to ingestion of a cylindrical battery is rare. *See* Staff's NPR Briefing Package at Tab B, Section II.B. Consequently, the Commission is not including cylindrical batteries in the proposed rule at this time. If CPSC becomes aware of a serious ingestion hazard associated with another battery type, section 2(g) of Reese's Law allows the Commission to undertake additional rulemaking to address the hazard at any time. 15 U.S.C. 2056e(g).

[3] Definitions in section 5 of Reese's Law are codified in the Notes to 15 U.S.C. 2056e.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Reese's Law defines a "consumer product containing button cell or coin batteries" as "a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately."[4] We preliminarily construe this definition to include products that are not sold with a battery, if they are designed to use a button cell or coin battery.

Section 2 of Reese's Law requires the Commission to issue a rule containing performance requirements for consumer products that contain button cell or coin batteries, and labeling requirements. Any rule issued under section 2(a) of Reese's Law will be considered a consumer product safety rule promulgated under section 9 of the Consumer Product Safety Act (CPSA). 15 U.S.C. 2056e(c); 15 U.S.C. 2058. CPSC's rule under section 2 of Reese's Law must be issued in accordance with the notice and comment provisions of the Administrative Procedure Act (APA). 5 U.S.C. 553; 15 U.S.C. 2056e(a). Insofar as this proposed rule is based on section 2 of Reese's Law, it sets forth provisions implementing the statute's required performance and labeling requirements—and "only" those requirements, as specified in section 2(a). The standard promulgated under section 2(a) of Reese's Law shall apply to consumer products and battery packaging manufactured or imported after the effective date of the standard. *See* 15 U.S.C. 2056e Notes.

Section 2(a)(1) of Reese's Law mandates that the rule must include performance requirements for button cell or coin battery compartments on consumer products to secure them in a manner that eliminates or adequately reduces the risk of injury from the ingestion of button cell or coin batteries by children who are 6 years old or younger, during reasonably foreseeable use or misuse of the product. 15 U.S.C. 2056e(a)(1).

[4] 15 U.S.C. 2056e Notes. The term "consumer product" has the same meaning as that in section 3(a) of the Consumer Product Safety Act (CPSA). 15 U.S.C. 2052(a).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Section 2(a)(2) of Reese's Law mandates warning label requirements in a rule. Warnings are required:

- On the packaging of button cell or coin batteries (15 U.S.C. 2056e(a)(2)(A));
- On the packaging of consumer products containing button cell or coin batteries (15 U.S.C. 2056e(a)(2)(A));
- In any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries (15 U.S.C. 2056e(a)(2)(B));
- As practicable, directly on a consumer product that contains button cell or coin batteries in a manner visible to the consumer upon installation or replacement of the button cell or coin battery (15 U.S.C. 2056e(a)(2)(C)(i));
- As practicable, in the case of a product for which the battery is not intended to be replaced or installed by the consumer, to be included directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information shall be placed on the packaging or instructions (15 U.S.C. 2056e(a)(2)(C)(ii)).

Warning labels required by section 2(a) of Reese's Law must: (1) clearly identify the hazard of ingestion; and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice. 15 U.S.C. 2056e(b).

Section 4 of Reese's Law specifically exempts from the performance and labeling requirements in section 2 of the law, any toy product[5] that is in compliance with the battery accessibility and labeling requirements in 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys. 15 U.S.C. 2056e Notes. However, children's products that contain button cell or

[5] Consistent with 16 CFR part 1250, a "toy product" is defined as "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." Notes to 15 U.S.C. 2056e.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

coin batteries and that are not a "toy product," would be required to meet the performance and labeling requirements in this proposed rule. An example of such products would be children's apparel, such as shoes, that light up and use a button cell or coin battery as a power source.

Section 2(d) of Reese's Law (15 U.S.C 2056e(d)(1)) requires the Commission to rely on the provisions in a voluntary standard if, before promulgating a final rule, the Commission determines that: (A) a voluntary standard exists that meets the requirements for a standard promulgated under section 2(a) of Reese's Law with respect to any consumer product, and (B) the voluntary standard is in effect at the time of the determination by the Commission, or will be in effect not later than the date that is 180 days after the date of the enactment of Reese's Law (*i.e*., February 12, 2023). The Commission must publish in the *Federal Register,* any determination regarding a voluntary standard under this provision. 15 U.S.C. 2056e(d)(2).

As set forth in section IV.A and V.A of this preamble, the Commission preliminarily determines that no existing voluntary standard fully meets the requirements in section 2(a) of Reese's Law. Accordingly, the Commission is proposing a rule that would meet the requirements of Reese's Law for all consumer products within the scope of the rule that is based on modifications to several existing voluntary standards. Because the Commission is proposing its own rule under Reese's Law, the procedural requirements in sections 2(e) and 2(f) of Reese's Law for relying upon a voluntary standard are not applicable. 15 U.S.C. 2056e(e) and (f).

Section 3 of Reese's Law requires special packaging for button cell or coin batteries. These requirements, codified in the Notes to 15 U.S.C. 2056e, are self-implementing, and do not require CPSC to issue a rule. Section 3(a) of Reese's Law states that not later than 180 days after the date of enactment of the Act, meaning February 12, 2023, button cell or coin batteries sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States, or included separately with a consumer product sold, offered for sale, manufactured for sale, distributed in commerce, or imported into the United States, must be packaged in accordance with the standards

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

provided in 16 CFR § 1700.15, and tested in accordance with 16 CFR § 1700.20 or another test method specified by rule by the Commission. 15 U.S.C. 2056e Notes. The requirements in section 3(a) shall be treated as a standard for special packaging of a household substance under section 3(a) of the Poison Prevention Packaging Act (PPPA). *Id.*; 15 U.S.C. 1472(a). At this time the Commission is not proposing a rule to implement section 3 of Reese's Law, which is effective by operation of the statute on February 12, 2023.[6]

B. Explanation of Section 27(e) of the CPSA

Finally, distinct from implementation of Reese's Law, and as described in section VI of this preamble, the Commission is also proposing to use its longstanding authority under section 27(e) of the CPSA (15 U.S.C. 2076(e)) to require notification of additional technical and performance data related to the safety of button cell or coin batteries that is to be provided to the original consumer at the time of sale, specifically on websites and in-store displays for the sale of button cell or coin batteries and consumer products that contain such batteries. Although these draft notification requirements are codified together with the safety standard requirements proposed under Reese's Law, this is for the convenience of the public and the Commission, to ease compliance and enforcement. The two sets of requirements arise from different statutory authority and are legally distinct.

II. Products Subject to the Proposed Rule

As required by Reese's Law, the proposed rule establishes performance requirements for child-resistant button cell or coin battery compartments on consumer products that contain, or are designed to contain, such batteries. Reese's Law also requires warning labels for the: (1) packaging

[6] Section 4 of Reese's Law exempts from the special packaging requirements in section 3(a) of Reese's Law, button cell or coin batteries that comply with the marking and packaging provisions in the ANSI Safety Standard for Portable Lithium Primary Cells and Batteries (ANSI C18.3M). Packaged button cell or coin batteries that meet the ANSI standard are exempt from the special packaging requirements in section 3(a) of Reese's Law, but not from the labeling requirements in section 2(a) of Reese's Law, as implemented in this proposed rule. Labeling on such battery packaging can meet both the ANSI standard and this rule; CPSC's labeling requirements are additive to ANSI C18.3M labeling requirements.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

of button cell or coin batteries; (2) packaging of consumer products containing such button cell or coin batteries; (3) where practicable, battery compartments on consumer products that use button cell or coin batteries (regardless of whether they are replaceable); and (4) any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries. 15 U.S.C. 2056e(a), (b).

A. Description of Button Cell or Coin Batteries Within the Scope of the NPR

In general, button cell batteries are small, single-cell batteries that range from 5 mm to 32 mm (0.2 in. to 1.3 in.) in diameter and 1 mm to 6 mm (0.04 in. to 0.24 in.) in thickness. Reese's Law defines "button cell or coin battery" as: (A) a single cell battery with a diameter greater than the height of the battery; or (B) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard. 15 U.S.C. 2056e Notes. As explained above, this proposed rule focuses on addressing button cell and coin batteries under part (A), because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type or degree of ingestion hazard as button cell or coin batteries.

A button cell or coin battery (also referred to as a cell or disc/disk battery) stores chemical energy, which is converted to electrical energy when the battery is connected to a circuit. A button cell or coin battery consists of an anode (negative terminal), a cathode (positive terminal), and a separator and electrolyte between the anode and cathode, as shown in Figure 1. When the battery terminals are connected with a conductive material, such as when the battery is pressed into moist human tissue, an electric circuit is formed, and electric current flows through the conductive material and between the terminals. Button cell or coin batteries come in many shapes and sizes and are composed of different materials and chemicals. Power (voltage and capacity) and size requirements are the main driver of battery shape, chemical composition, and the number of required batteries.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

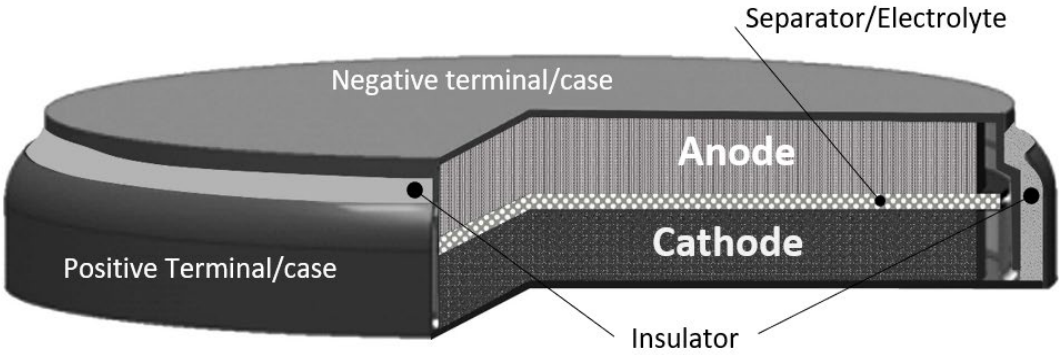


Figure 1. Battery Construction

Button cell batteries, like those shown in Figure 2, are used to power small, portable electronic products, such as wrist watches and calculators. Button cell batteries are usually disposable, single-cell batteries. Common anode materials are zinc or lithium. Common cathode materials are manganese dioxide, silver oxide, carbon monofluoride, cupric oxide, or oxygen from the air. Button cell batteries tend to be manganese dioxide (alkaline) (1.5v) or silver oxide (1.55v).

		
LR44 button cell, 11.6mm (0.45 inch) diameter x 5.4mm (0.21 inch) thick	LR754 button cell, 7.9 mm (0.31 inch) diameter, 5.4mm (0.21 inch) thick	LR626 button cell, 6.8 mm (0.26 inch) diameter, 2.6mm (0.10 inch) thick

Figure 2. Example Button Cell Batteries

Lithium coin batteries, shown in Figure 3, were originally developed as a 3-volt power source for low-drain and battery-backup applications; because of their high-energy density, correspondingly small size, and long shelf life, manufacturers have found lithium coin batteries useful for other applications as well. Lithium coin batteries are commonly around 20 mm (0.787 inch) in diameter.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

		
CR2032, 20mm (0.787 inch) diameter	CR2025, 20mm (0.787 inch) diameter	CR2450, 24mm (0.945 inch) diameter

Figure 3. Example Lithium Coin Batteries

B. Description of Consumer Products Within the Scope of the NPR

Consumer products containing, or designed to use, one or more button cell or coin batteries, whether they are replaceable or not, are subject to the rule. 15 U.S.C. 2056e Note. These products may be sold with batteries included, or batteries may be sold separately. The term "consumer product" has the same meaning as described in section 3(a)(5) of the CPSA, 15 U.S.C. 2052(a)(5): broadly, "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise."

Under the CPSA, a "consumer product" does not include any article that is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer, which may include products used only in a professional capacity (*i.e.*, expensive heavy machinery used only by professionally trained operators that is typically sold only to businesses and not to consumers). Moreover, a "consumer product" does not include products within the jurisdiction of some other federal agencies, such as motor vehicles and motor vehicle equipment (*e.g.*, motor vehicle key fobs), or food, drugs, medical devices, or cosmetics (*e.g.*, thermometers, hearing aids). 15 U.S.C. 2052(a)(5).

"Toy products" are also exempt from this proposed rule, pursuant to section 4 of Reese's Law, if they are in compliance with the battery accessibility and labeling requirements of 16 CFR part 1250 (the "toy standard"). A "toy product" is any object designed, manufactured, or marketed

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

as a plaything for children under 14 years of age. Section 4 of Reese's Law, 15 U.S.C. 2056e Notes. Not all children's products are toys, however. A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or younger." 15 U.S.C. 2052(a)(2). The Commission's regulation at 16 CFR part 1200 further interprets the term. For example, children's clothing containing button cell or coin batteries, or child-themed non-toy products that use button cell or coin batteries, are children's products subject to the requirements of this proposed rule.

Consumer products within the scope of the rule include common household portable devices, wearable accessories, and decorative electronic devices. Some examples of household objects that may use button cell or coin batteries are remote controls, games and toys, calculators, keychain flashlights, watches, flashing shoes and clothing, musical greeting cards, cameras, flameless candles, and holiday ornaments.

C. Description of Packaging Subject to the NPR

Reese's Law requires warnings on the packaging of button cell and coin batteries, and on consumer products that contain button cell or coin batteries. 15 U.S.C. 2056e(a), (b). Accordingly, CPSC staff reviewed consumer product and button cell and coin battery packaging to determine what, if any, warnings were already present. Staff found that some manufacturers of button cell or coin batteries include on the packaging of those batteries a safety statement, such as: "Keep away from small children. If swallowed promptly see a doctor," or "CAUTION: Keep batteries away from children. If swallowed, consult a physician at once." *See* Staff's NPR Briefing Package, p 7, Figures 5 and 6.

As reflected in ANSI Z535.4 American National Standard Product Safety Signs and Labels (ANSI Z535.4), use of the word "CAUTION" on a warning label signals less severe injuries than using "WARNING." For example, the word "WARNING" should be used for hazards where serious injury or death will occur. Staff found that packaging for the more hazardous lithium coin

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

batteries often includes the icon: "Keep out of Reach" on the front and the signal word "WARNING," followed by a statement that "Death or serious injury can occur in as little as 2 hours if swallowed" on the back side of the packaging, along with additional safety information related to the ingestion hazard and other hazards. *See, e.g.*, Staff's NPR Briefing Package, p. 8, Figure 7.

Unlike the packaging for button cell and coin batteries, CPSC staff's review of packaging for consumer products that contain a button cell or coin battery found that such packaging does not consistently warn that the product uses a button cell or coin battery; nor does the packaging consistently include warnings that button cell or coin batteries pose an ingestion hazard (*see, e.g.,* Staff's NPR Briefing Package, p. 8-9, Figures 8 and 9). However, accompanying literature, when provided with a consumer product, sometimes contains warning information pertaining to the ingestion hazard, even when the product packaging does not include such warnings.

As explained in sections V and VI of this preamble, the proposed rule would require standardized warning statements across packaging for button cell and coin batteries, and the packaging for consumer products that contain such batteries.

III. Incident Data and Hazard Patterns

Medical literature, CPSC data, and data from the National Capital Poison Center (NCPC) describe the deaths and serious injuries associated with the ingestion or insertion of button cell or coin batteries, including choking, internal chemical burns, chemical leakage, pressure necrosis (tissue damage), and the creation of hazardous chemicals (such as sodium hydroxide and hydrochloric acid) and related hazards. Tab A of Staff's NPR Briefing Package describes in more detail the incident data from the National Electronic Injury Surveillance System (NEISS) and from the Consumer Product Safety Risk Management System (CPSRMS). Staff also reviewed reports of deaths and injuries from NCPC data, as described in Tab B of Staff's NPR Briefing Package.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

A. Fatalities

The NCPC, or Poison.org, has tracked button cell or coin battery ingestions occurring from 1977 to the present. *See* Tab B of Staff's NPR Briefing Package. From 1977 to June 2022, the NCPC reported 69 deaths due to ingestion of button cell or coin batteries.[7] In the 47 cases where battery chemistry was known, 44 involved lithium batteries, two involved manganese dioxide chemistry, and one involved an alkaline button battery. The sources of these batteries, where known, were a remote control (8), toy (4), watch (2), camera (2), movie camera, camera flash, garage door opener, electric candle, remote car alarm, torch, tea light (spare battery), 3D TV glasses, key fob, and loose (battery fed to child by older brother). The button cell or coin battery size, where known, ranged from 10 mm to 25 mm (0.4 in. to 1 in.). The symptoms presented resembled those of a cold or upper respiratory infection and were often misdiagnosed as an infection or croup, or missed all together. In some cases, the first symptom was vomiting blood or blood coming from the nose, followed by death. Two deaths were caused by sepsis[8] after removal of the battery. Fifty of the 69 deaths in the NCPC data set were due to the battery burning through the esophagus and creating a hole to adjoining tissues, such as the trachea or arteries.

The Commission is also aware of 25 fatalities from button cell or coin battery ingestions reported nationally in the CPSRMS data from January 1, 2011 to December 31, 2021.[9] *See* Tab A of Staff's NPR Briefing Package. CPSC staff determined the source of the button cell or coin battery in seven of these fatalities: two from remote controls, two from a tracking device, one from a toy, one from the battery packaging, and one loose battery. The mechanisms of death represented in these fatalities are consistent with those seen in the medical literature and from the NCPC data.

[7] Fatal Cases (poison.org) Fatal Button Battery Ingestions: 69 Reported Cases (accessed June 2022).
[8] An infection of the blood stream resulting in a cluster of symptoms, such as drop in blood pressure, increase in heart rate, and fever.
[9] Incidents reported via CPSRMS as of May 2022. CPSC expects additional reporting of CPSRMS incidents for the most recent years 2020-2021, due to a time lag in reporting to CPSC. The reported incidents may be included in the NCPC data.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

B. Nonfatal incidents

From 1982 to June 2022, NCPC reported 267 cases of severe injury from button cell or coin battery ingestion.[10] Nine injuries were from manganese dioxide batteries, two were from mercuric oxide, two were from alkaline, one was from silver oxide, and 182 were from lithium batteries. Sources of the batteries, where known, were remote controls (26), toys (13), cameras (7), watches (7), scales (7), key fobs (7), calculators (5), battery packages (3), digital ear thermometers (2), flashlights (2), handheld computer games (2), soles of shoes (2), portable CD player, hair dryer, ab belt (exerciser), personal digital organizer, talking book, bicycle computer, computer, singing card, loose, guitar tuner, night light, baby monitor, lighted tweezers, book light, video camera, keychain, 3D TV glasses, portable speaker, lighted ring, and glucometer. Where battery size was known, most of the batteries were 20 mm in diameter, and the battery size range was from 11.6 mm to 24.6 mm (0.46 in. to 0.97 in.). In many cases, impaction of the button battery in the esophagus led to damage due to burning of the esophagus.

Based on incident information in NEISS, CPSC staff estimates that from January 1, 2011, through December 31, 2021, 54,300 emergency department-treated incidents involved button cell or coin battery ingestion or insertion into the mouth, nose, or ear. This excludes cases establishing ingestion of a battery in which the type of battery is not indicated. Staff's estimate generally relied upon the final diagnosis conclusion as recorded in short summaries from medical professionals. The lack of detection of a battery as a foreign body does not necessarily contraindicate battery presence (which may sometimes be missed by x-ray scans). Consequently, these estimates likely underestimate the actual number of button cell or coin battery ingestions or insertions. Table 1 summarizes the number of cases estimated per year.

[10] Severe Cases (poison.org) Nonfatal Button Battery Ingestions with Severe Esophageal or Airway Injury: 267 Cases. (Accessed June 2022).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 1. Estimated Number of Button Cell or Coin Battery Ingestions, Insertions, or Impactions Treated in Hospital Emergency Departments, 2011-2021.

Year	Estimate	N	CV
2011	4,600	170	0.20
2012	4,500	179	0.18
2013	5,000	178	0.21
2014	5,500	177	0.19
2015	3,500	163	0.15
2016	6,500	237	0.15
2017	5,400	196	0.20
2018	4,500	200	0.17
2019	4,200	178	0.26
2020	5,500	270	0.14
2021	5,200	235	0.18
Total	**54,300**	**2,183**	**0.15**

Source: NEISS, CPSC.
Summations of estimates may not add to the total estimates provided in the tables, due to rounding.
Staff derived estimates from data in the NEISS sample, with number of observations (N) and coefficient of variation (CV) provided. Estimates spanning periods of multiple years (such as the 11 years from 2011 to 2021) are total estimates, not annual averages.

Staff estimates that of the 54,300 cases that were indicated to involve a button cell or coin battery, approximately 88 percent involved ingestion through the mouth, while the remainder arose from insertion into the ear or nose. An estimated 8,800 (16% of 54,300) people were hospitalized as a result of these incidents, while an estimated 44,500 (82% of 54,300) people were treated and released.

Table 2 provides estimates of victim age at the time of initial treatment associated with button cell or coin battery incidents. Staff estimates that 16,100 (30%) of the 54,300 incidents involved young children under the age of 2 years, and an estimated 26,900 (50%) involved children between the ages of 2 and 6. In total, an estimated 43,000 (79%) of the incidents were associated with children 6 years of age or younger—the age group that is the focus of Reese's Law. *See* 15 U.S.C. 2056e(a)(1). Ingestions by adults and elders can be related to confusing loose button cell or coin batteries with medication and ingesting batteries, believing mistakenly that they are pills.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 2. Estimated Number of Button Cell or Coin Battery Ingestion or Insertion Incidents by Victim Age (or Age Range), 2011-2021.

Victim Age (or Age Range)	Estimate	Estimated Percent	N	CV
0-11 months	2,900	5%	129	0.27
12-23 months	13,200	24%	513	0.21
2 years	8,700	16%	378	0.19
3 years	7,100	13%	315	0.19
4 years	5,500	10%	220	0.12
5 years	3,200	6%	146	0.17
6 years	2,400	4%	84	0.18
7 years	1,900	4%	71	0.20
8 years	1,500	3%	59	0.24
9 to 14 years	2,900	5%	141	0.16
15-24 years	*	2%	33	*
25-34 years	*	1%	8	*
35-44 years	*	<1%	5	*
45-54 years	*	<1%	1	*
55-64 years	*	<1%	6	*
65-74 years	*	1%	17	*
75-84 years	*	2%	21	*
85+ years	1,500	3%	36	0.22
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.
*This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.

Table 3 shows 11,900 (22% of 54,300) incidents where the button cell or coin battery was known to have come from a product. Staff estimates that at least 5,300 batteries (45% of 11,900) were obtained from a "Non-Toy Consumer Product" (*i.e.*, in scope of Reese's Law). Such products included lights (*i.e.*, flashlights, pen lights), remote controls, watches, calculators, decorations and ornaments, electronic candles and tea lights, clocks and timers, electronic sound making books, pens, guitar tuners, and other consumer products. Staff estimates that 4,400 incidents (37%) classified as "toys/games" include children's toys and games that fall within the toy standard and are outside the scope of this rule. An estimated 18 percent of the 11,900 product-related incidents are associated with medical devices, which are outside the scope of the rulemaking for child-resistant battery compartments, including hearing aids (13%) and other medical devices (5%).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table3. Estimated Number of Button Cell or Coin Battery Incidents Where Obtained from a Product by Battery Source and Product Type, 2011-2021.

Battery Source Product Type	Estimate	Estimated Percent	N	CV
Consumer Product (excluding Toys/Games and Key Fobs)	5,300	42%	237	0.17
Toys/games	4,400	37%	176	0.17
Car remotes and key fobs	*	2%	11	*
Hearing aid	1,600	13%	52	0.21
Other Medical Device (excluding hearing aids)	*	5%	16	*
Unknown Product Type**	*	<1%	4	*
Total	**11,900**	**100%**	**496**	**0.14**

Source: NEISS, CPSC.
*This estimate does not meet NEISS reporting criteria.
**For a small proportion of cases, although it could be determined that the batteries were neither loose nor from packaging and came from *some* product or device, it could not be determined which *type* of product or device.

In the CPSRMS data, staff identified 87 nonfatal incidents involving button cell or coin battery ingestion (*i.e.*, "Ingestion" incidents) or unintended access to the button cell or coin battery with no ingestion (*i.e.*, "Battery Access" incidents) from January 1, 2016, through December 31, 2021. *See* Staff's NPR Briefing Package, p. 13. Table 4 provides a summary of the 74 nonfatal incidents that involved a product, rather than battery packaging, as the source of access to the battery.

Table 4. Reported Number of Product Classified Nonfatal Incidents by Incident Classification and Battery Source Product Type, 2016-2021.

	Incident Classification		Combined Nonfatal	
Battery Source Product Type	**Ingestion**	**Battery Access**	**Total**	**Total Percent**
Non-toy Consumer Product	13	16	29	42%
Toys/games	20	23	43	56%
Medical Device	1	1	2	3%
Total	**34**	**40**	**74**	**100%**

Source: CPSRMS, CPSC.

A high proportion of button cell and coin battery incidents reportedly involved toys and games. Based on products in the CPSRMS database where the exact product is known, many of the toys are subject to the requirements of the mandatory toy standard, codified in 16 CFR part 1250,

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

which requires toy products to meet the battery accessibility requirements in the voluntary standard for toys, ASTM F963-17.[11] CPSC staff has raised a concern with ASTM that ASTM F963-17's requirements for battery compartments do not adequately protect against the liberation of button cell or coin batteries from toys and becoming an ingestion hazard.[12]

C. Hazard/Injuries Associated with Button Cell or Coin Batteries

As set forth in detail in Tab B of Staff's NPR Briefing Package, CPSC staff reviewed medical literature related to battery-ingestion injuries, CPSC data, and data from Poison.org, and found that ingested batteries, particularly button cell or coin batteries, can lodge in the esophagus and cause severe tissue damage after only a few hours. The conductive soft tissue in the digestive tract can form a circuit between the battery terminals, creating an electric current. When lodged in the esophagus, button cell or coin batteries can lead to a burn in the esophagus, perforations, and burning of nearby tissue. Generation of hydroxide by the current created as a result of the battery contacting tissue in the digestive tract is the primary pathway to the chemical burn hazard associated with ingestion of lithium coin batteries, particularly, because of their higher voltage and capacity. Other mechanisms of injury associated with button cell or coin batteries include leakage of alkaline electrolyte from alkaline button cell batteries or pressure necrosis from extended contact of the foreign object with the soft tissue.

In addition to ingestion from swallowing, a proportion of nose insertions ultimately results in ingestion or aspiration, with batteries getting into the digestive tract or airways. Button cell or coin batteries impacted in the nose can lead to severe damage to the endonasal mucous membranes, necrosis (tissue damage) of the nasal septum cartilage, and nasal septum perforation. Tab B,

[11] Products referred to as "toys" in the incident data, that do not fall within the scope of part 1250, would be subject to this rule; thus, the rule will address some unknown portion of products indicated in the incident data as toys or games.
[12] https://www.cpsc.gov/s3fs-public/8-19-2022-Letter-to-ASTM-Battery-Operated-Toys.pdf?VersionId=PgFoeCeb0BYz0kyg6z87tbwHKv3x9W0y . Staff Correspondence Relating to Voluntary Standards – Letter to ASTM re: Battery Operated Toys, August 19, 2022.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Appendix G of Staff's NPR Briefing Package, provides examples of ear and nose insertion incidents.

CPSC staff specifically considered the ingestion hazard presented by zinc-air button cell and coin batteries in consumer products, and found that the risk is low. Staff estimates that at least 9 percent of button cell or coin battery ingestion or insertion incidents involve zinc-air batteries. But zinc-air batteries are primarily used in hearing aids, which are medical devices under the jurisdiction of the FDA. Staff did not identify zinc-air batteries being used in any consumer products. Furthermore, zinc-air batteries are typically much smaller than other button cell or coin batteries, and therefore, they do not present the same risk of choking. Staff did not identify any choking incidents in which zinc-air batteries were the source battery. Moreover, zinc-air batteries use a technology that needs air for the current to flow or voltage to be present on the terminals. Accordingly, if a zinc-air battery is swallowed or inserted into the nose, wet mucosa stops this flow of air and also the voltage, so there are no associated chemical or hydroxide burns. Zinc-air batteries are sealed with a hydrophobic material, so there is also little chance for electrolyte leakage. *See* Tab B of Staff's NPR Briefing Package.

Although hearing aids with zinc-air batteries would not be subject to performance requirements for consumer products (because hearing aids are medical devices), zinc-air batteries can be consumer products. Based on staff's assessment of the characteristics of zinc-air batteries and the lack of ingestion injury associated with these batteries, however, the Commission proposes that the labeling requirements of Reese's Law not apply to the packaging for zinc-air button cell or coin batteries. The Commission seeks comment on whether any consumer products contain, or are designed to contain, zinc-air button cell or coin batteries, if so, whether performance standards for battery compartments should apply to these consumer products, and whether the Commission should require ingestion warnings on zinc-air button cell or coin battery packaging.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

D. Hazard Patterns

CPSC staff identified the primary ways that children gain access to button cell or coin batteries before ingesting them:

1. Access to the battery from a product's intact battery compartment. Seventy-nine out of 112 fatal and nonfatal CPSRMS incident narratives staff identified in Tab A of Staff's NPR Briefing Package refer to products with button cell or coin battery compartments that are potentially easily accessed by children.[13] Ten of the 79 incident narratives refer to batteries in compartments that appeared easy to open or defeat. These batteries did not accidentally come out of a battery compartment, but appeared easily accessible to children while in a compartment.

2. Obtaining the battery from a battery compartment that broke or failed to contain the battery as intended. Sixty-nine of the 79 fatal and nonfatal CPSRMS incidents involving products describe the batteries unintentionally coming out of the battery compartment or the product, or the battery compartment opening or breaking, often while a child was interacting with the product. In some cases, the battery was found to have come from a product only after a child was diagnosed with having ingested the battery. Eighteen of these incidents specifically describe products with ineffective screws, including comments about stripped threads, continuous spinning, screws that were "too short," and compartments that popped open, even though there was a screw.

3. Removing the battery from its packaging, or obtaining a loose battery that was not contained within packaging or a product. Six out of 112 fatal and nonfatal CPSRMS incident narratives refer to loose batteries or battery-packaging hazards, and staff estimates that at least 7 percent of NEISS incidents involve loose batteries or batteries removed from their packaging.

[13] Out of the 79 products included in this hazard pattern analysis, 77 are consumer products, and two are household medical devices (body temperature thermometer and toothbrush).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

E. Recalls

Table 5 describes the six CPSC-conducted recalls that occurred between January 1, 2011, and July 31, 2022, involving consumer products containing button cell or coin batteries associated with a battery ingestion hazard. The recalled products were responsible for four reported battery-ingestion incidents and affected approximately 823,900 products (including toys).

Table 5. Summary of Recalls Involving Products with Button Cell and Coin Batteries.

Recall Date	Firm	Hazard	No. of Recalled Units	No. of Incidents & Injuries Reported	Press Release No.
10/10/2016	Target	The gel clings can separate and expose the inner decal and LED/button battery compartment, posing choking and button battery ingestion hazards to children.	About 172,000 units Halloween LED Gel Clings	No Injuries Reported	17-020
12/16/2016	Figi's Companies Inc.	The tin's music sound chip mechanism can separate and expose button batteries, posing choking and button battery ingestion hazards to children.	About 5,000 units "Christmas Wishes" Tins	No Injuries Reported	17-120
5/23/2017	Hobby Lobby	The battery cover can detach and expose the small coin cell batteries, posing choking and ingestion hazards to young children.	About 43,400 units Easter and July 4th-themed Light-Up Spinner Toys	Received one report of a 14-month-old child who ingested the battery.	17-166
12/19/2019	Toysmith	The battery cover can detach and expose the button-cell batteries, posing choking and ingestion hazards to young children.	About 58,000 units Light-Up Magic Wands	One report of a child swallowing one of the batteries removed from the toy. Medical attention was required to remove the battery.	20-045
5/12/2021	K & M International	The coin cell battery inside the slap watches can fall out, posing battery ingestion and choking hazards to young children.	About 463,000 units Wild Republic Slap Watches	No incidents or injuries have been reported.	21-134
12/1/2021	Halo Brand Solutions	A child can disassemble the projector flashlight and access the button cell batteries, posing ingestion and choking hazards.	About 82,500 units Projector Flashlights.	Received two reports of children accessing the button cell batteries from the flashlight, and in one case, a child required surgery to remove a swallowed battery.	22-024

IV. Assessment of Performance Requirements for Battery Compartments in Relevant Voluntary Standards, and Description of the Proposed Rule's Battery Compartment Requirements

In this section, the Commission describes staff's assessment of existing voluntary standards that establish performance requirements for button cell or coin battery compartments in consumer

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

products, and the elements of those standards that the Commission proposes to adopt as the basis for its proposed rule implementing Reese's Law.

A. Preliminary Determination Regarding Performance Requirements in Existing Voluntary Standards

Section 2(d) of Reese's Law states that the Commission shall not promulgate a final rule for consumer products that contain button cell or coin batteries if the Commission determines, with respect to any consumer product, that a voluntary standard that meets the requirements of section 2(a) of Reese's Law is either in effect at the time of the Commission's determination, or will be in effect not later than 180 days after the enactment of Reese's Law (meaning by February 12, 2023). Accordingly, CPSC staff assessed voluntary standards to determine whether any existing standards meet the requirements of section 2(a)(1) of Reese's Law, which mandates that the rule must include performance requirements for button cell or coin battery compartments on consumer products to secure them in a manner that eliminates or adequately reduces the risk of injury from the ingestion of button cell or coin batteries by children who are 6 years old or younger during reasonably foreseeable use or misuse of the product. 15 U.S.C. 2056e(a)(1).

Tab D of Staff's NPR Briefing Package contains a detailed review of six voluntary standards that relate to the accessibility of button cell or coin batteries. Four of these six standards most directly address the hazards associated with button cell and coin battery accessibility in consumer products, as required by Reese's Law. These four voluntary standards are:

- UL 4200A, *Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies* (UL 4200A);
- ASTM F963, *Standard Consumer Safety Specification for Toy Safety*;
- IEC 62368-1, *Audio/video, information and communication technology equipment-Part 1: Safety requirements*; and
- IEC 62115, *International Standard for Electric Toys – Safety*.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 6 provides CPSC staff's summary of how each of these standards addresses the battery-ingestion hazard, with requirements that are intended to minimize the risk of children removing button cell or coin batteries from a consumer product.

Table 6. Summary of Voluntary Standards Requirements for Button Cell or Coin Battery Access in a Consumer Product

Standard	Scope	Required Action(s) to Open Battery Compartment	Abuse Testing
UL 4200A	Household-type products that incorporate or may use button cell or coin batteries of lithium technologies	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment; screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand.	**Preconditioning**: (1) 7 hours of pre-conditioning in oven at 70°C (158°F); (2) Open/close and remove/install battery 10 times. **Abuse Tests**: (1) **Drop test** – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure; (2) **Impact test** – 3 impacts by steel sphere imparting 2-J of energy; and (3) **Crush test** –74 lbf. over 38 square inches for 10s in positions likely to produce the most adverse results.
ASTM F963	Toys intended for use by children under 14 years of age	Coin, screwdriver, or other common household tool required to open battery compartment.	(1) **Drop test** – maximum 10 times at 4.5 ft in random orientation; minimum of 4 times at 3 ft in random orientation; (2) **Torque test** – 2-4 in-lbs. of torque over 10 seconds; (3) **Tension test** – 10-15 lbs. of tension over 10 seconds; (4) **Tension test for pliable materials** – 10-15 lbs. of tension over 10 seconds; and (5) **Compression test** –20-30 lbf over 1 square inch for 10 seconds.
IEC 62368-1	Electrical and electroni equipment within the field of audio, video, information and communication technology, and business and office machines with a rated voltage not exceeding 600 V	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand	**Preconditioning:** (1) 7 hours of pre-conditioning in oven at 70°C (158°F); and (2) Open/close and remove/install battery 10 times. **Abuse Tests:** (1) **Drop test** – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure; (2) **Impact test** – 3 impacts by steel sphere imparting 2-J of energy; and (3) **Crush test** – apply 74 lbf. for 10s in positions likely to produce the most adverse results.
IEC 62115	Electric toys being any product designed or intended for use in play	Batteries that fit wholly within the small parts cylinder shall not be removable	(1) **Screw test** – Remove/replace screws 10 times with torque applied;

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

	by children under 14 years of age	without the aid of a tool, screw fastener must be captive.	(2) **Drop test** – maximum 10 times at 93 cm ± 5 cm (36.6 in.) in random orientation; minimum 4 times at 93 cm ± 5 cm (36.6 in.) in random orientation; (3) **Impact test** – 3 impacts by hammer imparting 0.5-J of energy; (4) **Tension test** – 70 N ± 2 N (15.7 lbs.) of tension over 10 seconds; and (5) **Tension test** – 70 N ± 2 N (15.7 lbs.) tension force on a textile seam over 10 seconds.

The left-hand column in Table 7 displays the categories staff evaluated to assess satisfaction of Reese's Law, and staff's evaluation of whether the standard eliminates or adequately reduces the risk of injury from button cell or coin battery ingestion by children age 6 or under. Specifically, Table 7 includes the scope of the voluntary standard, and whether the scope includes all or only some relevant battery chemistry types that create an ingestion hazard and associated consumer products as seen in the incident data; whether the standard's performance requirements for constructing and securing the battery compartment would eliminate or adequately reduce the risk of injury from access to batteries from consumer products and their ingestion, as seen in the incident data, or inadequately address the risk; and whether the standard addresses use-and-abuse testing at all, and if so, the adequacy of the use-and-abuse testing to eliminate or adequately reduce ingestion incidents as seen in the data.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 7 – Assessment of Existing Voluntary Standards for Button Cell or Coin Batteries

		UL 4200A	ASTM F963	IEC 62368-1	IEC 62115
Scope	Battery Chemistry Type	Lithium	Any	Any	Any
	Product Type	Any	Toys	Audio/ Visual Equipment	Electronic Toys
Construction	Opens with Tool	A	A	A	A
	Captive screws	I		I	A
	Threaded attachment requirements	A		I	
	Opens with two independent and simultaneous movements	I		I	
	Accessibility	A	A	A	A
Use and Abuse	Pre-conditioning in oven	A		A	
	Open/close and remove/install battery/screw(s) 10 times	A		A	I
	Drop test - based on product weight/type	I	I	I	I
	Drop test - based on age grading		I		
	Impact Test	A		I	I
	Crush Test (big surface area)	A		I	
	Torque Test		A		
	Tension Test		A		A
	Tension Test - Seams		A		A
	Compression Test (little surface area)		A		
	Accessibility Probe Compliance Test	I	I	I	A
	Securement (non-removable batteries)	A			

Blank – Does not address requirements, I –Inadequately addresses requirements, A – Adequately addresses requirements

Table 7 summarizes staff's assessment in Tab D of Staff's NPR Briefing Package, displaying an "I" where a standard contains a performance requirement that inadequately addresses the risk of ingestion, and an "A" if CPSC staff assessed the requirement as adequate to address the risk of ingestion. Table 7 shows that no existing voluntary standard includes within its scope all battery types and all consumer products that contain button cell or coin batteries, as reflected in the incident data. The scope of each voluntary standard staff reviewed is narrower than the scope of the proposed rule, which applies to all non-toy consumer products within the Commission's jurisdiction that contain button cell or coin batteries. For example, UL 4200A only applies to lithium batteries.

Regarding construction of the battery compartments, UL 4200A is the only voluntary standard that contains requirements that would address relevant incidents seen in the data, but in staff's view, not all the requirements are adequate to address the risk of injury. For example,

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

although UL 4200A contains a requirement for a double-action locking mechanism, staff found that the language in UL 4200A could lead to defective double-action locks, which could allow a child to gain access to the battery compartment. Staff also found that requirements in UL 4200A are not always clear and could result in different interpretations by testers, leading to inconsistent and unreliable testing and, ultimately, risk to children.

Regarding ASTM F963, Table 6 reflects that it requires a tool to open a battery compartment, but does not require captive screws. This means that consumers could undermine the screw requirement by not using them, discarding them, or losing the screws. ASTM F963 also does not have torque requirements for fasteners, nor does it provide requirements for fastener threading or retention. These omissions are a deficiency, given the incident data involving lost screws and stripped screw holes. Staff concluded that the IEC standards contain similar deficiencies related to battery compartment fasteners, as summarized in Tables 6 and 7.

As part of its requirements for secure battery compartments, Reese's Law requires a performance standard for consumer products addressing reasonably foreseeable use-and-misuse conditions. Accordingly, staff considered the adequacy of use-and-abuse testing of consumer products for each voluntary standard, and staff assessed whether the use-and-abuse testing would eliminate or adequately address deaths and injuries in the incident data. As shown in Table 7, and as described in more detail in Tab D of Staff's NPR Briefing Package, staff advises that none of the voluntary standards, alone, provides for all the use-and-abuse testing needed to eliminate or adequately reduce incidents seen in the data.

Based on CPSC staff's review and analysis of voluntary standards related to child-resistant battery compartments for consumer products that contain button cell or coin batteries, as set forth in Tables 6 and 7 above, and Tab D of Staff's NPR Briefing Package, the Commission preliminarily determines that no existing voluntary standard contains performance requirements that would eliminate or adequately reduce the risk of button cell or coin battery ingestion associated with

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

consumer products that contain button cell or coin batteries within the scope of the proposed rule. However, as set forth below, the Commission draws on elements of these four voluntary standards to propose a rule that meets the requirements of Reese's Law. We seek comment from the public regarding staff's assessment of the relevant voluntary standards, and on our preliminary conclusion that, for the reasons given by staff, none of the standards, alone, satisfy the requirements for adoption as a consumer product safety rule under section 2(d) of Reese's Law, 15 U.S.C. 2056e(d).

B. Elements of the Proposed Standards for Battery Compartment Accessibility in Products Incorporating Button Cell or Coin Batteries

Tables 8 and 9 summarize the performance requirements in the proposed rule.

Table 8. Requirements for Consumer Products with Compartments for Replaceable Batteries	
Button cell or coin batteries must not become accessible or liberated when tested to these requirements:	
Construction Requirements	
Battery Compartment Construction Options	*Option 1*: Coin, screwdriver, or other household tool. • Captive screws • Two threads engaged or minimum torque + spin angle *Option 2*: Two independent & simultaneous hand movements. • Cannot be combinable to a single movement with a finger or digit.
Accessibility Test	Open or remove any part of the compartment not meeting *Option 1* or *Option 2*. Apply Tension Test for Seams from 16 CFR part 1250 on pliable materials, using a force of 70.0 N (15.7 lbf). Determine whether Test Probe 11 from IEC 61032 can touch the battery.
Preconditioning Requirements	
Preconditioning in Oven	Thermoplastics - 7 hours at 158°F or greater, based on operational temperature.
Simulated Battery Replacement	Open/Close and remove/install battery 10 times.
Use and Abuse Tests	
Drop Test	10 drops from 1 m (39.4 in) on hardwood, in positions likely to produce maximum force.
Impact Test	3 impacts on battery compartment with steel sphere, 2 J (1.5 ft-lbf) of energy.
Crush Test	335 N (75.3 lbf) for 10 s, using 100 by 250 mm (3.9 by 9.8 in) flat surface.
Compression Test	Test from 16 CFR Part 1250, using a force of 136 N (30.6 lbf).
Torque Test	Test from 16 CFR part 1250, using a torque of 0.50 Nm (4.4 in.-lbf).
Tension Test	Test from 16 CFR part 1250, using a force of 72.0 N (16.2 lbf).
Probe for Accessibility	Apply 50 N (11.2 lbf) with Test Probe 11 from IEC 61032 to confirm compliance.

Table 9. Requirements for Consumer Products with Compartments for Non-Replaceable Batteries	
Option 1 – Not Accessible	Meets the same requirements as battery compartment for replaceable batteries.
Option 2 – Accessible	• Secured with soldering, fasteners such as rivets, or equivalent means. • Applicable preconditioning requirements apply. • Confirmed with secureness test: test hook applies a force of 22 N (4.9 lbf) directed outwards for 10 s, at all possible points. Battery cannot liberate from the product.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Below we describe the rationale for the proposed requirements.

1. Construction: Actions to Open the Battery Compartment

Each of the four voluntary standards specifies similar requirements for a locking mechanism to secure the battery compartment that requires a tool (or coin) to open, to reduce the possibility of children removing the battery. Generally, requiring a coin or tool to open a battery compartment addresses child access to the battery compartment, because younger children may lack the required cognitive ability and fine motor coordination to perform the necessary actions to access the battery compartment, as discussed in Tab C of Staff's NPR Briefing Package. UL 4200A, however, is the only voluntary standard that includes requirements for this locking mechanism, specifying either a minimum torque of 0.5 Nm (4.4 in-lbf) and a minimum angle of rotation of 90 degrees for the battery compartment fastener mechanism, or a minimum of two full threads engaged. These requirements are important to secure the battery compartment because staff found incidents involving battery compartments with stripped screw holes or screws of insufficient length, defeating the integrity of the screw requirement and allowing child access. In particular, ASTM F963 does not contain these torque and rotation requirements for the locking mechanism, and staff identified incidents of children accessing battery compartments on toys that purportedly met ASTM F963. Accordingly, the Commission proposes to include requirements for the locking mechanism, consistent with the requirements in UL 4200A.

Moreover, all of the assessed voluntary standards, except ASTM F963-17, include a requirement for captive screws, which are screws that remain in the compartment or cover when unscrewed. If the screw is not captive to the compartment door, consumers can more easily lose the screw or defeat this locking mechanism by removing the screw, potentially for convenience, without appreciating the safety purpose of the screw.

The Commission preliminarily concludes that the requirements in UL 4200A related to products that use a tool or coin to open the battery compartment, when applied to the full scope of

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

products subject to Reese's Law, and not just to lithium coin batteries, are adequate to address the battery compartment construction requirements related to the button cell or coin battery ingestion hazard. Although UL 4200A includes an exception to the captive screw requirement for large panel doors, the Commission is not including such an exception in the proposed rule. Instead, we are requesting comment on this, including what constitutes a "large panel door," the types of products intended for this exception, and why these doors would not present the same risk of injury as any other consumer product that contains button cell or coin batteries if the screws become lost or discarded by the consumer.

UL 4200A and IEC 62368-1 also specify an option for the battery compartment door to require a double-action locking mechanism (requiring at least two independent and simultaneous movements to open the compartment by hand) that ASTM F963 does not contain. Unlike screws, a double-action locking mechanism does not rely on the consumer to keep and reuse a screw. Thus, a double-action lock, if well-designed and constructed, can be more secure than a screw lock that relies on consumers to reuse the screw each time the battery compartment is closed. The Commission preliminarily concludes that double-action locking mechanisms that meet the requirements of the proposed rule, which are similar to the double-action lock provisions in UL 4200A, could be effective in preventing younger children from opening the battery compartment, while affording additional flexibility to design effective child-resistant battery enclosures.

2. Use and Abuse Testing

Reese's Law mandates that the rule must include performance requirements for button cell or coin battery compartments during reasonably foreseeable use or misuse of the product. Accordingly, staff evaluated use and abuse testing in each voluntary standard to address the actual hazard patterns that are apparent in the incident data. Although all of the voluntary standards reviewed by staff specify abuse tests, none of the voluntary standards, alone, would eliminate or adequately reduce the ingestion risks presented by the incident data. Based on staff's incident

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

review, engineering analysis, and testing of consumer products as described in Tab D of Staff's NPR Briefing Package, staff assessed that the drop test and impact test in UL 4200A adequately simulate use and abuse of consumer products by children. Staff assessed that the use and abuse testing in ASTM F963-17 is inadequate, alone, to address the risk of injury, because it does not precondition the products before abuse testing and does not contain an impact test, which is the test staff found most likely to simulate foreseeable use and abuse of consumer products.

Staff, however, also assessed that the compression tests, torque tests, and tension tests in ASTM F963-17, the toy standard, are adequate to simulate foreseeable interactions, such as when a child grasps a part of a product with fingers or teeth, and twists, pulls, or presses on part of the product, while UL 4200A and IEC 62368-1 do not contain performance requirements to address these risks. A detailed assessment of these test methods can be found in Tab D of Staff's NPR Briefing Package. Staff specifically observed the following regarding abuse testing:

- UL 4200A specifies heat pre-conditioning of plastic component parts of the product. Staff's testing demonstrated that heat pre-conditioning of the consumer products stresses plastic components to simulate more realistically, the expected condition of the product during normal use. ASTM F963 and IEC 62115 do not require heat pre-conditioning, and therefore, are inadequate to assess consistently and reliably, the integrity of battery compartments through use-and-abuse testing.

- UL 4200A specifies mechanical pre-conditioning of the product by requiring a battery compartment on a consumer product to be opened, the battery removed, the battery reinstalled, and then the compartment closed, a total of 10 times. As with heat pre-conditioning, staff's testing confirmed that mechanical pre-conditioning assesses more consistently the durability of a battery compartment to maintain its integrity over time, by preventing, for example, stripping of threads, compared to standards that do not require pre-conditioning. ASTM F963 and IEC

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

62115 do not require pre-conditioning by opening and closing the battery compartment, and therefore, inadequate to test reliably the durability of battery compartments on consumer products during foreseeable use and misuse.

- UL 4200A subjects "portable" products to three drops during abuse testing, while "hand-held" portable products are subjected to 10 drops. All drops are from a height of 3.3 feet in positions likely to produce the maximum force on the battery compartment. Staff assessed that the 10-cycle drop test for handheld items in UL 4200A is adequate to address and prevent incidents of breaking consumer products or battery compartments. The abuse testing requirements in ASTM F963 and IEC 62115, however, are inadequate to address the risk of button cell or coin batteries being liberated from broken battery compartments, because they allow for as few as four drops from a height of 3 feet, in random orientations that may not exert maximum force on the battery compartment.

- UL 4200A requires three impact tests that each impart two joules of energy directly on the battery compartment with a steel ball. Staff advises that this impact test reasonably indicates the durability of the battery compartment during foreseeable use and misuse, as required by Reese's Law. However, ASTM F963 is inadequate to eliminate or adequately reduce access to batteries caused by foreseeable stress on the battery compartment, because the standard does not require impact tests directly on the compartment. IEC 62368-1 varies the required impact energy based on the type of product, and IEC 62115 requires less energy per impact, which does not adequately reduce access to the battery compartment for certain products.

- ASTM F963 specifies torque test and tension test methods to simulate interactions during reasonably foreseeable use and misuse conditions, such as a child grasping a part of the product with fingers or teeth and twisting, pulling, or pressing on the product. Staff advises that these requirements in the toy standard are adequate to test the durability and integrity of battery

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

compartments in products with pliable materials such as shirts and greeting cards that light up or make sound using batteries. The proposed rule includes torque and tension tests to eliminate or adequately reduce the risk of ingestion in pliable products, as required by Reese's Law.

- UL 4200A specifies a compression test of 74.2 pounds over a 3.9-inch x 9.8-inch area, which staff assesses adequately addresses a child pushing on the product with hands or feet. ASTM F963 and IEC 62115 specify a concentrated compression load of 30 pounds over a 1-square-inch area, which staff assesses adequately addresses a child unintentionally opening a battery compartment that cannot be impacted directly during the drop test, but that can be pushed open with hands or fingers. However, staff advises that the smaller compression test area in ASTM F963 and IEC 62115 is inadequate to assess a child pushing on the product with hands or feet. Conversely, the larger compression area of the UL 4200A is inadequate to address the risk of injury associated with a child pushing on the product with fingers. Accordingly, the proposed rule includes both tests to address adequately the foreseeable possible range of child interactions and incidents.

- UL 4200A specifies that if a product has a battery that is not intended to be removed or replaced by the user, and that is held fully captive by soldering, fasteners, or any equivalent means, then the product is not subject to abuse testing, and is subject only to pre-conditioning tests and secureness testing using a test hook and a force of 4.5 lb. IEC 62368-1 also excludes from abuse testing any products with non-removable batteries; but it does not require any secureness test. The Commission is aware of incidents involving children gaining access to non-removable batteries in products like computers. Although the proposed rule requires only the applicable pre-conditioning tests and the secureness test based on UL 4200A for non-removable batteries, with no additional abuse testing, the Commission requests comment on

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

whether the proposed secureness test based on UL 4200A is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries.

3. Accessibility Test

Each of these four voluntary standards relies on a test probe based on a child's finger to verify whether certain components are accessible to children. Staff advises that the test probe used in ASTM F963 is inadequate to test accessibility, because the probe articulates and therefore cannot be used to apply much force. IEC 62368-1, IEC 62115, and UL 4200A do require a force to be applied with their respective probes to verify compliance with the standard. The IEC 62368-1 test probe head has a 3.5 mm (0.14 in.) radius, and compliance is verified with a force of 30 N ± 1 N (6.7 lbf ± 0.2 lbf). IEC 62115 and UL 4200A use Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032. This test probe has a head with a 4 mm (0.16 in.) radius. Staff assesses that using test Probe 11 with a force of 50 newtons (11.2 lbf), per IEC 62115, is adequate to assess a child's ability to get into a battery compartment. The Commission seeks comments on the adequacy of the probes and accessibility tests in these voluntary standards.

V. Assessment of Warning Label Requirements in Relevant Voluntary Standards, and Description of the Proposed Rule's Warning Label Requirements

Section 2(a)(2) of Reese's Law mandates warning label requirements for:

- The packaging of button cell or coin batteries (15 U.S.C. 2056e(a)(2)(A));
- The packaging of consumer products containing button cell or coin batteries (15 U.S.C. 2056e(a)(2)(A));
- Any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries (15 U.S.C. 2056e(a)(2)(B));

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- As practicable, a consumer product that contains button cell or coin batteries in a manner visible to the consumer upon installation or replacement of the button cell or coin battery (15 U.S.C. 2056e(a)(2)(C)(i)); and
- As practicable, a product for which the battery is not intended to be replaced or installed by the consumer, in a manner that is visible to the consumer upon access to the battery compartment; if it is impracticable to label the product, this information shall be placed on the packaging or instructions (15 U.S.C. 2056e(a)(2)(C)(ii)).

The warning labels required by section 2(a) of Reese's Law must (1) clearly identify the hazard of ingestion, and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice. 15 U.S.C. 2056e(b).

Tab C of Staff's NPR Briefing Package reviews and assesses warning label requirements in existing voluntary standards, and provides recommendations for warnings with a detailed rationale for each recommended requirement. This section discusses and proposes to adopt staff's recommended implementation of Reese's Law's warning label requirements.

A. Adequacy of Existing Voluntary Standards

To fulfill the requirement in section 2(d) of Reese's Law, the Commission first considers whether the labeling requirements in an existing voluntary standard meet the requirements of section 2(a)(2) and 2(b) of Reese's Law. Tab C of Staff's NPR Briefing Package and its Appendix contain a detailed analysis of the warning label requirements in 10 voluntary standards associated with button cell or coin batteries. For each standard, staff considered the scope, placement, format, and content of the required labels, and whether it adequately addresses the ingestion hazard warnings required by Reese's Law. Table 10 summarizes staff's assessment of the voluntary standards relevant to labeling of consumer products that contain button cell or coin batteries.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 10. Summary of Staff's Assessment of Labeling Requirements in Standards for Consumer Products Containing Button Cell or Coin Batteries

		ASTM F963	UL 4200A	ASTM F2999-19	ASTM F2923-20	IEC 62115
Scope	Battery Chemistry Type	All	Lithium	All	All	All
	Product Type	Toys	All	Jewelry	Children's Jewelry	Toys
Labeling	On Consumer Product Packaging	I				I
	In instructions or accompanying literature	I	I			I
	On consumer product		I			

Blank – Does not address requirements, I –Inadequately addresses requirements, A – Adequately addresses requirements

Table 11 summarizes staff's assessment of the voluntary standards relevant to labeling of packaging for button cell or coin batteries.

Table 11. Summary of Staff's Assessment of Labeling Requirements in Standards for Batteries

		ANSI C18.1M	ANSI C18.3M	UL 1642	IEC 60086-4	IEC 60086-5
Scope	Battery Chemistry Type	Aqueous	Lithium	Lithium	Lithium	Aqueous
Labeling	On batteries*	I	I		I	I
	On battery packaging	I	I	I	I	I
	In instructions or accompanying literature		I			

Blank – Does not address requirements, I –Inadequately addresses requirements, A – Adequately addresses requirements
*Not directly addressed by Reese's Law

As reflected in Table 10 and explained more fully in Tab C of Staff's NPR Briefing Package and its Appendix, none of the voluntary standards relevant to consumer products that contain button cell or coin batteries have a scope that includes all consumer products. For example, the warnings required in ASTM F963 are limited to toys, and they also do not address spare batteries included with a consumer product. For UL 4200A, the required warnings do not use ANSI formatting and do not clearly warn of an ingestion hazard; this standard requires warning of a "chemical burn" without informing consumers how this hazard can occur. IEC 62115 permits a "Contains coin battery" symbol on the product packaging, but it does not instruct consumers to "Keep out of reach of children" on the packaging, instructions, or product. ASTM F2999-19 and ASTM F2923-20, for jewelry, do not satisfy any of the labeling requirements of Reese's Law.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 11 summarizes staff's assessment that the voluntary standards' labeling requirements for battery packaging, likewise, do not satisfy Reese's Law. As reflected in Table 11 and explained more fully in Tab C of Staff's NPR briefing package and its Appendix, none of the voluntary standards relevant to button cell or coin batteries have a scope that includes all button cell or coin batteries for which the ingestion hazard applies. Warnings in ANSI C18.1M and IEC 60086-5 are limited to aqueous battery chemistries (including alkaline batteries), while ANSI C18.3M, UL 1642, and IEC 60086-4 are limited to lithium battery chemistries. Each of the relevant standards addresses warnings on battery packaging, but do not contain requirements specifically addressing the contents in Reese's Law. For example, ANSI C18.3M contains two statements relevant to the ingestion hazard: "Keep batteries out of the reach of children, especially those batteries fitting within the limits of the truncated cylinder," in section 8.4; and "Immediately seek medical attention if a cell or battery has been swallowed. Also, contact your local poison control center," in section 8.5. However, the section containing these two statements provides manufacturers with information regarding safe use of lithium batteries, and does not require the statements to be placed on packaging. Additional warning statements similar to those in section 8.4 and section 8.5 can be found in Annex C, but are only required for lithium coin cells 16 mm in diameter and larger.

Based on CPSC staff's review and analysis of voluntary standards and for the reasons summarized above, the Commission determines preliminarily that no existing voluntary standard contains the warnings required by Reese's Law, for either consumer products containing button cell or coin batteries, or the packaging of such batteries. Although no standard, alone, contains labeling requirements that are adequate to satisfy Reese's Law section 2, the standards collectively contain elements that can be combined to establish succinct warnings that address the ingestion hazard associated with button cell or coin batteries. Accordingly, as discussed below, the labeling requirements in the proposed rule are based on elements of several voluntary standards.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

B. Formatting Requirements for Warning Labels

The warning labels in the proposed rule follow requirements found in ANSI Z535.4, American National Standard Product Safety Signs and Labels, which is the primary voluntary consensus standard providing guidelines for the design of safety signs and labels for application to consumer products. The ANSI Z535.4 standard includes recommendations for the design, application, use, and placement of warning labels, such as including the signal word, "WARNING," and the safety alert symbol of an equilateral triangle surrounding an exclamation mark. The following format requirements, drawn from this ANSI standard, apply to all warning labels in the NPR:

1. All warnings must be clearly visible, prominent, legible, and permanently marked.
2. Warnings must be in contrasting color to the background onto which they are printed.
3. Warnings must be in English.
4. The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.
5. The signal word "WARNING" must be in black letters on an orange background. The signal word must appear in sans serif letters in upper case only.
6. Certain text in the message panel must be in bold and in capital letters, as shown in the example warning labels, to get the attention of the reader.
7. For labels that are provided on a sticker, hangtag, instructions, or manual, the safety alert symbol and the signal word "WARNING" must be at least 0.2 in. (5 mm) high. The remainder of the text must be in characters whose upper case must be at least 0.1in. (2.5 mm), except where otherwise specified.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

8. For labels that are required to be on the packaging of button cell and coin batteries, on the packaging of consumer products containing such batteries, and directly on consumer products, text size must be dependent on the area of the principal display panel. Text size must be determined based on Table 12, which is based on the information found in 16 CFR part 1500.19(d)(7).

Table 12. Letter size for warning labels: Information based on 16 CFR § 1500.19(d)(7).

Letter size measurements in inches								
Display Area: Inches²	*0–2*	*+2–5*	*+5–10*	*+10–15*	*+15–30*	*+30–100*	*+100–400*	*+400*
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display Area: cm²	*0-13*	*+13-32*	*+32-65*	*+65-97*	*+97-194*	*+194-645*	*+645-2,581*	*+2,581*
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397

Placement of labels on packaging of button cell or coin batteries, consumer product packaging, and on consumer products, as set forth in the proposed rule, rely on the following definitions:

- The "principal display panel" is defined as the display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.
- The "secondary display panel" means a display panel for a retail package of a button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- The "product display panel" means the surface area on, near, or in the battery compartment. For consumer products with replaceable button cell or coin batteries, the product display panel must be visible while a consumer installs or replaces the button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel must be visible upon access to the battery compartment.

C. Required Warnings for Button Cell or Coin Battery Packaging

Using the foregoing formatting requirements, the proposed rule requires a warning for the principal display panel of the battery packaging, shown in Figure 4, that meets the requirements in section 2 of Reese's Law.

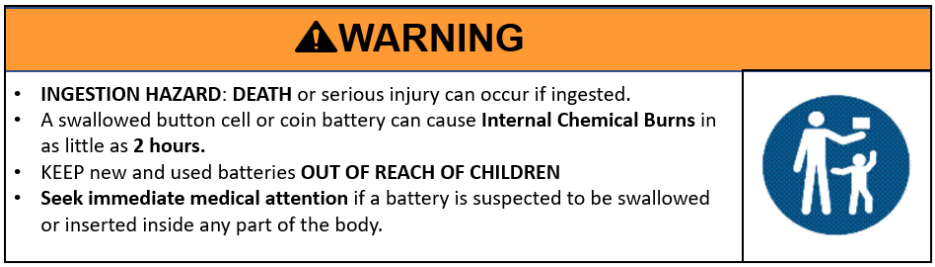


Figure 4. Warning of Ingestion Hazard for Battery Packaging.

Accordingly, battery packaging must include the following warnings statements:

- **"INGESTION HAZARD: DEATH** or serious injury can occur if ingested." This sentence identifies the hazard of ingestion, as required by section 2(b)(1) of Reese's Law.
- "A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**." This sentence provides warning label requirements, as stated in Reese's Law; an effective warning should have an explanation of how and why ingestion of a button cell or coin battery is hazardous.
- "KEEP new and used batteries **OUT OF REACH OF CHILDREN**." This sentence implements language in section 2(b)(2) of Reese's Law. In addition, use of the icon recognized for keeping items out of children's reach is intended to quickly convey the required message and direct the reader's attention to the label. The icon incorporated with

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

the warning must be at least 8 mm (0.31 in.) in diameter for visibility. Text size must be calculated per Table 12.

- **"Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body." This sentence implements language in section 2(b)(2) of Reese's Law and informs the consumer what actions should be taken if a button cell or coin battery is ingested or inserted into any part of the body. The warning includes the term "inserted" because insertions into the nose can be aspirated into the trachea and lead to ingestion, with the same risk of injury as oral ingestion.

If space prohibits the full warning with the icon shown in Figure 4 in accordance with the formatting requirements of Table 12, packaging is required to use the "Keep out of Reach" icon (Figure 5) on the principal display panel and the warning text must be placed on the secondary display panel, as shown in Figure 6. The icon must be at least 20 mm (0.79 in.) in diameter for visibility.

Figure 5. "Keep Out of Reach" Icon

WARNING **INGESTION HAZARD • DEATH** or serious injury can occur • A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours** • KEEP new and used batteries **OUT OF REACH OF CHILDREN** • **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 6. Warning Text Without Icon.

To address the hazard of button cell or coin batteries that become loose or separated from packaging, and to provide critical safety-related information should an ingestion incident occur, the following information implementing section 2(b)(2) of Reese's Law must be placed on the secondary display panel of the packaging:

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- "Keep in original package until ready to use." This statement instructs consumers to leave the batteries in child-resistant packaging as a specific means of keeping new batteries out of the reach of children.
- "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash." This statement instructs consumers on how to prevent ingestion hazards from used batteries by keeping used batteries out of the reach of children, including out of household trash.
- "Call a local poison control center for treatment information." This statement makes more actionable the guidance to "immediately seek medical attention" as described in section 2(b)(2) of Reese's Law, and provides consumers with a resource for obtaining medical advice suitable to their situation.

D. Required Warnings for Button Cell or Coin Batteries Included Separately with the Consumer Product

Button cell or coin batteries included with a consumer product, but not yet installed in the product, must contain the warning label in Figure 4 on the principal display panel. If space does not allow the full warning consistent with the formatting requirements of Table 12, then the icon shown in Figure 5 must be placed on the principal display panel with the text shown in Figure 6 on the secondary display panel, and the icon must be at least 20 mm in diameter for visibility. The goal is to ensure consumers have the opportunity to see the appropriate safety-related warning information and take appropriate action to store spare batteries safely away from children until installed in a consumer product.

E. Required Warnings for Packaging of Consumer Products that Contain Button Cell or Coin Batteries

Reese's Law requires warning labels on the packaging of consumer products containing button cell or coin batteries. Each warning label must contain the same wording and icon as the battery packaging, except to make the first warning more explicit about the hazard: "**INGESTION**

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

HAZARD: This product contains a button cell or coin battery." The warning shown in Figure 7 must be on the principal display panel of the consumer product packaging. Covered consumer products that do not include packaging must affix the warning to the product with a hang tag or sticker label.

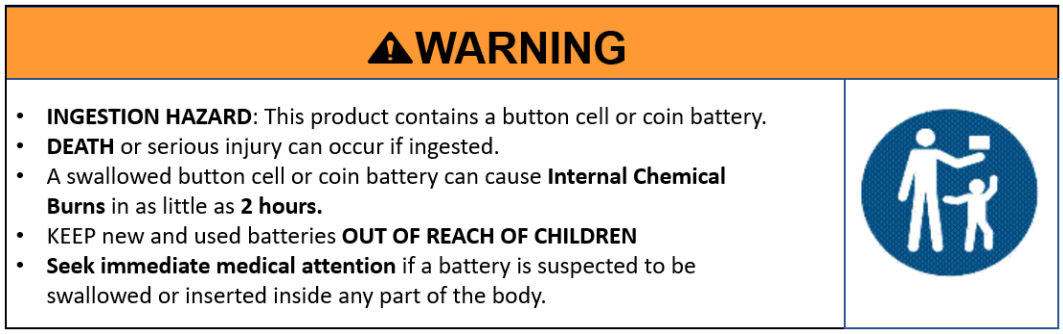


Figure 7. Warning for consumer product packaging to indicate the presence of button cell or coin battery and the ingestion hazard.

Product packaging that does not have the space to permit the full warning as indicated in Table 12, must include an abbreviated warning on the principal display panel, with the remaining statements ("KEEP new and used batteries **OUT OF REACH OF CHILDREN"** and "Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body") placed on the secondary display panel, as shown in Figure 8. The icon must be at least 8 mm (0.31 in.) in diameter for visibility. Text size must be calculated per Table 12.

Figure 8. Abbreviated warning if the consumer product packaging does not have space for the full warning on the front.

F. Required On-Product Warnings for Consumer Products that Contain Button Cell or Coin Batteries

Reese's Law requires, as practicable, warnings directly on the consumer product that contains button cell or coin batteries. A consumer product must be permanently marked with an

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

ingestion warning on the product display panel. The warning in Figure 9 must be used:

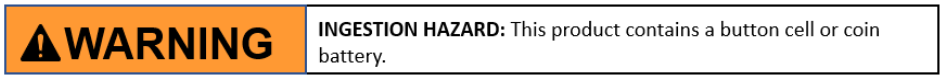


Figure 9. On-product warning label.

If space on the product does not allow the full warning text shown in Figure 9 in accordance with Table 12, then the product must display the internationally recognized: "Warning: contains coin battery" icon, as shown in Figure 10, which is permitted without text.

Figure 10. Safety Alert Symbol to Indicate "Warning: Contains coin battery"

See Staff's NPR Briefing Package at Tab C. For visibility, the icon must be at least 7 mm (0.28 in.) in width and 9 mm (0.35 in.) in height and must be on the product display panel and must be in yellow with black outlines, as shown in Figure 10. The icon must be defined in accompanying printed materials, such as instructions, manual, insert, or hangtag.

Figure 11 illustrates the scaled version of this icon on a product containing a battery, with a 20 mm (0.79 in.) diameter, as well as a scaled version with a 5 mm (0.20 in.) diameter.

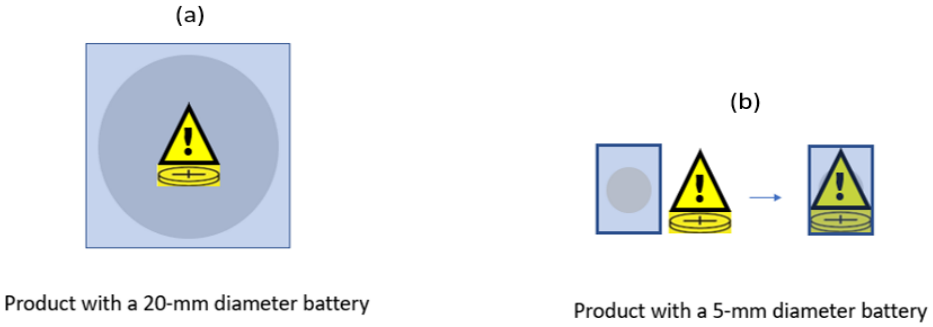


Figure 11. (a) 20mm diameter battery and icon, (b) 5 mm (0.20 in.) battery and icon

Based on staff's assessment, we tentatively find that virtually all consumer products can accommodate either the full warning or one of the scaled icons, and we seek comment on that

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

conclusion. However, if the product is too small to include any of the warnings in Figures 9-11, the product is required to:

1. have packaging containing the warning (see requirements for consumer product packaging), or
2. have a hangtag or sticker label with the full warnings, as shown in Figure 7.

G. Required Warnings for Instructions/Manuals Accompanying Consumer Products

Instructions and manuals for consumer products that contain button cell or coin batteries, if they exist, must contain the full warning label text required for button cell or coin battery packaging, as shown in Figure 7, as well as the three statements implementing section 2(b)(2) of Reese's Law to address the hazard of button cell or coin batteries that become loose or separated from packaging, which provide critical safety-related information should an ingestion incident occur:

- "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash."
- "Even used batteries may cause severe injury or death."
- "Call a local poison control center for treatment information."

If instructions or manuals are not provided with the consumer product, this information must be present on the principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label. This ensures that the consumer has the opportunity to see the appropriate safety-related information, even when a consumer product that uses a button cell or coin battery is not sold with a button cell or coin battery.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

VI. Required Notifications to Purchasers

In addition to the required warnings specified in Reese's Law, and pursuant to the Commission's independent authority under section 27(e) of the CPSA, the proposed rule requires delivery of technical and performance data to purchasers. These notifications will improve safety communication to consumers for the same products subject to the proposed requirements discussed above, and based on the same hazard assessment. Because these proposed notification requirements rest on legal authority independent of Reese's Law, adopting them is not inconsistent with Reese's Law's specification that the *safety rule promulgated pursuant to section 2 of that statute* "shall only contain" the provisions listed by Congress. 15 U.S.C. 2056e(a). For ease of understanding and administration, however, we propose to integrate the text of the notification requirements established under section 27(e) with the warning requirements established in the safety rule under Reese's Law.

A. Websites or Applications that Enable Consumers to Purchase Products Online

Consumers should be able to view battery-related safety information when purchasing products online. Otherwise, consumers would not be exposed to the warnings until they receive the physical product. Learning of the hazard associated with button cell or coin batteries at the time the consumer is searching for product information and making purchasing decisions may influence those purchasing decisions or the actions taken to protect children against the hazard. Therefore, pursuant to its authority under section 27(e) of the CPSA, the Commission is proposing point-of-sale warning requirements for websites or other Internet presence that manufacturers (including importers, per CPSA section 3(a)(11), 15 U.S.C. 2052(a)(11)) use to allow consumers to purchase these products.

Specifically, online sales materials must include the warning in Figure 7 for purchases of button cell or coin batteries, and the warning in Figure 9 for purchases of consumer products

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

containing button cell or coin batteries. The warning must be clearly visible, prominent, and legible next to the product description or near the product image or near the product price.

B. Other Battery Safety Information on the Battery Packaging and Consumer Product Packaging

In addition to the ingestion hazard warning, the proposed rule requires other safety-related information on the battery packaging and consumer product packaging. To reduce battery leakage, fire, and/or explosion hazards that could lead to personal injury, consumers should be aware of, and have ready access to, technical information about safe handling and use of button cell and coin batteries, as well as the characteristics of the batteries themselves. Therefore, we propose the following additional safety information under the authority in section 27(e) of the CPSA:

1. Battery packaging

- Battery type (*e.g.,* LR44, CR2032)
- Battery chemistry (*e.g.,* silver oxide button or lithium)
- Nominal voltage

Having battery type, chemistry, and voltage on the packaging constitutes performance and technical data that may help identify the battery if an ingestion is suspected. If a button cell or coin battery is ingested, knowing this information could assist medical providers to assess the severity of the risk of injury, and to treat the patient accordingly. For example, lithium button cell or coin batteries are associated with a higher likelihood of injury or death, in part, because they have a greater voltage than other button cell or coin batteries. The compatible battery type and voltage information on the product packaging will also help consumers avoid hazards associated with using incompatible batteries, such as leakage, fire, and/or explosion hazards. In addition, this statement will assist consumers in selecting the correct type of battery for the product, reducing the likelihood that incorrect battery cells will be taken from their secure packaging and left loose and accessible to children.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- Year and month or week of manufacture or expiration date
- Name or trademark of the manufacturer or supplier

Identification of manufacture date and other manufacturer information is technical data that may facilitate recalls resulting from ingestion of button or coin batteries.

- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."

Mixing batteries can contribute to battery leakage, fire, and/or explosion hazards that could lead to personal injury. In addition, this statement will inform the consumer to use the correct type of battery cell that is called for use in the product, reducing the likelihood that incorrect battery cells will be taken from their secure packaging and left loose and accessible to children.

- "Ensure the batteries are installed correctly according to polarity (+ and -)."

Batteries installed with the wrong polarity can leak or explode. Also, incorrect installation may result in the consumer removing the batteries to install another set of batteries, creating loose batteries.

- "Remove and immediately discard batteries from equipment not used for an extended period of time."

This statement is intended to ensure that consumers immediately dispose of batteries in unused products, because if left for an extended period, these batteries can leak, discharge, or explode unexpectedly, creating risks of injury. Furthermore, used button cell or coin batteries may have sufficient energy to cause damage if ingested.

- "Non-rechargeable batteries are not to be recharged."

Placing non-rechargeable batteries in a charger can cause battery leakage, fire, and/or exploding hazards. This statement is intended to ensure that consumers do not attempt to

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

recharge non-rechargeable batteries, or leave used batteries accessible to children with the intention of recharging them.

- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

This statement warns against actions that may result in external injuries from chemical burns. Damaged button cell or coin batteries also can leak toxic chemicals that poses a risk if ingested.

2. Consumer product packaging or accompanying hang tag or sticker label.

Also pursuant to section 27(e) of the CPSA, the principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must include the following:

- Products with non-replaceable batteries must include a statement indicating the product contains non-replaceable batteries. If a consumer attempts to replace a non-replaceable battery, this action may damage the consumer product or the battery, and contribute to battery leakage, fire and/or explosion hazards. This may also cause the original or the replacement battery to become accessible, contributing to the ingestion hazard.

The following additional requirements were previously described for battery packaging, and for the same reasons are also required on either the principal display panel or secondary display panel of the consumer product packaging, or in the absence of consumer product packaging, on the accompanying sticker or hangtag:

- Battery type (*e.g.,* LR44, CR2032)
- Nominal voltage

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

3. Instructions and manuals:

Likewise, under the authority of CPSA section 27(e), instructions and manuals, when provided with consumer products must include the following additional battery safety-related information that is also required on the battery packaging:

- Battery type (*e.g.,* LR44, CR2032)
- Nominal voltage
- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."
- "Remove and immediately discard batteries from equipment not used for an extended period of time."
- "Non-rechargeable batteries are not to be recharged."
- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

If instructions or manuals are not provided with the consumer product, this information must be present on the principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label. This ensures that the consumer has the opportunity to see the appropriate safety-related information, even when a consumer product that uses a button cell or coin battery is not sold with a button cell or coin battery.

C. Request for Comment on Requiring a Warning Icon on Button Cell or Coin Batteries

Reese's Law does not require marking or labeling regarding the ingestion hazard directly on button cell or coin batteries. However, the voluntary standard ANSI C18.3M advises to durably and indelibly mark coin cells with the "Keep Out of Reach" icon, with a minimum icon size of 6 mm in

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

diameter. In accordance with Reese's Law, the Commission recommends the "Keep Out of Reach" icon be used in conjunction with warning labels on battery and consumer product packaging to quickly convey the required message and direct the reader's attention to the warning label. CPSC staff advises that requiring button cell or coin batteries that are visible within the packaging at the point of sale to have the "Keep Out of Reach" icon will further remind the consumer of the ingestion hazard, and direct attention to the icon and warning label on the battery packaging. Additionally, placing the "Keep Out of Reach" icon on button cell or coin batteries would continue to inform consumers of the ingestion hazard posed by the battery at all stages of its lifecycle, including while it is in battery packaging, when placed in a consumer product, or when loose.

The Commission requests comment on whether the rule should require button cell or coin batteries to be durably and indelibly marked with the "Keep Out of Reach" icon where size permits, at a minimum size of 6 mm in diameter, and if so, whether the appropriate legal authority is Reese's Law, section 27(e) of the CPSA, or another statute.

Figure 12. "Keep out of Reach" Icon Etched onto Battery

VII. Description of the Proposed Rule

As noted, we propose for the sake of clarity, convenience, and consistency to integrate the rule text adopted under Reese's Law with that adopted under the separate authority of CPSA section 27(e), using the same definitions and exceptions for the section 27(e) requirements as for the requirements based on Reese's Law. Below, we describe the resulting provisions of proposed 16 CFR part 1263.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

A. Section 1263.1 Scope, Purpose, Effective Date, Units, and Exemption

Proposed § 1263.1(a) explains the scope and purpose of the safety standard required by Reese's Law. 15 U.S.C 2056e, Public Law No. 117-171. Reese's Law requires a rule intended to eliminate or adequately reduce the risk of injury and death to children 6 years old and younger from ingesting button cell or coin batteries. Based on section 2 of Reese's Law, the scope of the proposed rule includes consumer products that contain, or are designed to use, button cell or coin batteries, the packaging of such consumer products and accompanying literature, and the packaging of button cell or coin batteries.

Section 2(a) of Reese's Law requires performance requirements for child-resistant button cell or coin battery compartments during reasonably foreseeable use and misuse of consumer products that use such batteries. Proposed § 1263.1(a) also explains that Reese's Law provides warning label requirements for packaging containing button cell or coin batteries, packaging of consumer products containing such batteries, consumer products, and instructions and manuals accompanying consumer products. The proposed rule also explains that the Commission will require point-of-sale notification of performance and technical data under the Commission's authority in section 27(e) of the CPSA, 15 U.S.C. 2076(e).

Section 1263.1(b) describes the effective date of the proposed rule. Consistent with section 6 of Reese's Law (15 U.S.C. 2056e Notes), the rule proposes that all consumer products and packaging containing button cell or coin batteries that are subject to the rule, and that are manufactured or imported after the proposed effective date of 180 days following publication of the final rule in the *Federal Register*, must comply with the requirements of this part.

Section 1263.1(c) provides that values stated without parentheses are the requirement, while values in parentheses are approximate values. This proposal is consistent with UL 4200A. Section 1263.1(d) sets forth the statutory exemption for toys that meet the mandatory toy standard in section 4 of Reese's Law, proposing that "any object designed, manufactured, or marketed as a plaything

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

for children under 14 years of age that is in compliance with the battery accessibility and labeling requirements of 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys, is exempt from the requirements of this part." *See* 15 U.S.C. 2056e Notes.

Because section 2(a) of Reese's Law directs the Commission to adopt a rule addressing the risk of injury from ingestion, and because the purpose of the proposed rule is to address the ingestion hazard associated with button cell or coin batteries, proposed § 1263.1(e) states that button cell or coin batteries that the Commission has determined do not present an ingestion risk are not subject to this rule. The proposal applies to zinc-air button cell or coin batteries.

B. Section 1263.2 Definitions

Proposed § 1263.2 describes the definitions used for this consumer product safety rule and notification requirements. The proposed rule explains that in addition to the definitions given in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) and the definitions in section 5 of Reese's Law (15 U.S.C. 2056e Notes), the Commission proposes to add eight definitions that specifically apply to this rule. The definitions are listed in the rule in alphabetical order.

Accessible and Accessibility Probe. As described in section VII.C, the proposed performance requirements for battery compartments require that after use-and-abuse testing, a button cell or coin battery must not become accessible to children. The proposed rule measures accessibility using a test probe. Accordingly, proposed § 1263.2 defines the required test probe, stating that an "accessibility probe" means "Test Probe 11 in IEC 61032 Protection of Persons and Equipment by Enclosures - Probes for Verification." Similarly, proposed § 1263.2 defines "accessible" to mean that the tests probe is "able to be contacted by the accessibility probe." This means a battery is accessible if the test probe can touch a button cell or coin battery. Specifying the test probe and the definition of "accessible" in the proposed rule is intended to assist those who test consumer products to test consistently and reliability for the accessibility of button cell or coin batteries during testing to the standard.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Button Cell or Coin Battery. Proposed § 1263.2 restates the statutory definition of a "button cell or coin battery" in section 5 of Reese's Law. 15 U.S.C. 2056e Notes. A "button cell or coin battery" means "(1) a single cell battery with a diameter greater than the height of the battery; or (2) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard." *Id*. For this proposed rule, the Commission is focusing on addressing button cell and coin batteries under part (A) of the definition, because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type of ingestion hazard as button cell or coin batteries. For example, cylindrical batteries can pose a choking hazard, and CPSC is aware that consumers have ingested cylindrical batteries; however, the medical literature shows that injury or death due to ingestion of a cylindrical battery is rare. Consequently, the Commission is not including cylindrical batteries in the proposed rule at this time, but will expect staff to continue to monitor battery ingestion data. If CPSC becomes aware of a serious ingestion hazard associated with another battery type, section 2(g) of Reese's Law allows the Commission to undertake additional rulemaking to address the hazard at any time. 15 U.S.C. 2056e(g).

Consumer product containing button cell or coin batteries. Proposed § 1263.2 contains the statutory definition of a "consumer product containing button cell or coin batteries" from section 5 of Reese's Law. 15 U.S.C. 2056e Notes. The Commission preliminarily interprets this definition as providing that these consumer products include consumer products that are sold with a button cell or coin battery, and consumer products that are sold without a battery but are designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately.

Ingestion Hazard. Proposed § 1263.2 describes the "ingestion hazard" addressed by the proposed rule. Based on a review of the medical literature, CPSC incident data, and data from the NCPC, an ingestion hazard is caused when a button cell or coin battery becomes lodged in the body,

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

and can potentially cause death or serious injury through choking, generation of hazardous chemicals, leaking of hazardous chemicals, electrical burns, pressure necrosis, or other means.

Principal Display Panel and Secondary Display Panel. Proposed § 1263.2 also explains what a "principal display panel" means to aid in understanding the required placement of warning statements on consumer product and button cell or coin battery packaging. The proposed rule explains that a "principal display panel" is typically on the front of the retail package of button cell or coin batteries or consumer products containing such batteries. The principal display panel is the panel most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. This definition assists in distinguishing the principal display panel from the proposed definition of a "secondary display panel," described as a "display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package."

Product Display Panel. Finally, proposed § 1263.2 describes a "product display panel" to differentiate the surface of a consumer product battery compartment, as opposed to the packaging of button cell or coin batteries and the packaging of consumer products that contain such batteries. A product display panel is:

> the surface area on, near, or in the battery compartment. For consumer products with replaceable button cell or coin batteries, the product display panel must be visible while a consumer installs or replaces the button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel must be visible upon access to the battery compartment.

The intent of this definition is to inform industry that warnings on a product display panel must be located where a consumer will see the warning when interacting with the battery compartment, as required in section 2(a)(2)(C) of Reese's Law. 15 U.S.C. 2056e(a)(2)(C).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

C. Section 1263.3 Requirements for Consumer Products Containing Button Cell or Coin Batteries

The primary way that children access button cell or coin batteries and then ingest them is by accessing batteries from a consumer product. Accordingly, as required by section 2(a) of Reese's Law, the proposed rule would establish performance requirements for child-resistant button cell or coin battery compartments on consumer products during reasonably foreseeable use and misuse. Performance requirements are based on staff's incident review, engineering analysis, testing of consumer products, and assessment that none of the relevant voluntary standards meet the risk reduction and warning requirements of Reese's Law sections 2(a) and (d). The proposed rule is based on the provisions of several existing voluntary standards, including UL 4200A-21, IEC 62368-1, and ASTM F963-17 (as codified in 16 CFR part 1250). Performance requirements in the rule would apply to consumer products containing button cell or coin batteries with replaceable and non-replaceable batteries.

General Requirements. Proposed § 1263.3(a) contains general requirements for consumer products containing button cell or coin batteries. This section explains that, in general, consumer products containing button cell or coin batteries must meet the performance and labeling requirements in the rule to minimize the risk of children accessing and ingesting button cell or coin batteries.

Performance requirements for consumer products containing button cell or coin batteries that are removable. Proposed § 1263.3(b) describes the specific performance requirements for consumer products containing button cell or coin batteries that are removable. A removable or replaceable button cell or coin battery in a consumer product cannot be made accessible, meaning able to be contacted with the accessibility probe, when tested to § 1263.3(d); must meet the performance tests in § 1263.3(e); and must require a tool, such as a screwdriver or coin, to open, or

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

be secured using an enclosure that requires a minimum of two independent and simultaneous hand movements to open (a double-action locking mechanism).

The proposed rule also requires that battery compartments secured by one or more screws, or a twist-on access cover, meet a test for minimum torque (0.5 Nm (4.4 in-lb)) and minimum angle of rotation (90 degrees), or the fastener(s) must engage a minimum of two full threads. Moreover, screws or fasteners used to secure the battery compartment enclosure must be captive to the compartment door, cover, or closure. Unlike UL 4200A and IEC 62368-1, the proposed rule does not exclude from the requirement for captive screws large panel doors leading to button cell or coin battery compartments. CPSC requests comment on the rationale for such an exception and the types of products to which it should apply, if adopted.

Performance requirements for consumer products containing button cell or coin batteries that are non-removable. Proposed § 1263.3(c) explains that consumer products containing button cell or coin batteries not intended for removal or replacement must be made inaccessible by using a battery compartment enclosure that complies with the performance requirements of § 1263.3(b), meaning secured in a compartment that meets the same requirements as removable button cell or coin batteries, or by securing a button cell or coin battery compartment using soldering, fasteners such as rivets, or equivalent means, that passes the *Secureness Test* in § 1263.3(f).

Accessibility test method. Proposed § 1263.3(d) assesses whether a child can access a button cell or coin battery installed in a consumer product by determining whether the specified accessibility probe can make contact with a button cell or coin battery. If children can touch the battery, then they may be able to remove the battery, leading to a potential ingestion. The test method requires that any part of the battery compartment enclosure that can be opened or removed without a tool, and with fewer than two independent and simultaneous movements (*e.g.,* a zipper or hook and loop), be removed (§ 1263.3(d)(1)). The test method also states that if any part of the battery compartment is protected by pliable materials, such as fabric, paper, foam, or vinyl, or a

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

seam, the tester must first apply the Tension Test for Seams in Stuffed Toys and Beanbag-Type Toys in 16 CFR part 1250, to determine whether the battery compartment enclosure can become exposed or accessible, using the specified force of 70.0 N (15.7 lbf) (§ 1263.3(d)(2)). The test method instructs that if during this assessment a new part of the battery compartment enclosure becomes exposed or accessible, the tester must repeat the test in § 1263.3(d)(1), and the test in paragraph (d)(2), until no new part of the battery compartment enclosure becomes exposed or accessible, and then conduct the test in § 1263.3(d)(3).

The test in § 1263.3(d)(3) instructs the tester to insert or apply the accessibility probe to any depth that a battery compartment opening will permit, and rotate or angle the accessibility probe before, during, and after insertion or application through the battery compartment opening to any position that is necessary to determine whether the probe can contact the button cell or coin battery. This test is intended to simulate a child attempting to reach a button cell or coin battery installed in the consumer product; however, this test is not intended to judge the strength of the material comprising the battery compartment. Testers should use the minimum force necessary to determine whether the accessibility probe can contact a button cell or coin battery installed in the consumer product.

Performance tests for consumer products containing button cell or coin batteries. Proposed § 1263.3(e) states that testers should first conduct the required pre-conditioning steps in § 1263.3(e)(1) before testing consumer products to the performance requirements in § 1263.3(e)(2) (for products with replaceable battery compartments), and § 1263.3(f) (for products with accessible non-replaceable batteries). Testers are also instructed to perform pre-conditioning and performance requirements in the order presented in the rule.

Performance test: Pre-conditioning: Stress Relief. Proposed § 1263.3(e)(1) requires each test sample of a consumer product to be pre-conditioned prior to conducting the applicable performance tests. The first pre-conditioning step, § 1263.3(e)(1)(i), is "stress relief" and applies to

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

all covered consumer products, *i.e.*, those with replaceable and non-replaceable batteries. Stress relief requires heating each sample consumer product that has a battery compartment enclosure made from molded or formed thermoplastic materials in a circulating air oven for at least 7 hours, at an oven temperature of the higher of at least 70°C (158°F) or at least 10°C (18°F) higher than the maximum temperature of the thermoplastic battery compartment enclosure during the most stringent normal operation of the consumer product. The rule proposes that testers must allow the product sample to cool to room temperature after removal from the oven before proceeding, to achieve more consistent results across tests and test labs.

Performance test: Pre-conditioning: Battery replacement. Mechanical pre-conditioning breaks-in the component parts associated with securing the battery compartment and is needed to address durability issues associated with battery compartments, such as stripping of threads. Accordingly, proposed § 1263.3(e)(1)(ii), which applies only to consumer products with button cell or coin batteries intended to be removable or replaceable, requires opening the battery compartment enclosure, removing and replacing the button cell or coin battery, and closing the battery compartment enclosure for a total of 10 cycles. When battery compartment enclosures are secured with one or more screws, the screws must be loosened and then tightened using a suitable screwdriver, and applying a continuous linear torque, according to the Torque to Be Applied to Screws table, Table 20, of the Standard for Audio, Video and Similar Electronic Apparatus – Safety Requirements, UL 60065. If the screw(s) do not meet the specified torque requirements during this step, the test method requires removing the screws and repeating the accessibility test in proposed § 1263.3(d).

Performance test: Abuse tests. After pre-conditioning consumer product samples, the proposed rule requires that all consumer product samples with removable or replaceable batteries must pass a series of six abuse tests, conducted in the sequence set forth in the proposed rule. After testing, each sample must meet the compliance requirement in proposed § 1263.3(e)(3).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Performance test: Abuse tests: Drop test. To address foreseeable risks of breaking consumer products or their battery compartments, proposed § 1263.3(e)(2)(i) requires each sample to be dropped 10 times from a height of 1.0 m (39.4 in) onto a horizontal hardwood surface in positions likely to produce the maximum force on the battery compartment enclosure. The hardwood surface must be at least 13 mm (0.5 in) thick, mounted on two layers of nominal 19 mm (0.75 in) thick plywood, and placed on a concrete or equivalent non-resilient surface.

Performance test: Abuse tests: Impact test. Consistent with the UL 4200A standard, proposed § 1263.3(e)(2)(ii) requires that the battery compartment enclosure door or cover on each sample consumer product be subjected to three, at least 2-J (1.5-ft·lbf) impacts, as shown in Figures 1 and 2 to proposed paragraph § 1263.3(e)(2)(ii).

Performance test: Abuse tests: Crush test. To address the scenario of a child opening a battery compartment that cannot be impacted directly during the drop test proposed § 1263.3(e)(2)(iii) requires each sample consumer product to be subjected to a crush test using requirements similar to UL 4200A and IEC 62368-1. The crush test simulates a child pushing on the product with hands or feet, which cannot be assessed during the drop test on some consumer products. The proposed rule requires that each sample be supported by a fixed, rigid surface, in positions likely to produce the most adverse results, as long as the position of the consumer product is self-supported, and then apply a crushing force of at least 335 N (75.3 lbf) to the exposed surface for a period of 10 seconds. The test method states the force should be applied using a flat surface measuring approximately 100 mm by 250 mm (3.9 in by 9.8 in).

Performance test: Abuse tests: Compression test. Proposed § 1263.3(e)(2)(iv) requires the compression test in ASTM F963 as codified in the toy standard. It further subjects consumer products to a crushing load that addresses children unintentionally opening battery compartments that cannot be impacted directly during the drop test, but can be pushed open with hands or fingers. The test method requires that if any surface of the battery compartment enclosure is accessible to a

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

child and inaccessible to flat surface contact during the drop test, then apply the Compression Test from 16 CFR part 1250 (the mandatory toy standard) to that surface, using a force of at least 136 N (30.6 lbf).

Performance test: Abuse tests: Torque test. The proposed rule applies to products not specifically contemplated by UL 4200A or IEC 62368-1, such as shirts and shoes that light up and rely on a button cell or coin battery to provide a power source. Accordingly, the proposed rule includes torque and tension tests to address battery accessibility to children in pliable products. If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, proposed § 1263.3(e)(2)(v) requires the battery compartment enclosure to be tested to the Torque Test for Removal of Components from 16 CFR part 1250 (the toy standard), using a torque of at least 0.50 Nm (4.4 in.-lbf).

Performance test: Abuse tests: Tension test. For the same reasons stated for the proposed torque requirement, if a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, proposed § 1263.3(e)(2)(vi) requires application of the Tension Test for Removal of Components from 16 CFR part 1250 (the toy standard) to the battery compartment enclosure, using a force of at least 70.0 N (15.7 lbf).

Performance test: Abuse tests: Compliance. Proposed § 1263.3(e)(3) provides that if a button cell or coin battery becomes accessible or is liberated from a consumer product as a result of any of the abuse tests in section 1263.3(e)(2), the consumer product is noncompliant and fails testing. Additionally, after completing all abuse testing, the rule requires that the tester apply a force of at least 50 N (11.2 lbf) for 10 seconds to the battery compartment enclosure door or cover using the accessibility probe at the most unfavorable position on the battery compartment enclosure, and in the most unfavorable direction. The force must be applied in only one direction at a time. If

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

the battery compartment enclosure door or cover opens or does not remain functional, or the button cell or coin battery becomes accessible, the consumer product is noncompliant and fails testing.

Performance test: Secureness test. Proposed § 1263.3(f) applies only to button cell or coin batteries not intended for removal or replacement that are installed in a consumer product, and that are accessible based on the test in § 1263.3(b). Such products must be tested by applying a test hook, as shown in Figure 3 to paragraph § 1263.3(f) of the regulation text, using a force of at least 22 N (4.9 lbf), directed outwards, applied for 10 seconds at all points where application of a force is possible. To pass the test, the button cell or coin battery cannot become accessible or liberate from the consumer product during testing.

D. Section 1263.4 Requirements for Marking and Labeling

As explained in sections V and VI of this preamble, the proposed rule establishes warning label requirements for packaging containing button cell or coin batteries; packaging of consumer products containing such batteries (regardless of whether the batteries are permanent or replaceable); battery compartments of consumer products that contain button cell or coin batteries (where practicable and regardless of whether the batteries are permanent or replaceable); instructions or manuals that accompany such consumer products; as well as time-of-sale (internet and in-store) notification of performance and technical data that provides information about the safety of button cell or coin batteries. Please see sections V and VI of this preamble for a detailed description and rationale for the proposed warning label requirements.

E. Section 1263.5 Severability

Section 1263.5 proposes a severability clause. The proposed provision states the Commission's intent that if certain requirements in the rule are stayed or determined to be invalid by a court, the remaining requirements in the rule should continue in effect. This severability clause would apply to all provisions whether adopted as part of the safety standard under Reese's Law or

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

as a notification requirement under section 27(e) of the CPSA, to reflect the Commission's intent that part 1263 as whole be given its greatest effect.

VIII. Testing, Certification, and Notice of Requirements

Section 14(a) of the CPSA includes requirements for certifying that consumer products comply with applicable mandatory standards. 15 U.S.C. 2063(a). Section 14(a)(1) addresses required certifications for non-children's products, and sections 14(a)(2) and (a)(3) address certification requirements specific to children's products.

Non-Children's Products. Section 14(a)(1) of the CPSA requires every manufacturer (which includes importers per 15 U.S.C. 2052(a)(11)) of a non-children's product that is subject to a consumer product safety rule under the CPSA or a similar rule, ban, standard, or regulation under any other law enforced by the Commission to certify that the product complies with all applicable CSPSC-enforced requirements. 15 U.S.C. 2063(a)(1). Section 14(g) of the CPSA contains content and availability requirements for certificates. 15 U.S.C. 2063(g).

Children's Products. A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or younger." 15 U.S.C. 2052(a)(2). Section 4 of Reese's Law specifically exempts from the performance and labeling requirements in section 2 of the law, any toy product that is in compliance with the battery accessibility and labeling requirements in 16 CFR part 1250, the mandatory toy standard. However, all non-toy children's products that contain button cell or coin batteries are subject to the rule and must be tested by a CPSC-accepted third party laboratory and certified as compliant.

The following factors are relevant when determining whether a product is a children's product:

- manufacturer statements about the intended use of the product, including a label on the product if such statement is reasonable;

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger;
- whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger; and
- the Age Determination Guidelines issued by CPSC staff in January 2020, and any successor to such guidelines.

Id. "For use" by children 12 years and younger generally means that children will interact physically with the product based on reasonably foreseeable use. 16 CFR § 1200.2(a)(2). Children's products, for example, may be decorated or embellished with a childish theme, be sized for children, or be marketed to appeal primarily to children. *Id*. § 1200.2(d)(1).

Section 14(a)(2) of the CPSA requires the manufacturer or private labeler of a children's product that is subject to a children's product safety rule to certify that, based on a third party conformity assessment body's testing, the product complies with the applicable children's product safety rule. 15 U.S.C. 2063(a)(2). The Commission's requirements for children's product testing and certification are codified in 16 CFR part 1107. Section 14(a) of the CPSA also requires the Commission to publish a notice of requirements (NOR) for a third party conformity assessment body (*i.e.*, testing laboratory) to obtain accreditation to assess conformity with a children's product safety rule. 15 U.S.C.. 2063(a)(3)(A). Because some consumer products that contain button cell or coin batteries are children's products, the proposed rule is a children's product safety rule, as applied to those products. Accordingly, if the Commission issues a final rule, it must also issue an NOR.

The Commission published a final rule, codified at 16 CFR part 1112, entitled *Requirements Pertaining to Third Party Conformity Assessment Bodies*, which established requirements and criteria concerning testing laboratories. 78 FR 15836 (Mar. 12, 2013). Part 1112 includes

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

procedures for CPSC to accept a testing laboratory's accreditation and lists the children's product safety rules for which CPSC has published NORs. When CPSC issues a new NOR, it must amend part 1112 to include that NOR. Accordingly, as part of this NPR for child-resistant battery compartments on consumer products, the Commission proposes to amend part 1112 to add the "Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries" to the list of children's product safety rules for which CPSC has issued an NOR.

Testing laboratories that apply for CPSC acceptance to test consumer products containing button cell or coin batteries, that are children's products, to comply with the new rule, would have to meet the requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to include 16 CFR part 1263, *Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries*, in the laboratory's scope of accreditation of CPSC safety rules listed on the CPSC website at: www.cpsc.gov/labsearch.

IX. Effective Date

The APA generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The Commission proposes that a final rule containing (1) performance and warning label requirements for consumer products containing button cell or coin batteries, and (2) warning label requirements for button cell or coin battery packaging, will become effective 180 days after publication of a final rule in the *Federal Register*. Therefore, in accordance with section 6 of Reese's Law, products manufactured or imported after 180 days from publication of a final rule would be required to comply with the rule.

The Commission is proposing 180 days to comply with the rule because a substantial number of consumer products containing button cell or coin batteries currently do not meet the performance requirements in UL 4200A or ASTM F963, and many affected industries will be

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

unfamiliar with all or part of the proposed requirements. These industries may need to redesign, test, and certify to the requirements in the rule. Children's products that are not toys will require third party testing to the rule, and 180 days will provide sufficient time for test labs to become ISO-accredited and have this accreditation accepted by CPSC to test children's products. Additionally, the warning label requirements in the proposed rule include specific language that requires manufacturers to revise or reprint all existing packaging and to revise on-product warnings, where practicable.

A 180-day effective date reflects similar language in Reese's Law, which in section 3(a) sets a 180-day effective date for the child-resistant packaging requirements. The Commission requests comment on whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and asks commenters to provide specific information to support such a later or an earlier effective date.

X. Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes an NPR. 5 U.S.C. 603. The IRFA must describe the impact of the proposed rule on small entities and identify significant alternatives that accomplish the statutory objectives and minimize any significant economic impact of the proposed rule on small entities. CPSC staff prepared an IRFA for this rulemaking that appears at Tab E of the Staff's NPR Briefing Package. We provide a summary of the IRFA below.

A. Reasons for Agency Action and Legal Basis for NPR

The proposed rule is intended to address ingestion of button cell or coin batteries by children 6 years old and younger, and the associated deaths and injuries, as required by Reese's Law, 15

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

U.S.C. 2056e, and authorized by section 27(e) of the CPSA, 15 U.S.C. 2076(e). As detailed in Tab D of Staff's NPR Briefing Package, the proposed rule would require performance requirements for button cell or coin battery-powered consumer products, and require marking and labeling of consumer products, consumer product packaging, and button cell or coin battery packaging, as provided in Tab C of Staff's NPR Briefing Package.

B. Small Entities to Which the Proposed Rule Would Apply

The North American Industry Classification System (NAICS) defines product codes for U.S. firms. Firms that manufacture button cell or coin battery-powered consumer products may list their business under a large variety of NAICS product codes. Most of these firms likely fall under the following NAICS codes: 334118 Computer Terminal and Other Computer Peripheral Equipment Manufacturing; 334310 Audio and Video Equipment Manufacturing; 335999 All Other Miscellaneous Electrical Equipment and Component Manufacturing; and 339920 Sporting and Athletic Goods Manufacturing. Importers of button cell or coin battery-powered consumer products are also as varied as the manufacturers. Staff expects most of the firms to fall under the following NAICS codes as wholesalers: 423620 Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers; 423430 Computer and Computer Peripheral Equipment and Software Merchant Wholesalers; and 423690 Other Electronic Parts and Equipment Merchant Wholesalers.

Retailers of button cell or coin battery-powered consumer products consist of a large variety of retailer types from large, "big box" retailers, to smaller specialized product firms. Nearly every NAICS code listed under retail trade (44, 45) may sell a product within scope of the proposed rule. Staff estimates that most of these products are sold by firms listed in NAICS codes 443140 Electronics and Appliance Retailers; 455219 All Other General Merchandise Retailers; 459420, Gift, Novelty, and Souvenir Retailers; 452000 General Merchandise Stores; and 459110 Sporting Goods Retailers.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Under U.S. Small Business Administration guidelines, a manufacturer, importer, and retailer of button cell or coin battery-powered consumer products is categorized as "small," based on the associated NAICS code. Manufacturers are categorized as small by the number of employees and importers/retailers by annual revenues. Based on 2017 data from U.S. Census Bureau, and a sample of retailers' estimated revenues, staff estimated the number of firms classified as small for each NAICS code listed above (Census Bureau, 2020). The tables below provide the estimates of the number of small firms by each code.

Table 13. Estimated Number of Small Manufacturers and Importers

NAICS Code	Description	SBA Size Standard for Manufacturers/Importers (# of Employees)	Number of firms that meet size standard
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000	509
334290	Other Communications Equipment Manufacturing	750	305
334310	Audio and Video Equipment Manufacturing	750	453
335210	Small Electrical Appliance Manufacturing	1,500	119
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	500	734
339920	Sporting and Athletic Goods Manufacturing	750	1,564
339940	Office Supplies (except Paper) Manufacturing	750	412
339999	All Other Miscellaneous Manufacturing	500	5,714
423420	Office Equipment Merchant Wholesalers	200	2,197
423430	Computer and Computer Peripheral Equipment and Software Merchant Wholesalers	250	5,743
423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers	225	1,956
423690	Other Electronic Parts and Equipment Merchant Wholesalers	250	8,826

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

NAICS Code	Description	SBA Size Standard for Manufacturers/Importers (# of Employees)	Number of firms that meet size standard
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	100	4,521
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100	8,350

Table 14. Estimated Number of Small Retailers

NAICS Code	Description	SBA Size Standard for Retailers (Annual Revenue) $millions	Number of firms that meet size standard
444110	Home Centers	$41.50	1,526
444130	Hardware Retailers	$14.50	9,623
444240	Nursery, Garden Center, and Farm Supply Retailers	$19.00	13,228
443140	Electronics and Appliance Retailers	$35.00	18,906
455110	Department Stores	$35.00	11
455211	Warehouse Clubs and Supercenters	$41.50	3
455219	All Other General Merchandise Retailers	$35.00	7,812
456110	Pharmacies and Drug Retailers	$33.00	18,912
459110	Sporting Goods Retailers	$23.50	16,123
459410	Office Supplies and Stationery Retailers	$35.00	2,646
459420	Gift, Novelty, and Souvenir Retailers	$12.00	15,264
459999	All Other Miscellaneous Retailers	$10.00	36,225
452000	General Merchandise Stores	$35.00	7,832

C. Costs and Impact of the Proposed Rule on Small Entities

Button cell or coin battery-powered consumer products may require redesign to meet the rule's requirement for a battery compartment that requires a coin or tool to secure the enclosure ("tool lock"), or a double-action lock. Button cell or coin battery-powered consumer product manufacturers would most likely adopt a tool lock secured with a screw for affected products that currently do not conform to the proposed rule requirements. The potential costs of this rule,

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

therefore, are the incremental cost to incorporate a screw lock, and the one-time research, development, and retooling costs associated with any changes to battery compartments. For products that incorporate a double-action lock to secure the compartment, the Commission expects the only design-related cost incurred would be the redesign of the compartment to accommodate the change.

Staff's estimate of the incremental costs to modify a battery compartment for a tool lock ranges from $0.02 to $0.04 per product. The estimate of possible research, development, and retooling costs is a maximum of $15,400 per firm. We expect firms that choose to meet the requirement of the rule using a double-action lock would only incur research and development costs.

Manufacturers would likely incur additional costs to certify that their button cell or coin battery-powered consumer products meet the proposed rule, as required by Section 14 of the CPSA, 15 U.S.C. 2063. For general use products, the certification must be based on a test of each product or a reasonable testing program. Manufacturers may complete the testing themselves or use a testing laboratory. Certification of children's products, however, must be completed by a CPSC-accepted, third party conformity assessment body (*i.e.,* third party laboratory). The cost of laboratory certification testing is expected to range from $150 to $350 per product sample. These third party testing costs should be considered as a possible maximum testing cost of the proposed rule, because less costly alternatives may be available.[14]

To comply with the proposed rule, small manufacturers would incur a one-time redesign cost and continuous incremental component costs, described above, for some product lines that currently do not meet the requirements. We do not expect most small manufacturers to suffer a

[14] Certificate content requirements are set forth in section 14(g) of the CPSA and codified in 16 CFR part 1110. A reasonable testing program performed by the manufacturer would meet the requirements for general use (non-children's) products, but children's products are required to be tested and certified based on the third party testing requirements in 16 CFR part 1107.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

disproportionate cost effect from the proposed rule. Firms that rely heavily on the production of small, unique or novel electronic products, or high-volume, low-price products, could be affected adversely, however. Retail prices for button cell or coin battery-powered consumer products vary widely, with the least expensive product, on a per-unit basis, being mini flashlights at $1.00.[15] A small manufacturer could incur costs that exceed 1 percent of annual revenue if the firm only produced these high-volume, low-price, or novel electronic products. Also, smaller manufacturers with less than $770,000 to $1,540,000 in annual revenue could incur one-time costs that exceed 1 percent of annual revenue, based on CPSC staff's estimate of the potential research and development costs, which range from $7,700 to $15,400 per firm.

Generally, CPSC staff considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. CPSC staff anticipates a potentially significant impact on some small firms that manufacture button cell or coin battery-powered consumer products. Staff assesses, however, that most small firms would not incur costs that exceed 1 percent of annual revenues, and therefore, would not be significantly impacted by the proposed rule.

D. Alternatives

Under section 603(c) of the Regulatory Flexibility Act, an IRFA analysis should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." 5 U.S.C. 603(c). CPSC staff assessed that the broad scope of Reese's Law does not allow for a significant alternative that would reduce impacts to small businesses, such as limiting scope, providing exemptions, and educating consumers in lieu of regulatory action. To reduce the impact of the rule on small firms, CPSC proposes not to require labeling of zinc-air batteries, which do not pose the same type of ingestion hazard as other button cell or coin batteries.

[15] Based on staff's review of product offerings on retailer websites and in-store locations.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

This proposal will decrease burden, but not consequentially, because incremental labeling costs are not significant. CPSC also could refrain from proposing the additional labeling requirements under section 27(e) of the CPSA, which are not required by Reese's Law. However, removing section 27(e) performance and technical data requirements would reduce burden by an inconsequential amount, because firms would still have to conform to the other labeling provisions mandated by Reese's Law. The incremental increase in burden from staff's additional labeling requirements is insignificant.

XI. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment," and therefore, do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c)(1). Safety standards providing performance and labeling requirements for consumer products that contain button cell or coin batteries fall within this categorical exclusion.

XII. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). Under the PRA, an agency must publish the following information:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- an estimate of the burden that will result from the collection of information; and
- notice that comments may be submitted to OMB.

44 U.S.C. 3507(a)(1)(D). In accordance with this requirement, the Commission provides the following information:

Title: Amendment to Third Party Testing of Children's Products, approved previously under OMB Control No. 3041-0159.

Summary, Need, and Use of Information: Based on the requirements in Reese's Law, 15 U.S.C. 2056e(a) and (b), and section 27(e) of the Consumer Product Safety Act, 15 U.S.C. 2076(e), the proposed consumer product safety standard prescribes performance requirements for child-resistant battery compartments on consumer products that contain button cell or coin batteries, and warning requirements for button cell and coin-battery packaging, consumer product packaging, consumer products, and instructions and manuals. These performance and labeling requirements are intended to reduce or eliminate injuries and deaths associated with children 6 years old and younger ingesting button cell or coin batteries.

Section 4 of Reese's Law specifically exempts from the performance and labeling requirements in section 2 of the law, any toy product[16] that is in compliance with the battery accessibility and labeling requirements in 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys. However, some consumer products that are not toys subject to the toy standard are considered children's products. A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or younger." 15 U.S.C. 2052(a)(2). The Commission's regulation at 16 CFR part 1200 further interprets the term. Section 14 of the CPSA requires that children's products be tested by a third party conformity assessment body, and that the manufacturer of the product, including an importer, must issue a children's product certificate

16 For purposes of Reese's Law, a "toy product" is "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." 15 U.S.C. 2056e Notes.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

(CPC). Based on such third party testing, a manufacturer or importer must attest to compliance with the applicable consumer product safety rule by issuing the CPC. The requirement to test and certify children's products falls within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

The requirements for the CPCs are stated in Section 14 of the CPSA, and in the Commission's regulation at 16 CFR parts 1107 and 1110. Among other requirements, each certificate must identify the manufacturer or private labeler issuing the certificate and any third party conformity assessment body, on whose testing the certificate depends, the date and place of manufacture, the date and place where the product was tested, each party's name, full mailing address, telephone number, and contact information for the individual responsible for maintaining records of test results. The certificates must be in English. The certificates must be furnished to each distributor or retailer of the product and to the CPSC, if requested.

The Commission has an OMB control number, 3041-0159, for children's product testing and certification. This proposed rule would amend this collection of information to add testing and certification to the performance requirements for child-resistant battery compartments on children's products (that are not toys) that contain button cell or coin batteries, as well as warnings on the packaging of these children's products, the battery compartment of these children's products, and any accompanying instructions and manuals, as set forth in the proposed rule.

Respondents and Frequency: Respondents include manufacturers and importers of non-toy children's products that contain button cell or coin batteries. Manufacturers and importers must comply with the information collection requirements when children's products that contain button cell or coin batteries are manufactured or imported after the effective date of the rule.

Estimated Burden: CPSC has estimated the respondent burden in hours, and the estimated labor costs to the respondent.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Estimate of Respondent Burden: The hourly reporting burden imposed on firms that manufacture or import non-toy children's products that contain button cell or coin batteries include the time and cost to maintain records related to third party testing, the time to issue a CPC, and the time to include required warning labels on children's product battery compartments, children's product packaging, and to update instructions or manuals with required warnings.

Table 15: Estimated Annual Reporting Burden.

Burden Type	Total Annual Reponses	Length of Response	Annual Burden (hours)
Third-party testing, recordkeeping and record maintenance	6,046	5.0 hours	30,230
Certification and labeling	1,209	1.0 hours	1,209
Total Burden			31,439

Three types of third party testing of children's products are required: certification testing, material change testing, and periodic testing. Requirements state that manufacturers must conduct sufficient testing to ensure that they have a high degree of assurance that their children's products comply with all applicable children's product safety rules before such products are introduced into commerce. If a manufacturer conducts periodic testing, they are required to keep records that describe how the samples of periodic testing are selected.

CPSC estimates that 0.4 percent of all children's products sold annually, or 6,046 children's products, are children's products that contain button cell or coin batteries and would be subject to third-party testing, for each of which 5.0 hours of recordkeeping and record maintenance will be required. Thus, the total hourly burden of the recordkeeping associated with certification is 30,230 hours (5.0 × 6,046).

Additionally, battery compartments, product packaging, and instructions and manuals must be updated to include the required warnings statements. We estimate that the time required to make these modifications is about 1 hour per product. Based on an evaluation of a sample of supplier product lines, there are a total of 1,209 affected products; therefore, the estimated burden associated with warnings and labeling is 1 hour per product x number of product lines = 1,209 hours. We

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

estimate the hourly compensation for the time required to create and update labels is $36.80 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," Sept. 2022, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/news.release/archives/ecec_12152022.pdf). Therefore, the estimated annual cost to industry associated with the labeling requirements is $1,156,955 ($36.80 per hour x 31,439 hours = $1,156,955.2). No operating, maintenance, or capital costs are associated with the collection.

This burden estimate is the largest reasonably possible, assuming that every manufacturer had to modify three product labels (battery compartment, packaging, and instructions/manual). However, based on staff's review of non-toy children's products that contain button cell or coin batteries, many of these products already contain some type of warning on the product or product packaging. Accordingly, staff believes it possible that product modification for warnings and any associated burden could be very low.

Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." If warning statements on one or more battery compartments, product packaging, and instructions/manuals is usual and customary for non-toy children's products that contain button cell or coin batteries, CPSC could estimate that no burden hours are associated with the labeling requirements in the proposed rule, because any burden associated with warning labels would be "usual and customary" and not within the definition of "burden" under the OMB's regulations. We request comments on this potential estimate of no burden for warning labels, or any aspect of labeling. We also request comment on the preliminary analysis demonstrating that the largest

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

possible burden estimate for the proposed standard to require warning labels is 1,209 hours at a cost of $44,491 annually.

The total estimated burden associated with the proposed rule on non-toy children's products that contain a button cell or coin battery for third party testing, recordkeeping, issuing a certificate (CPC), and placing the required warning statements on the battery compartment of the children's product, on the packaging of the children's product, and on any associated instructions or manuals is 31,439 labor hours annually.

Labor Cost of Respondent Burden. According to the U.S. Bureau of Labor Statistics (BLS), Employer Costs for Employee Compensation, the total compensation cost per hour worked for all private industry workers was $39.61 (September 2022, https://www.bls.gov/ncs/ect/). Based on this analysis, CPSC staff estimates that labor cost of respondent burden would impose a cost to industry of approximately $1,245,299 annually (31,439 hours × $39.61 per hour = $1,245,298.79).

Cost to the Federal Government. The estimated annual cost of the information collection requirements to the federal government is approximately $4,448, which includes 60 staff hours to examine and evaluate the information, as needed, for Compliance activities. This is based on a GS-12, step 5 level salaried employee. The average hourly wage rate for a mid-level salaried GS-12 employee in the Washington, DC metropolitan area (effective as of January 2023 is $51.15(GS-12, step 5). This represents 69.0 percent of total compensation (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2022, Table 2., percentage of wages and salaries for all civilian management, professional, and related employees: https://www.bls.gov/news.release/archives/ecec_12152022.pdf). Adding an additional 31.0 percent for benefits brings average annual compensation for a mid-level salaried GS-12 employee to $74.13 per hour. Assuming that approximately 60 hours will be required annually, this results in an annual cost of $4,448 ($74.13 per hour × 60 hours = $ 4,447.8).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Comments. CPSC has submitted the information collection requirements of this rule to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d). CPSC requests that interested parties submit comments regarding information collection to the Office of Information and Regulatory Affairs, OMB (see the **ADDRESSES** section at the beginning of this NPR).

Pursuant to 44 U.S.C. 3506(c)(2)(A), the Commission invites comments on:

- whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility;
- the accuracy of CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information the Commission proposes to collect;
- ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology;
- the estimated burden hours associated with labels and hang tags, including any alternative estimates; and
- the estimated respondent cost other than burden hour cost.

XIII. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the federal

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances.

Section 2(a) of Reese's Law requires the Commission to issue a "consumer product safety standard for button cell or coin batteries and consumer products containing button cell or coin batteries," and section 2(c) of Reese's Law states that a consumer product safety standard promulgated under subsection (a) shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058). Therefore, the preemption provision of section 26(a) of the CPSA would apply to a final rule issued under section 2 of Reese's Law. 15 U.S.C. 2056e. A notification requirement under section 27(e) of the CPSA is not a consumer product safety rule and would not be subject to the preemption provision in section 26(c) of the CPSA.

XIV. Request for Comments

The Commission requests comment on all aspects of the proposed rule, including specifically the following items:

A. Performance Requirements

- Whether any consumer products (as opposed to medical devices, such as hearing aids) contain zinc-air button cell or coin batteries, and whether such products should be required to meet the performance requirements for battery compartments on consumer products;
- Whether any voluntary standard meets the performance and labeling requirements of Reese's Law;
- Whether the requirements for accessibility of battery compartments should incorporate test methods commonly used on toy products, such as the torque and tensile tests for parts of the product that can be gripped by a child's fingers or teeth, or a tensile test for pliable materials;
- For consumer products that use button cell or coin batteries and have large panel doors, what consumer products have such doors, and should the Commission exclude large panel doors from the

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

requirement for captive screws; why or why not (*i.e.*, why does a large panel door represent a different risk of injury from battery access without using captive screws than a smaller battery compartment door does?);

- Whether a double-action locking mechanism used to secure battery compartment enclosures, meaning those mechanism that rely on two independent and simultaneous hand movements to open (versus a screw, for example), should be allowed to secure button cell or coin battery compartments;
- Whether the proposed secureness test based on UL 4200A is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries;
- Whether Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032, is adequate to verify accessibility of a button cell or coin battery in a battery compartment;
- Whether there are any additional performance requirements that should be considered, either for specific types of products, or in general;
- Whether one or more performance requirements should be based on IEC 62368-1, in addition to, or instead of, performance requirements based on UL 4200A; and
- Whether the proposed performance requirements are needed and are likely to eliminate or adequately reduce the ingestion hazard associated with access to button cell or coin batteries from consumer products.

B. Marking and Labeling Requirements

- Whether the Commission should require ingestion warnings on zinc-air button cell or coin battery packaging;
- Whether all button cell or coin battery packaging should include the warning on the principal display panel;

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- Whether the requirement for the "Keep Out of Reach" icon to be 20 mm in diameter for visibility purposes, when alone on the front of battery packaging, provides a sufficient warning of the ingestion hazard;
- Whether the requirement to provide other information related to the safety of button cell or coin batteries is sufficient to address the risk of ingestion and other hazards associated with button cell or coin batteries;
- For technical and performance data related to the safety of button cell or coin batteries required at the time of purchase, whether the proposed warnings' content and location requirements are adequate to advise consumers who purchase a product online or in-store about the hazards associated with these batteries;
- Whether staff's assessment in V.F of this preamble that virtually all consumer products can accommodate either the full warning or one of the scaled icons is accurate;
- Whether the rule should require button cell or coin batteries to be durably and indelibly marked with the "Keep Out of Reach" icon where size permits, at a minimum size of 6 mm in diameter, and if so, whether the appropriate legal authority is Reese's Law, section 27(e) of the CPSA, or another statute; and
- Whether the internationally recognized safety alert symbol, as shown in yellow color, indicating the presence of a button cell or coin battery, should be required on all consumer products containing such batteries.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

C. Other Comments

- Whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and to provide specific information to support such a later or an earlier effective date.
- In the IRFA, the number of small firms impacted and expected cost impact on small firms (as a percentage of annual revenue) of the proposed rule.

Submit all comments in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1263

Batteries, Consumer protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. Amend the authority citation for part 1112 to read as follows:

   Authority: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017.

2. Amend § 1112.15 by adding paragraph (b)(55) to read as follows:

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(55) 16 CFR part 1263, Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries.

* * * * *

3. Add part 1263 to read as follows:

PART 1263-SAFETY STANDARD AND NOTIFICATION REQUIREMENTS FOR BUTTON CELL OR COIN BATTERIES AND CONSUMER PRODUCTS CONTAINING SUCH BATTERIES

Sec.

Authority: 15 U.S.C. 2052, 2056e, 2058, 2076(e).

§ 1263.1 Scope, Purpose, Effective Date, Units, and Exemption

(a) *Scope and purpose*. As required by Reese's Law (15 U.S.C 2056e, Public Law 117-171), this part establishes performance requirements for child-resistant button cell or coin battery compartments on all consumer products that contain, or are designed to contain, such batteries to prevent child access to batteries during reasonably foreseeable use and misuse of the consumer product. The rule is intended to eliminate or adequately reduce the risk of injury and death to children 6 years old and younger from ingesting these batteries. This part also establishes warning label requirements for packaging containing button cell or coin batteries, packaging of consumer products containing such batteries, consumer products, instructions and manuals accompanying

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

consumer products, as well as point-of-sale performance and technical data pursuant to section 27(e) of the Consumer Product Safety Act (15 U.S.C. 2076(e).

(b) *Effective Date*. Except as provided in paragraph (d) of this section, all consumer products containing button cell or coin batteries and all packaging containing button cell or coin batteries subject to the rule that are manufactured or imported after [INSERT 180 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*] must comply with the requirements of this part.

(c) *Units*. In this part, values stated without parentheses are the requirement. Values in parentheses are approximate information.

(d) *Exemption for Toy Products*. Any object designed, manufactured, or marketed as a plaything for children under 14 years of age that is in compliance with the battery accessibility and labeling requirements of 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys, is exempt from the requirements of this part.

(e) *Batteries that Do Not Present an Ingestion Risk.* Button cell or coin batteries that the Commission has determined do not present an ingestion risk are not subject to this rule. These are: zinc-air button cell or coin batteries.

§ 1263.2 Definitions

In addition to the definitions given in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) and section 5 of Reese's Law (15 U.S.C. 2056e Notes), the following definitions apply for purposes of this part:

Accessibility probe means Test Probe 11 in IEC 61032 Protection of Persons and Equipment by Enclosures - Probes for Verification.

Accessible means able to be contacted by the accessibility probe.

Button cell or coin battery means (1) a single cell battery with a diameter greater than the height of the battery; or (2) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Consumer product containing button cell or coin batteries means a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately.

Ingestion hazard means a hazard caused by a person swallowing or inserting a button cell or coin battery into their body whereby (1) the button cell or coin battery can become lodged in the digestive tract or airways, and (2) can potentially cause death or serious injury through choking, generation of hazardous chemicals, leaking of hazardous chemicals, electrical burns, pressure necrosis, or other means.

Principal display panel means the display panel, for a retail package of one or more button cell or coin batteries or retail package of a consumer product containing button cell or coin batteries, that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.

Product display panel means the surface area on, near, or in the battery compartment of a consumer product containing button cell or coin batteries. For consumer products containing button cell or coin batteries where such batteries are replaceable, the product display panel must be visible while a consumer installs or replaces any button cell or coin battery. For consumer products with one or more nonreplaceable button cell or coin batteries, the product display panel must be visible upon access to the battery compartment.

Secondary display panel means a display panel for a retail package of one or more button cell or coin batteries or retail package of a consumer product containing button cell or coin batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

§ 1263.3 Requirements for Consumer Products Containing Button Cell or Coin Batteries

(a) *General*. Consumer products containing button cell or coin batteries must meet the performance and labeling requirements in this part to minimize the risk of children accessing and ingesting button cell or coin batteries. Consumer products with battery compartments that allow consumers to remove or replace a button cell or coin battery must comply with the performance requirements in § 1263.3(b). Consumer products with battery compartments that do not allow for the removal or replacement of any button cell or coin batteries must comply with the performance requirements in § 1263.3(c).

(b) *Performance requirements for consumer products containing button cell or coin batteries that are removable*. (1) A removable or replaceable button cell or coin battery in a consumer product must not be made accessible when tested pursuant to § 1263.3(d).

(2) Battery compartments for removable or replaceable button cell or coin batteries must meet the requirements in § 1263.3(e) and be secured using at least one of the following methods:

(i) Secure the battery compartment enclosure so that it requires a tool, such as a screwdriver or coin, to open the battery compartment. Opening a battery compartment secured by one or more screws, or a twist-on access cover, must require a minimum torque of 0.5 Nm (4.4 in-lb) and a minimum angle of 90 degrees of rotation, or the fastener(s) must engage a minimum of two full threads. Screws or fasteners used to secure the battery compartment enclosure must be captive to the compartment door, cover, or closure.

(ii) Secure the battery compartment enclosure so that it requires a minimum of two independent and simultaneous hand movements to open. The movements to open cannot be combinable to a single movement with a single finger or digit.

(c) *Performance requirements for consumer products containing button cell or coin batteries that are non-removable*. Consumer products containing button cell or coin batteries not intended for removal or replacement must be made inaccessible by (1) using a battery compartment

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

enclosure that complies with the performance requirements of § 1263.3(b), or (2) securing the button cell or coin battery using soldering, fasteners such as rivets, or equivalent means, that passes the Secureness Test in § 1263.3(f).

(d) *Accessibility test method*. This test assesses whether a child can access a button cell or coin battery installed in a consumer product by determining whether the accessibility probe can contact a button cell or coin battery. The test method is as follows:

(1) To determine whether a button cell or coin battery is accessible, first open and remove any part of the battery compartment enclosure that can be opened or removed without a tool or that can be opened or removed with anything less than two independent and simultaneous movements (for example, a zipper or hook and loop).

(2) If a part of the battery compartment enclosure is protected by pliable material such as fabric, paper, foam, or vinyl, or a pliable material with a seam, apply the Tension Test for Seams in Stuffed Toys and Beanbag-Type Toys test in 16 CFR part 1250 to determine whether the battery compartment enclosure can become exposed or accessible, using a force of at least 70.0 N (15.7 lbf). If a new part of the battery compartment enclosure becomes exposed or accessible, repeat the test in § 1263.3(d)(1) and the test in this paragraph until no new part of the battery compartment enclosure becomes exposed or accessible, and then conduct the test in § 1263.3(d)(3).

(3) Insert or apply the accessibility probe to any depth that a battery compartment opening will permit, and rotate or angle the accessibility probe before, during, and after insertion or application through the battery compartment opening to any position that is necessary to determine whether the probe can contact the button cell or coin battery. This test is not intended to judge the strength of the material comprising the battery compartment. Use the minimum force necessary in determining whether the probe can contact a button cell or coin battery.

(e) *Performance tests for consumer products containing button cell or coin batteries*. After pre-conditioning in accordance with § 1263.3(e)(1), consumer products containing a button cell or coin

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

battery must pass the performance requirements in § 1263.3(e)(2) or § 1263.3(f) in the order presented, as applicable.

(1) *Pre-conditioning*. Subject each test sample consumer product to applicable pre-conditioning:

(i) *Stress relief*. Subject each sample consumer product with a battery compartment enclosure, door/cover, or door/cover opening mechanism that is made from molded or formed thermoplastic materials to a stress relief test. Place each test sample consumer product in a circulating air oven for at least 7 hours, using an oven temperature of the higher of at least 70°C (158°F) or at least 10°C (18°F) higher than the maximum temperature of thermoplastic battery compartment enclosures, doors/covers, or door/cover opening mechanisms during the most stringent normal operation of the consumer product. Allow the sample consumer product to cool to room temperature after removal from the oven.

(ii) *Battery replacement*. This step applies only to consumer products with button cell or coin batteries intended to be removable or replaceable. Open the battery compartment enclosure, remove and replace the button cell or coin battery, and close the battery compartment enclosure for a total of 10 cycles. For battery compartment enclosures that are secured with a screw(s), the screw(s) must be loosened and then tightened each time using a suitable screwdriver, applying a continuous linear torque according to the Torque to be Applied to Screws table, Table 20, of the Standard for Audio, Video and Similar Electronic Apparatus – Safety Requirements, UL 60065. If the screw(s) do not meet the specified torque requirements during this step, remove the screw(s) and repeat the test in § 1263.3(d).

(2) *Abuse tests*. Subject each test sample consumer product to the following abuse tests, performed sequentially, as applicable. Check compliance of the sample using § 1263(e)(3). If the consumer product contains button cell or coin batteries that are not intended for removal or

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

replacement, and that are accessible based on § 1263.3(c), then the consumer product must be tested under § 1263.3(f) and this § 1263.3(e)(2) does not apply.

(i) *Drop test*. Drop each sample consumer product ten times from a height of 1.0 m (39.4 in) onto a horizontal hardwood surface in positions likely to produce the maximum force on the battery compartment enclosure. The hardwood surface must be at least 13 mm (0.5 in) thick, mounted on two layers of nominal 19 mm (0.75 in) thick plywood, and placed on a concrete or equivalent non-resilient surface.

(ii) *Impact test*. Subject the battery compartment enclosure door or cover on each sample consumer product to three, at least 2-J (1.5-ft·lbf) impacts. Produce the impact by dropping a steel sphere, 50.8 mm (2 in) in diameter, and weighing approximately 0.5 kg (1.1 lb) from the height required to produce the specified impact, as shown in Figure 1 to this paragraph, or suspend the steel sphere by a cord and swing as a pendulum, dropping through the vertical distance required to cause the steel sphere to strike the battery compartment enclosure door or cover with the specified impact, as shown in Figure 2 to this paragraph. The steel sphere must strike the battery compartment enclosure door or cover perpendicular to the surface of the battery compartment enclosure.

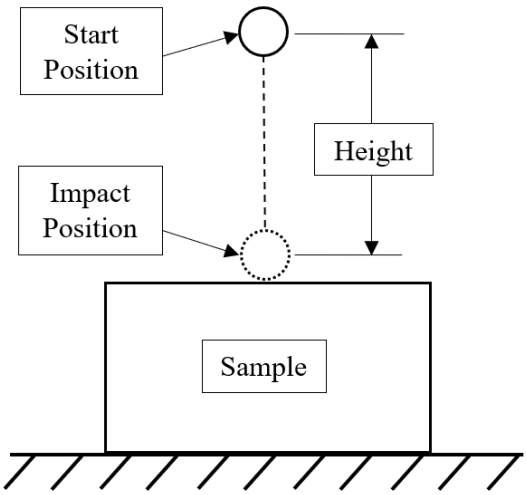


Figure 1 to Paragraph (e)(2)(ii). Example impact test with a dropped steel sphere.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

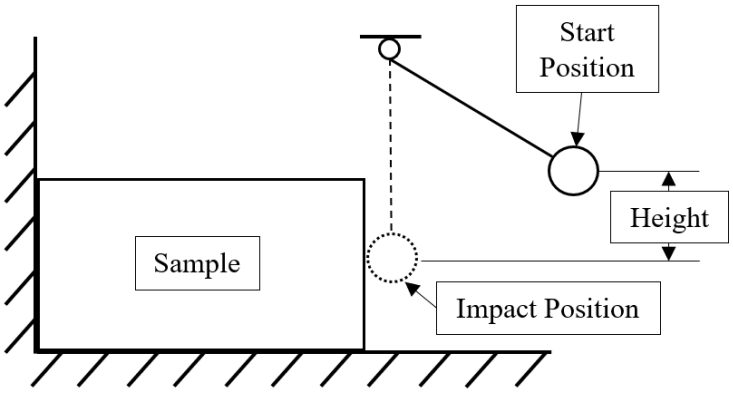


Figure 2 to Paragraph (e)(2)(ii). Impact Test with a swinging steel sphere.

(iii) *Crush test*. Support each sample consumer product by a fixed rigid supporting surface, in positions likely to produce the most adverse results as long as the position of the consumer product is self-supported. Apply a crushing force of at least 335 N (75.3 lbf) to the exposed surface for a period of 10 seconds. Apply the force using a flat surface measuring approximately 100 by 250 mm (3.9 by 9.8 in).

(iv) *Compression test*. If any surface of the battery compartment enclosure is accessible to a child and inaccessible to a flat surface contact during the drop test, apply the Compression Test from 16 CFR part 1250 to that surface, using a force of at least 136 N (30.6 lbf).

(v) *Torque test*. If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, apply the Torque Test for Removal of Components from 16 CFR part 1250 to the battery compartment enclosure, using a torque of at least 0.50 Nm (4.4 in.-lbf).

(vi) *Tension test*. If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, apply the Tension Test for Removal of Components from 16 CFR part 1250 to the battery compartment enclosure, using a force of at least 72.0 N (16.2 lbf).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(3) *Compliance*. If a button cell or coin battery becomes accessible or liberates from a consumer product as a result of any of the abuse tests in §1263.3(e)(2), the consumer product is non-compliant and fails testing. Additionally, after completing all abuse testing, apply a force of at least 50 N (11.2 lbf) for 10 seconds to the battery compartment enclosure door or cover using the accessibility probe. Apply the accessibility probe at the most unfavorable position on the battery compartment enclosure, and in the most unfavorable direction. Apply a force in only one direction at a time. If the battery compartment enclosure door or cover opens or does not remain functional, or the button cell or coin battery becomes accessible, the consumer product is non-compliant and fails testing.

(f) *Secureness test*. Button cell or coin batteries installed in a consumer product that are not intended for removal or replacement, and that are accessible based on § 1263.3(d), must be tested by applying a steel test hook, as shown in Figure 3 to this paragraph, using a force of at least 22 N (4.9 lbf), directed outwards, applied for 10 seconds at all points where application of a force is possible. To pass the test, the button cell or coin battery cannot liberate from the consumer product during testing.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

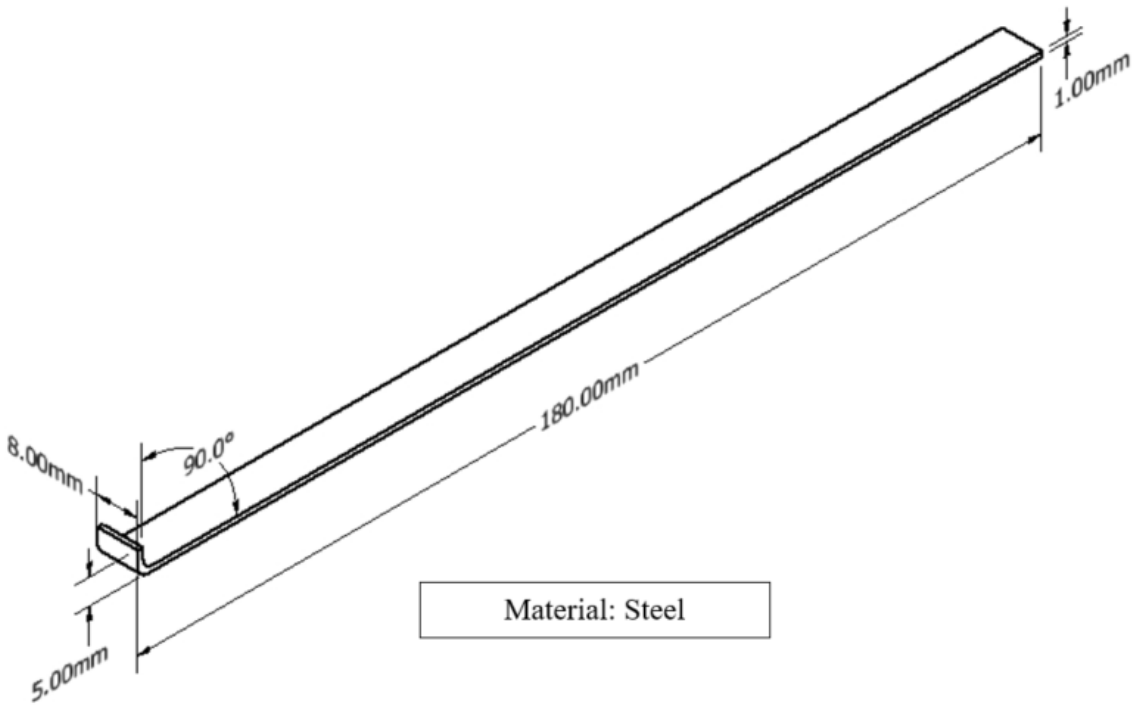


Figure 3 to Paragraph (f). Secureness test hook for consumer products with accessible button cell or coin batteries not intended for removal or replacement.

§ 1263.4 Requirements for Marking and Labeling

(a) *General Requirements*. (1) All warning statements or icons must be clearly visible, prominent, legible, and permanently marked.

(2) Warning statements or icons must be in contrasting color to the background onto which the warning statement or icon is printed.

(3) Warning statements must be in English.

(4) The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.

(5) The signal word "WARNING" must be in black letters on an orange background. The signal word must appear in sans serif letters in upper case only.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(6) Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels to get the attention of the reader.

(7) For labels that are provided on a sticker, hang tag, instructions or manual, the safety alert symbol and the signal word "WARNING" must be at least 0.2 in. (5 mm) high. The remainder of the text must be in characters whose upper case must be at least 0.1in. (2.5 mm), except where otherwise specified.

(8) For labels that are required to be on the packaging of button cell and coin batteries, the packaging of consumer products containing such batteries, and directly on consumer products, text size must be dependent on the area of the principal display panel. Text size must be determined based on Table 1 to this paragraph.

Table 1 to Paragraph (a)(8). Letter size for recommended warning labels. Information based on 16 CFR part 1500.19(d)(7).

Letter size measurements in inches								
Display Area: Inches²	*0–2*	*+2–5*	*+5–10*	*+10–15*	*+15–30*	*+30–100*	*+100–400*	*+400*
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display Area: cm²	*0-13*	*+13-32*	*+32-65*	*+65-97*	*+97-194*	*+194-645*	*+645-2,581*	*+2,581*
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397

(b) *Warning label requirements for button cell or coin battery packaging*. (1) The principal display panel of the packaging must include the warning label in Figure 4 to this paragraph. The icon must be at least 8 mm (0.3 inches) in diameter. The text must state the following warnings as shown on Figure 4 to this paragraph.

WARNING

- **INGESTION HAZARD: DEATH** or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

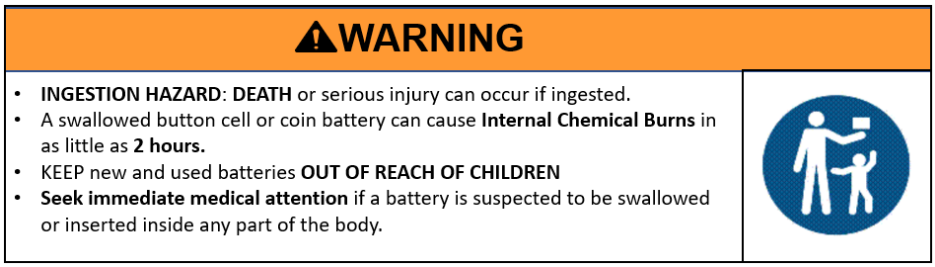


Figure 4 to Paragraph (b)(1)

(2) If space prohibits the full warning label shown in Figure 4 to paragraph (b)(1), place the icon shown in Figure 5 to this paragraph on the principal display panel with the text shown in Figure 6 to this paragraph on the secondary display panel. The icon must be at least 20 mm in diameter. The text must state the following warnings as shown on Figure 6:

WARNING

- **INGESTION HAZARD: DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 5 to Paragraph (b)(2)

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

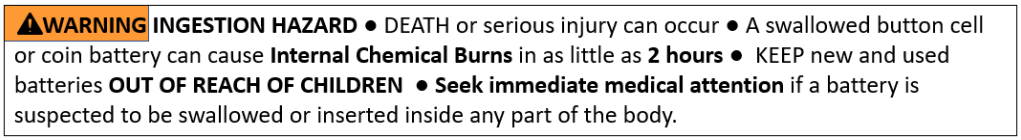


Figure 6 to Paragraph (b)(2)

(3) The following safety-related statements must be included on the principal display panel or secondary display panel:

- "Keep in original package until ready to use."
- "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash."
- "Call a local poison control center for treatment information."
- Battery type (*e.g.* LR44, CR2032)
- Battery chemistry (e.g. silver oxide or lithium)
- Nominal voltage
- Year and month or week of manufacture or expiration date
- Name or trademark of the manufacturer or supplier
- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."
- "Ensure the batteries are installed correctly according to polarity (+ and -)."
- "Remove and immediately discard batteries from equipment not used for an extended period of time."
- "Non-rechargeable batteries are not to be recharged."
- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(4) For button cell or coin batteries that are packaged and included separately with a consumer product, only (b)(1) and (b)(2) of this subsection (b) apply.

(c) *Warning label requirements for packaging of consumer products containing button cell or coin batteries*. (1) The principal display panel must contain the warning label in Figure 7 to this paragraph. The icon must be at least 8 mm in diameter. The text must state the following as shown in Figure 7:

WARNING

- **INGESTION HAZARD:** This product contains a button or coin cell battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

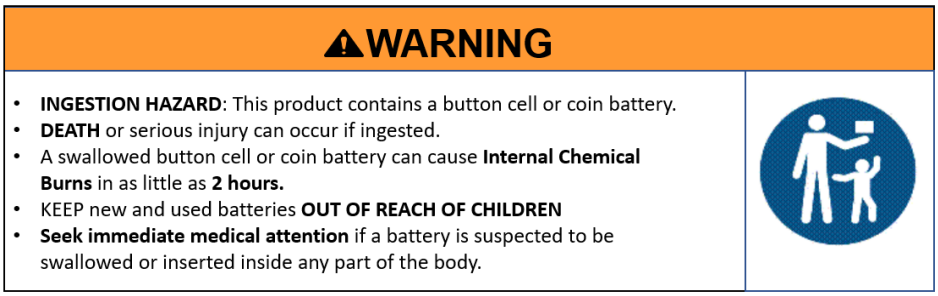


Figure 7 to Paragraph (c)(1)

(2) Consumer products that are not contained in packaging must have the warning label in Figure 7 to paragraph (c)(1) affixed to the consumer product with a hang tag or a sticker label.

(3) If space on the principal display panel of the consumer product packaging does not permit the warning label in Figure 7 to paragraph (c)(1), the principal display panel must include the warning in Figure 8 to this paragraph in a conspicuous location. The icon must be at least 8 mm in diameter. The remaining warning statements must be on a secondary display panel, as shown in

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Figure 9 to this paragraph. The text must state the following on the principal display panel as shown in Figure 8:

WARNING

- **INGESTION HAZARD:** This product contains a button or coin cell battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.

The text must state the following on the secondary display panel as shown in Figure 9 to paragraph (c)(3):

WARNING

- KEEP new and used batteries **OUT OF REACH OF CHILDREN**
- **Seek immediate medical attention** if battery is suspected to be swallowed or inserted inside any part of the body.

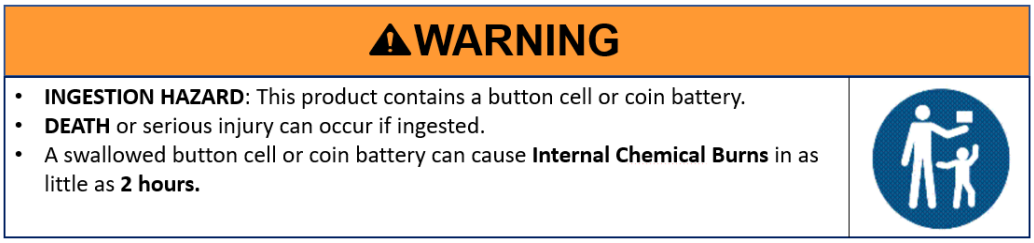


Figure 8 to Paragraph (c)(3)

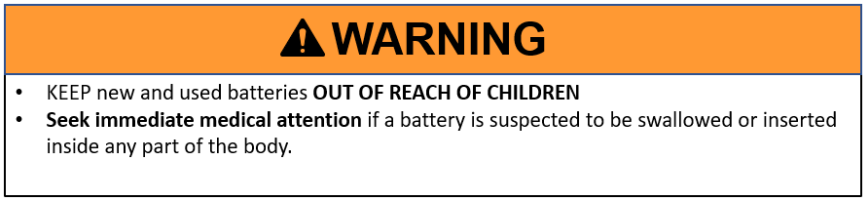


Figure 9 to Paragraph (c)(3)

(4) The principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must include the following text:

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- For products with non-replaceable batteries, include a statement indicating the product contains non-replaceable batteries.
- Battery type (*e.g.* LR44, CR2032)
- Nominal voltage

(d) *Warning label requirements for consumer products containing button cell or coin batteries*.

(1) Consumer products must be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or coin battery. The warning text must include the safety alert symbol, signal word, and text, as shown in Figure 10 to this paragraph.

Figure 10 to Paragraph (d)(1)

(2) If space on the product is limited, use the "Warning: contains coin battery" icon shown in Figure 11 to this paragraph, without text. The icon must be at least 7 mm in width and 9 mm in height and must be on the product display panel and must be in yellow with black outlines as shown in Figure 11 to paragraph (d)(2). The icon must be defined in accompanying printed materials such as instructions, manual, insert, or hangtag.

Figure 11 to Paragraph (d)(2)

(3) If the product itself is too small to include the warning with text in Figure 10 to paragraph (d)(1) or the icon in Figure 11 to paragraph (d)(2), the product must:

(i) Have packaging containing the warning label following the requirements in § 1263.4(c), or

(ii) Contain a hangtag or sticker label with the full warning label using requirements for the packaging of consumer products containing batteries in § 1263.4(c).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(e) *Instructions/Manuals accompanying consumer products containing button cell and coin batteries*. (1) Instructions and manuals, if provided, must include the warning label shown in Figure 7 to paragraph (c)(1) and the following warning statements:

- "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash."
- "Even used batteries may cause severe injury or death."
- "Call a local poison control center for treatment information."
- Compatible battery type (e.g. LR44, CR2032)
- Nominal voltage
- For products with non-replaceable batteries, include a statement indicating the product contains non-replaceable batteries.
- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."
- "Ensure the batteries are installed correctly according to polarity (+ and -)."
- "Remove and immediately discard batteries from equipment not used for an extended period of time."
- "Non-rechargeable batteries are not to be recharged."
- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

(2) If instructions and manuals are not provided, the warning statements in § 1263.4(e)(1) must be present on the principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(f) *Online information*. Manufacturers shall include, in a manner that is clearly visible, prominent, and legible (either next to the product description, the product image, or the product price):

(1) in their online materials that enable consumers to purchase button cell or coin batteries, the warning in Figure 4 to paragraph (b)(1); and

(2) in their online materials that enable consumers to purchase products containing button cell or coin batteries, the warning in Figure 7 to paragraph (c)(1).

§ 1263.5 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

Dated: _____

_____
Alberta E. Mills,
Secretary, Consumer Product Safety Commission

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission

Staff Briefing Package

Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

January 11, 2023

For additional information, contact:

Daniel Taxier, Mechanical Engineer,
Battery Project Manager,
Division of Mechanical and Combustion Engineering
Directorate for Engineering Sciences
Office of Hazard Identification and Reduction
Email: dtaxier@cpsc.gov

U.S. Consumer Product Safety Commission
5 Research Place
Rockville, MD 20850

This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table of Contents

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Briefing Memorandum

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Briefing Memorandum

TO: The Commission
Alberta E. Mills, Secretary

DATE: January 11, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason Levine, Acting Executive Director
DeWane Ray, Deputy Executive Director for Operations

FROM: Duane E. Boniface, Assistant Executive Director,
Office of Hazard Identification and Reduction

Daniel Taxier, Project Manager,
Division of Mechanical and Combustion Engineering,
Directorate for Engineering Sciences

SUBJECT: Draft notice of proposed rulemaking: Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

---

I. Introduction

President Biden signed Reese's Law into law on August 16, 2022. 15 U.S.C. § 2056e (Pub. L. No. 117-171). The purpose of Reese's Law is to protect children and other consumers against hazards associated with accidental ingestion of button cell or coin batteries. Button cell or coin batteries are small parts which resemble buttons or coins. Like buttons or coins, if a child ingests a button cell or coin battery, the battery may become impacted (meaning wedged or lodged) in the esophagus. However, button cell or coin batteries are substantially more hazardous than buttons or coins, because button cell or coin batteries can cause burns to the tissue contacting the battery. The medical literature, CPSC data, and data from the National Capital Poison Center (NCPC) show that button cell or coin batteries cause severe injury and death when ingested due to impaction in the esophagus. As described in this briefing package, based on the incident data, staff interprets an ingestion hazard to include: choking, internal chemical burns, chemical leakage, pressure necrosis, or the creation of hazardous chemicals (such as sodium hydroxide and hydrochloric acid) and related hazards. Reese's Law directs the U.S. Consumer Product Safety Commission (CPSC) to "promulgate a final consumer product safety standard for button cell or coin batteries and consumer products containing button cell or coin batteries," not later than 1 year after the date of enactment (August 16, 2022). *Id.* § 2056e(a).

Reese's Law states that the safety standard shall only contain:[1]

(1) a performance standard requiring the button cell or coin battery compartments of a consumer product containing button cell or coin batteries to be secured in a manner that would eliminate or adequately reduce the risk of injury from button or coin cell battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions; and

[1] 15 U.S.C.§ 2056e(a)(1)-(2).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

(2) warning label requirements—
  (A) to be included on the packaging of button cell or coin batteries and the packaging of a consumer product containing button cell or coin batteries;
  (B) to be included in any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries; and
  (C) to be included, as practicable—
    (i) directly on a consumer product containing button cell or coin batteries in a manner that is visible to the consumer upon installation or replacement of the button cell or coin battery; or
    (ii) in the case of a product for which the battery is not intended to be replaced or installed by the consumer, to be included directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information shall be placed on the packaging or instructions.

CPSC staff recommends that the Commission issue a draft notice of proposed rulemaking (NPR), under Reese's Law and the Administrative Procedure Act (5 U.S.C. § 553), to address the accessibility of batteries from consumer products that use or come with button cell or coin batteries to address ingestion hazards to children. Staff's recommended draft proposed rule for consumer products containing button cell or coin batteries includes all consumer products, as described in section 3 of the Consumer Product Safety Act (CPSA), but it does not include toys that meet the requirements of the toy safety standard, 16 CFR part 1250 (*i.e.,* ASTM F963-17 Standard Consumer Safety Specification for Toy Safety),[2] or products not within CPSC's jurisdiction, such as medical devices (*i.e*., hearing aids and body-temperature thermometers), motor vehicle equipment (such as car remotes), and equipment used in trades, professions, or industries that are not customarily produced or distributed for personal use or enjoyment by a consumer.

Although this proposed rule is intended to address ingestion of button cell or coin batteries by children 6 years old or younger, staff notes that the performance and labeling requirements in the rule will likely also reduce insertion and impaction of these batteries in the nose and ears. The data on button cell or coin batteries also demonstrates that insertions of batteries into the nose can be aspirated and become ingestions that lodge in the esophagus, which presents the same risk of injury as ingestions. Accordingly, the proposed labeling requirements include warnings regarding ingestion and insertion.

This briefing package includes:

- A description of the button/coin batteries and the products that use them
- A description of warnings on battery and consumer product packaging
- A review of the incident data, hazard patterns, injury type, and severity
- A review of the relevant current voluntary standards
- Recommended performance requirements
- Recommended warning label requirements
- Initial Regulatory Flexibility Act Analysis

[2] Reese's Law exempts from the rule "toys" that meet the toy standard, which are already required to meet battery compartment requirements in section 4.25 of the toy standard and warning label requirements. Pub. L. No. 117-171 § 4, 15 U.S.C. § 2056e note.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

II. Discussion

A. Description of Button Cell or Coin Batteries

A button cell or coin battery (also called a cell or disc battery) stores chemical energy, which is converted to electrical energy when the battery is connected to a circuit. A button cell or coin battery consists of an anode (negative terminal), a cathode (positive terminal), a separator and electrolyte between the anode and cathode, as shown in Figure 1. When the battery terminals are connected with a conductive material, such as moist human tissue, an electric circuit is formed, and electric current flows through the conductive material and between the terminals. Button cell or coin batteries come in many shapes and sizes and are composed of different materials and chemicals. Power (voltage and capacity) and size requirements are the main driver of battery shape, chemical composition, and the number of required batteries.

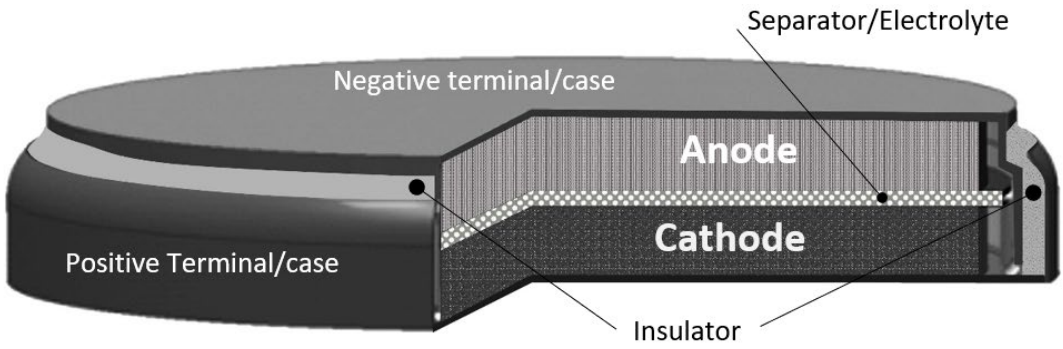


Figure 1. Battery construction.

A button cell battery is a small, single-cell battery that generally ranges from 5 mm to 32 mm (0.2 in. to 1.3 in.) in diameter and 1 mm to 6 mm (0.04 in. to 0.24 in.) in thickness. Reese's Law defines "button cell or coin battery" as:[3]

> *(A) a single cell battery with a diameter greater than the height of the battery; or*
> *(B) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard.*

For the purposes of this rulemaking, staff has focused on button cell or coin batteries falling under part A of the definition in Reese's Law.[4]

[3] 15 U.S.C. § 2056e note (Pub. L. No. 117-171, § 5(1)).
[4] For now, staff recommends focusing this rulemaking on addressing button cell and coin batteries under part (a) of the definition, because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type of ingestion hazard as button cell or coin batteries. For example, cylindrical batteries can pose a choking hazard, and staff is aware that consumers have ingested cylindrical batteries; however, the medical literature shows that injury or death due to ingestion of a cylindrical battery is rare. Consequently, staff is not including cylindrical batteries in this proposed rule, but will continue to monitor battery ingestion data. If staff becomes aware of a serious safety hazard associated with another battery type, section 2(g) of Reese's Law allows the Commission to undertake additional rulemaking to address the associated hazard.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Button cells, like those shown in Figure 2, are used to power small portable electronic products like wrist watches and pocket calculators. Button cells are usually disposable, primary single-cell batteries. Common anode materials are zinc or lithium. Common cathode materials are manganese dioxide, silver oxide, carbon monofluoride, cupric oxide, or oxygen from the air. Button cells tend to be manganese dioxide (alkaline) (1.5v) or silver oxide (1.55v).

		
LR44 button cell, 11.6mm (0.45 inch) diameter x 5.4mm (0.21 inch) thick	LR754 button cell, 7.9 mm (0.31 inch) diameter, 5.4mm (0.21 inch) thick	LR626 button cell, 6.8 mm (0.26 inch) diameter, 2.6mm (0.10 inch) thick

Figure 2. Example button cell batteries.

Lithium coin batteries, shown in Figure 3, were originally developed as a 3-volt miniature power source for low-drain and battery-backup applications; but because of their high-energy density and long shelf life, manufacturers found them useful for other applications. As electronics have evolved over the decades, consumer product designers have found lithium coin batteries to be a useful power source because of their small size in comparison to their high capacity. Lithium coin batteries are commonly around 20 mm (0.787 inch) in diameter.

		
CR2032, 20mm (0.787 inch) diameter	CR2025, 20mm (0.787 inch) diameter	CR2450, 24mm (0.945 inch) diameter

Figure 3. Example lithium coin batteries.

B. Description of Products that use Button Cell or Coin Batteries

Because of their small size and efficient energy capacity, a wide variety of consumer products use button cells or coin batteries for their source of power. Products include common household portable products, wearable accessories, or decorative electronic products. Products may be sold with batteries included, or batteries may be sold separately. Some examples of household objects that may use button cell or coin batteries are in the list below and shown in Figure 4.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- Remote controls
- Flashlights
- Games and toys
- Calculators
- Bathroom scales
- Key fobs[5]
- Watches and electronic jewelry
- Flashing shoes & clothing
- Cameras
- Holiday ornaments
- Flameless candles
- Musical greeting cards

Figure 4. Example products that use button cell or coin batteries: LED candles (left), watches (middle), keychain flashlights (right).

Products that are not "consumer products" as defined in the CPSA and that also may use button cell or coin batteries, such as medical devices (*i.e.*, body-temperature thermometers, tooth brushes, and hearing aids) are not within scope of Reese's Law and are not covered by the proposed rule.[6]

C. Description of Warnings on Battery and Consumer Product Packaging

Staff's review of button cell battery packaging found that some manufacturers do include some version of a safety statement, such as: "Keep away from small children. If swallowed promptly see a doctor (see Figure 5), or "CAUTION: Keep batteries away from children. If swallowed, consult a physician at once" (see Figure 6).

[5] Key fobs exclusively for use with motor vehicles are regulated by the National Highway Traffic Safety Administration (NHTSA).
[6] 15 U.S.C. § 2056e note (Pub. L. No. 117-171, § 5).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Figure 5. Typical button cell battery packaging. Front of packaging (left). Back of packaging (right) includes the safety statement but does not use a signal word.

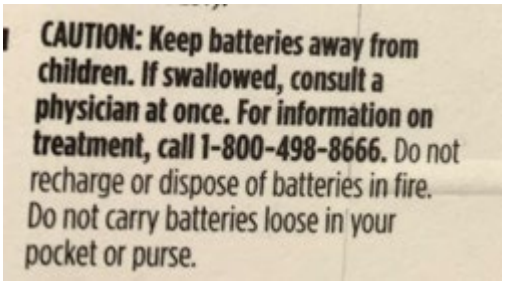


Figure 6. Example “CAUTION” statement on button cell battery packaging.

Use of the word “CAUTION” on a warning label signals less severe injuries than using “WARNING.”[7] For example, the word “WARNING” should be used for hazards where serious injury or death will occur. As shown in Figure 7, staff found that coin battery packaging often includes the icon: “Keep out of Reach” on the front and the signal word “WARNING” followed by a statement that “Death or serious injury can occur in as little as 2 hours if swallowed” on the back side of the packaging, along with additional safety information related to the ingestion hazard and other hazards.

[7] ANSI Z535.4 American National Standard Product Safety Signs and Labels.

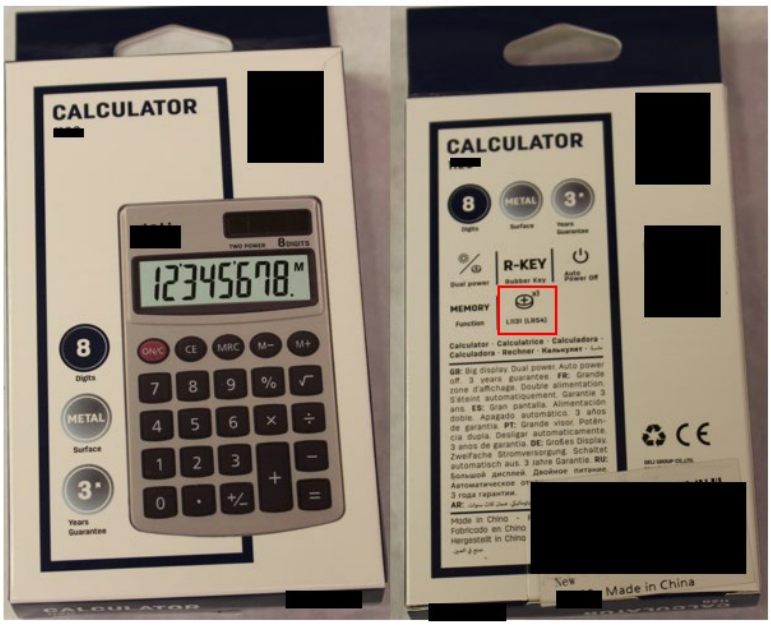
THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Front of packaging with Keep Out of Reach Icon	Back side with signal WARNING

Figure 7. Typical coin battery packaging

Staff found that packaging for consumer products containing button cell or coin batteries does not consistently warn that the product uses a button cell or coin battery, nor does the packaging consistently include warnings that button cell or coin batteries pose an ingestion hazard (See Figure 8 and Figure 9). Accompanying literature, when provided, sometimes contains warning information pertaining to the ingestion hazard, even when the product packaging does not include such warnings.



Front side of package Back side of package

Figure 8. Example of consumer product packaging without ingestion warnings. Red selection highlights an image staff interprets to mean the product contains a button cell or coin battery.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

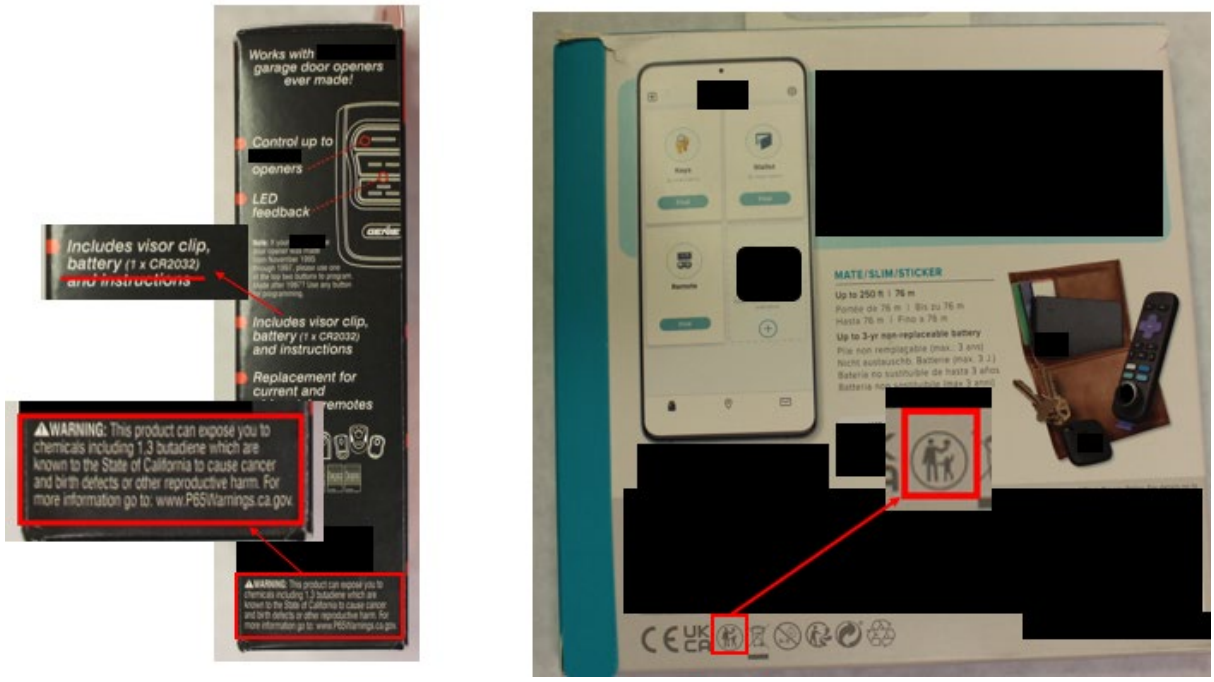


Figure 9. Packaging on left identifies use of a CR2032 battery but the warning does not include an ingestion hazard. Packaging on the right contains the "Keep out of Reach" icon.

D. Incident Data and Hazard Patterns

1. Fatal incidents

The National Capital Poison Center (NCPC), or Poison.org, tracked button cell or coin battery ingestions occurring from 1977 to the present. References for these incidents come from the news, medical literature, or from the National Battery Ingestion Hotline.[8] From 1977 to June 2022, the NCPC reported 69 deaths due to ingestion of button cell or coin batteries.[9] In the 47 cases where battery chemistry was known, 44 involved lithium batteries, 2 involved manganese dioxide chemistry, and one involved an alkaline button battery. The sources of these batteries, where known, were a remote control (8), toy (4), watch (2), camera (2), movie camera, camera flash, garage door opener, electric candle, remote car alarm, torch, tea light (spare battery), 3D TV glasses, key fob,[10] and loose (battery fed to child by older brother). The button cell or coin battery size, where known, ranged from 10 mm to 25 mm (0.4 in. to 1 in.). Presenting symptoms resembled those of a cold or upper respiratory infection and were often misdiagnosed as an infection or croup, or missed all together. In some cases, the first symptom was

[8] Poison Control Center (batteryingestionhotline.com). The National Battery Ingestion Hotline transferred from the National Capital Poison Center to the Rocky Mountain Poison Center in 2017, and has not been included in the National Capital Poison Center data since then.
[9] Fatal Cases (poison.org) Fatal Button Battery Ingestions: 69 Reported Cases (accessed June 2022).
[10] The data does not distinguish motor vehicle key fobs from consumer product key fobs. *See supra*, footnote 5.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

vomiting blood or blood coming from the nose, followed by death. Two deaths were caused by sepsis[11] after removal of the battery. Most of the deaths were due to the battery burning through the esophagus and creating a hole to adjoining tissues, such as the trachea or arteries.

Staff is aware of 25 fatalities from button cell or coin battery ingestions reported nationally in the Consumer Product Safety Risk Management System (CPSRMS) from January 1, 2011 to December 31, 2021 (Tab A).[12] Staff determined the source of the battery in 7 cases: 2 from remote controls, 2 from a tracking device, 1 from a toy, 1 from the battery packaging, and 1 loose. The cases are consistent with the mechanism of death seen in the medical literature and from the NCPC. Example incidents in Tab B show impaction in the esophagus, damage to the esophagus, and possible fistula formation leading to death.

2. Nonfatal incidents

From 1982 to June 2022, NCPC reported 267 cases of severe injury from button cell or coin battery ingestion.[13] Nine injuries were from manganese dioxide batteries, 2 were from mercuric oxide, 2 were from alkaline, 1 was from silver oxide, and 182 were from lithium batteries. Sources of the batteries, where known, were remote control (26), toy (13), camera (7), watch (7), scale (7), key fob (7),[14] calculator (5), battery package (3), digital ear thermometer (2),[15] flashlight (2), handheld computer game (2), sole of shoe (2), portable CD player, hair dryer, ab belt (exerciser), personal digital organizer, talking book, bicycle computer, computer, singing card, loose, guitar tuner, night light, baby monitor, lighted tweezers, book light, video camera, keychain, 3D TV glasses, portable speaker, lighted ring, and glucometer.[16] Where battery size was known, most of the batteries were 20 mm in diameter, and the battery size range was from 11.6 mm to 24.6 mm (0.46 in. to 0.97 in.). In many cases, impaction of the button battery in the esophagus led to damage due to burning of the esophagus.

Based on information in the National Electronic Injury Surveillance System (NEISS), CPSC staff estimates that from January 1, 2011 through December 31, 2021, 54,300 emergency department treated incidents involved button cell or coin battery ingestion or insertion into the mouth, nose, or ear. This assessment excludes cases establishing ingestion of a battery in which the type of battery is not indicated. Staff's assessment generally relied upon the final diagnosis conclusion as recorded in short summaries from medical professionals. The lack of detection of a battery as a foreign body does not necessarily contraindicate battery presence (which may sometimes be missed by x-ray scans). Consequently, these estimates likely underestimate the actual number of button cell or coin battery ingestions/insertions. Table 1 summarizes the number of cases estimated per year.

---

[11] An infection of the blood stream resulting in a cluster of symptoms, such as drop in a blood pressure, increase in heart rate, and fever.
[12] Incidents reported via CPSRMS as of May 2022. Staff expects additional reporting of CPSRMS incidents for the most recent years 2020-2021, due to a time lag in reporting to CPSC. The reported incidents may be included in the NCPC data.
[13] Severe Cases (poison.org) Nonfatal Button Battery Ingestions with Severe Esophageal or Airway Injury: 267 Cases. (Accessed June 2022) (Note: the number of cases in the website title is likely to change as additional cases are publicized.)
[14] See footnote 9.
[15] Body temperature thermometers are medical devices and do not fall within CPSC jurisdiction. The Food and Drug Administration (FDA) regulates medical devices.
[16] Glucometers are medical devices that fall within the FDA's jurisdiction.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 1. Estimated Number of Button Cell or Coin Battery Ingestions, Insertions, or Impactions Treated in Hospital Emergency Departments, 2011-2021.

Year	Estimate	N	CV
2011	4,600	170	0.20
2012	4,500	179	0.18
2013	5,000	178	0.21
2014	5,500	177	0.19
2015	3,500	163	0.15
2016	6,500	237	0.15
2017	5,400	196	0.20
2018	4,500	200	0.17
2019	4,200	178	0.26
2020	5,500	270	0.14
2021	5,200	235	0.18
Total	**54,300**	**2,183**	**0.15**

Source: NEISS, CPSC.

Summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample, with number of observations (N) and coefficient of variation (CV) provided. Estimates spanning periods of multiple years (such as the 11 years from 2011 to 2021) are total estimates, and *not* annual averages.

Staff estimated that of the 54,300 cases that involved a button cell or coin battery, approximately 88 percent were ingested through the mouth, while the remainder were inserted in the ear or nose.[17] An estimated 8,800 (16%) were hospitalized or transferred to another hospital. An estimated 44,500 (82%) were treated and released.[18]

Table 2 provides estimates of victim age at the time of initial treatment associated with button cell or coin battery incidents. Staff estimated 16,100 (30%) were young children under the age of 2 years, and an estimated 26,900 (50%) were children between the ages of 2 and 6. In total, an estimated 43,000 (79%) button cell or coin battery incidents were associated with children *under* 7 years of age. The remaining estimated 11,300 (21%) incidents are associated with victim ages 7 years and older (including adults). Adult and elder ingestions can be related to loose button cell or coin batteries being confused with medication and ingested under the mistaken belief that the batteries are pills.

[17] Insertions in the nose primarily resulted in impaction. However, a small proportion of nose insertions ultimately resulted in ingestion, with batteries subsequently getting into the stomach or digestive tract (*e.g.*, after aspiration through the nose).
[18] In comparison, among all consumer product-related, emergency room visits in the same period (regardless of relationship to batteries) only an estimated 9 percent resulted in hospitalization or transfer to another hospital, with an estimated 89 percent treated and released. This comparison suggests button cell or coin battery ingestion or insertion cases are relatively more severe than average.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 2. Estimated Number of Button Cell or Coin Battery Ingestion or Insertion Incidents by Victim Age (or Age Range), 2011-2021.

Victim Age (or Age Range)	Estimate	Estimated Percent	N	CV
0-11 months	2,900	5%	129	0.27
12-23 months	13,200	24%	513	0.21
2 years	8,700	16%	378	0.19
3 years	7,100	13%	315	0.19
4 years	5,500	10%	220	0.12
5 years	3,200	6%	146	0.17
6 years	2,400	4%	84	0.18
7 years	1,900	4%	71	0.20
8 years	1,500	3%	59	0.24
9 to 14 years	2,900	5%	141	0.16
15-24 years	*	2%	33	*
25-34 years	*	1%	8	*
35-44 years	*	<1%	5	*
45-54 years	*	<1%	1	*
55-64 years	*	<1%	6	*
65-74 years	*	1%	17	*
75-84 years	*	2%	21	*
85+ years	1,500	3%	36	0.22
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.

*This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.

Table 3 shows 11,900 (22% of 54,300) incidents where the button cell or coin battery was known to have come from a product. Staff estimates at least 5,300 (45% of 11,900) come from a "Non-toy Consumer Product" (*i.e.*, in scope of Reese's Law). Such product's included lights (flash lights, pen lights, laser lights, and book/reading lights), remote controls, watches, calculators, decorations and ornaments, electronic candles and tea lights, clocks and timers, electronic sound making books, pens, guitar tuners, and other consumer products. Staff's estimate of 4,400 (37% of 11,900) incidents classified as "toys/games" includes children's toys and games. An estimated 18 percent of 11,900 product-related incidents are associated with medical devices, including hearing aids (13%) and other medical devices (5%).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 3. Estimated Number of Product Button Cell or Coin Battery Source Incidents by Battery Source Product Type, 2011-2021.

Battery Source Product Type	Estimate	Estimated Percent	N	CV
Consumer Product (excluding Toys/Games and Key Fobs)	5,300	42%	237	0.17
Toys/games	4,400	37%	176	0.17
Car remotes and key fobs	*	2%	11	*
Hearing aid	1,600	13%	52	0.21
Other Medical Device (excluding hearing aid)	*	5%	16	*
Unknown Product Type**	*	<1%	4	*
Total	**11,900**	**100%**	**496**	**0.14**

Source: NEISS, CPSC.

*This estimate does not meet NEISS reporting criteria.

**For a small proportion of cases, although it could be determined that the batteries were neither loose or from packaging and came from *some* product or device, it could not be determined which *type* of product or device.

In the CPSRMS data, staff identified 87 nonfatal incidents involving button cell or coin battery ingestion (*i.e.*, "Ingestion" incidents) or unintended access to the button cell or coin battery with no ingestion (*i.e.*, "Battery Access" incidents) from January 1, 2016 through December 31, 2021. Staff determined the source of the battery to be from a product in 74 out of 87 cases. Products involved in these incidents include clothing and accessories, a cup, decorations, a pen, a teether, a headlamp, a bicycle bell, balloon lights, electronic books, guitar tuners, pet toys, a light-up candy ring, and several examples of toys or games. Table 4 provides a summary of the 74 nonfatal incidents that involve a product, rather than battery packaging, as the source of access to the battery.

Table 4. Reported Number of Product Classified Nonfatal Incidents by Incident Classification and Battery Source Product Type, 2016-2021.

	Incident Classification		Combined Nonfatal	
Battery Source Product Type	Ingestion	Battery Access	Total	Total Percent
Non-toy Consumer Product	13	16	29	42%
Toys/games	20	23	43	56%
Medical Device	1	1	2	3%
Total	**34**	**40**	**74**	**100%**

Source: CPSRMS, CPSC.

CPSC staff particularly notes the high proportion of button cell and coin battery incidents reportedly involving toys and games. Based on products in the CPSRMS database where the exact product is known, many of the toys are subject to the requirements of the toy safety standard. Based on these incidents and staff's assessment of the requirements in ASTM F963-17 (see engineering analysis of voluntary standards in a later section and Tab D), staff is concerned the toy safety standard does not adequately protect against the ingestion hazard. Staff sent a letter to the ASTM Subcommittee for Toy

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Safety on August 19, 2022,[19] and requested a meeting to engage this issue. However, no meeting has been scheduled as of the date of this memorandum. Staff is working on a second letter to propose specific language for ASTM to ballot that would align ASTM F963 with the requirements in this proposed NPR. Staff intends to finalize the letter once the Commission approves this NPR.

Staff notes that any products referred to as "toys" in the incident data that do not fall within the scope of ASTM F963 would be subject to the draft proposed rule. Therefore, it is likely that the draft proposed rule implementing Reese's Law would address some unknown portion of products indicated in the incident data as toys or games.

E. Hazard/Injuries Associated with Button Cell or Coin Batteries

CPSC staff reviewed medical literature related to battery ingestion injuries, CPSC data, and data from Poison.org.[20] Staff's review indicates that ingested batteries, particularly button cell or coin batteries, can lodge in the esophagus and cause severe tissue damage. If impacted (or lodged) in the esophagus, as shown in Figures 10 and 11, button cell or coin batteries cause significant damage to the surrounding tissue through generation of an electric current that causes electrolysis of tissue fluids and damage to the tissue by production of hydroxide at the battery anode (negative terminal). After only a few hours of contact with a button cell or coin battery terminals, tissue alkalinity on either side of the battery terminal increases, causing substantial tissue injury. When a child swallows a battery, the conductive soft tissue in the digestive tract can form a circuit between the battery terminals, creating an electric current. When lodged in the esophagus, button cell or coin batteries can lead to a burn in the esophagus, perforations, and burning of nearby tissue. Generation of hydroxide by the current created as a result of the battery contacting tissue in the digestive tract is the primary pathway to the chemical burn hazard associated with ingestion of lithium coin batteries because of their higher voltage and capacity. Other mechanisms of injury associated with button cell or coin batteries may include leakage of alkaline electrolyte from alkaline button cell batteries or pressure necrosis from extended contact between the foreign object and the soft tissue.

[19] https://www.cpsc.gov/s3fs-public/8-19-2022-Letter-to-ASTM-Battery-Operated-Toys.pdf?VersionId=PgFoeCeb0BYz0kyg6z87tbwHKv3x9W0y . Staff Correspondence Relating to Voluntary Standards – Letter to ASTM re: Battery Operated Toys, August 19, 2022.

[20] References for citations in this section can be found in the Tab B References.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

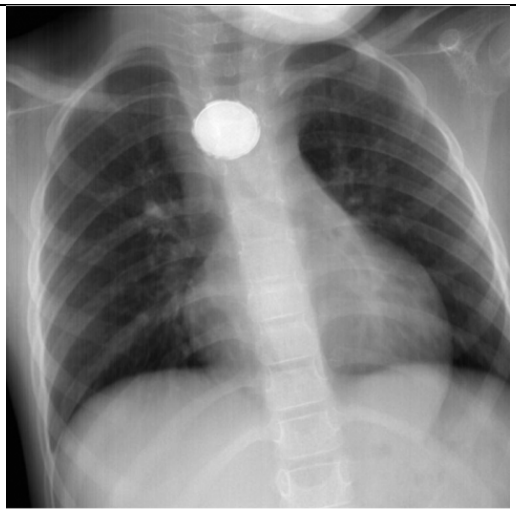


Figure 10. Button cell or coin battery lodge in the esophagus.[21]

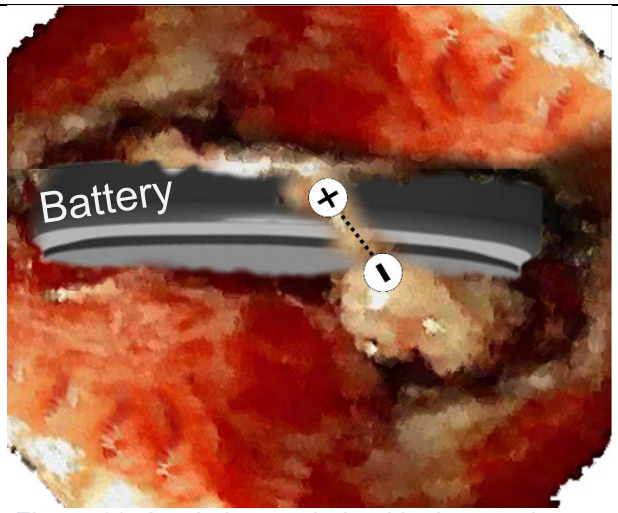


Figure 11. A coin battery lodged in the esophagus produces electric current due to the terminals contacting tissue.

1. Literature Review

Battery Impaction in the Esophagus

Staff conducted a literature review of case studies of button cell or coin battery impaction in the esophagus. As summarized in Appendix A of Tab B, 167 incidences of impacted button cell or coin batteries occurred in the esophagus; of these, 126 occurred in children. In 11 cases the product from which the battery came was identified: fidget spinner, handheld game, garage door opener, hair dryer, pedometer, personal organizer, toy (3), and watch. Esophageal damage, such as burns, perforations, and strictures occurred in 71 cases. Permanent vocal cord paralysis leading to the child not being able to speak occurred in 5 cases. Tracheoesophageal fistulas (TEF's) occurred in 59 cases, and aortoesophageal fistulas (AEF's) occurred in 19 cases, including cases where the child died. In 21 cases, the impaction of button cell or coin batteries in the esophagus led to death of the child. Impaction of a button cell or coin battery in the esophagus leads to a burn of the esophagus in as little as 2 hours. A burn in the esophagus may cause a perforation of the esophagus or an esophageal stricture, or a narrowing of the esophagus. Perforation or stricture of the esophagus can make feeding difficult and require a feeding tube in the stomach or dilations of the esophagus to expand the stricture to allow normal swallowing.

In 2010, Toby Litovitz (Litovitz et al., 2010a) performed a review of 65,246 battery ingestions between 1985 and 2009. The study reported a 6.7-fold increase in major outcomes[22] occurring between the first and final 3 years of the reviewed period, without an increase in number of ingestions (See Figure 12). This increase is consistent with increasing number of reported lithium battery ingestions (up 1.3 to 24 percent), and with the increasing number of ingestion incidents of batteries 20-25 mm in diameter (up 1

[21] Navarro-Baño et al. Button battery ingestion in children: What the emergency radiologist should know. Eurorad. September 8, 2017. www.eurorad.org/case/14897

[22] Major outcomes were defined as severe burns with sequelae.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

to 18 percent), reflecting increased use of these batteries in home electronic products. The report identified that 93.9 percent of major or fatal outcomes involved button cell or coin batteries greater than or equal to 20 mm in diameter. These larger diameter batteries are commonly lithium batteries.

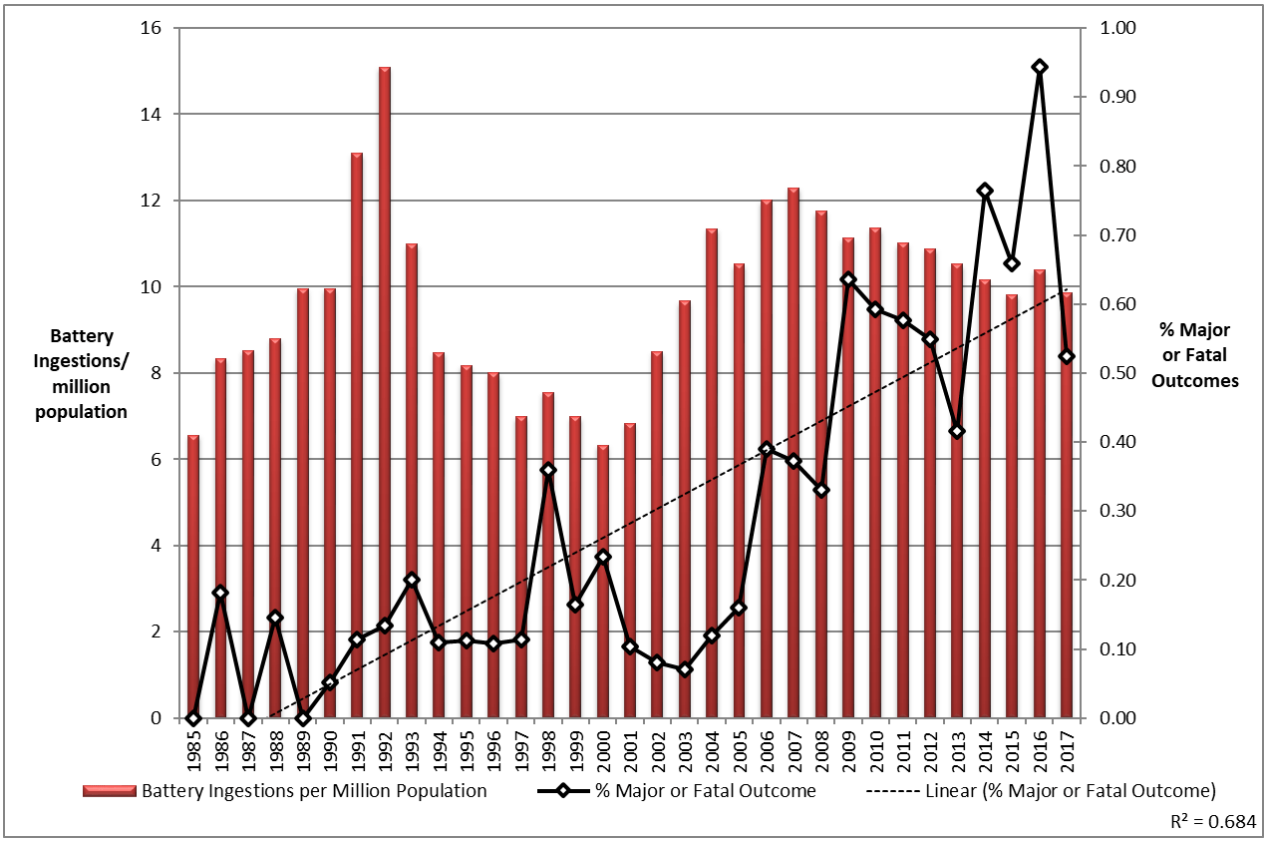


Figure 12: National Poison Data System (NPDS) and National Battery Ingestion Hotline (NBIH) Button Battery Ingestions Frequency and Severity for Major and Fatal Outcomes 1985-2017 (based on Litovitz et al., 2010a)

Dawe et al., 2013 made several points about lithium button cell or coin battery ingestions. Lithium button cell or coin battery ingestion has escalated with their increased use in household products. Also, lithium batteries generate a relatively high voltage, causing rapid local injury, even in a partially discharged state. Therefore, even used or partially discharged lithium button cell or coin batteries can cause life-threatening injuries. The window of opportunity for injury-free removal of an esophageal lithium button cell or coin battery is less than 2 hours (Gao et al., 2020).

Also, in 2010, Toby Litovitz (Litovitz et al., 2010b) found that from more than 8,000 ingestion cases reported to the National Battery Ingestion Hotline over a period of 18 years, for children under the age of 6, the button cell or coin battery was obtained from a product in 61.8 percent of the incidents. The button cell or coin batteries ingested were loose 29.8 percent of the time and came directly from the button cell or coin battery packaging 8.2 percent of the time. Remote controls were the source of incident batteries in 37.3 percent of ingestions (Litovitz et al., 2010).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

In the CPSC data, injuries occurred with a similar mechanism of injury as seen in the medical literature and from Poison.org. Examples in Tab B Appendix E show cases where the button cell or coin battery impacted in the esophagus and had to be removed. Some cases resulted in severe injuries.

Staff is aware of 25 fatalities associated with button cell or coin battery ingestion reported in the CPSC data (Tab A). The cases are consistent with the mechanism of death seen in the medical literature and from the NCPC. Fatality examples provided in Tab B Appendix F show impaction in the esophagus, damage to the esophagus, and possible fistula formation, which may lead to death.

Battery Impaction in the Nose and Ear

Button cell or coin batteries impacted in the nose can lead to severe damage to the endonasal mucous membranes. Impacted button cell or coin batteries can lead to necrosis of the nasal septum cartilage and to nasal septum perforation (Bachmann 2009). The damage to surrounding structures can occur within minutes, and many of the children generally experience long-term effects, such as saddle nose, which is a flattening of the nose due to lack of the nasal septum. This requires reconstructive surgery to correct. Development of complications depends on the duration of the impaction, type of button cell or coin battery (including cell size, chemistry, and voltage), and in which part of the nasal cavity the battery gets lodged. Septum perforation complications can result in lifelong consequences, such as facial deformity, and it is advisable to keep these patients on regular follow-up (Bakshi et al., 2016). Dislodgement of a nasal disc battery can lead to ingestion and the dangers of that exposure (Alvi et al., 1997).[23] Animal studies conducted show that when a button cell or coin battery is inserted into the nasal cavity of anesthetized rabbits, full thickness necrosis of nasal septal cartilage occurs in as short as 15 minutes (Chua and Tan 2006).

Staff found 56 cases of nasal insertion with button cell or coin batteries, from 1985 to 2015 in the literature. The most severe injury is septal perforation, which is caused by the button cell or coin battery burning a hole in the tissue that separates the left and right nostril. When the button cell or coin battery remained lodged in the nose for long periods of time, sometimes for months, this led to extensive damage to the nose (Fosarelli et al., 1988). When an impaction occurred for only a couple of hours, this could also lead to septal perforation of the nose (Liao et al., 2015).

Injury associated with button cell or coin batteries as foreign bodies in the ear occurs when the batteries become impacted. In the external auditory canal, impacted button/coin batteries may cause tympanic membrane perforation or destruction, marked erosion of the ear canal with exposed bone, hearing impairment, facial nerve paralysis, and destruction of the small bones in the middle ear (Bhisitkul and Dunham 1992).

In 10 cases from the medical literature of insertion of button cell or coin batteries into the ear,[24] the most severe damage that occurred was after insertion of a button cell or coin battery in the ear for 3 weeks, which resulted in tympanic membrane perforation with erosion of the skin and bone (Premachandra and McRae 1990).

[23] At least 14 cases from the NEISS sample describe button cell or coin batteries initially inserted into the nose and subsequently diagnosed as aspirated or ingested.
[24] See Tab B, Appendix C.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

CPSC data mirrored the medical literature in showing that children insert button cell or coin batteries into the nose and ear. Staff estimates 6,300 cases of insertion into the ear or nose from 2011 through 2021 in the NEISS data (Tab A). Tab B Appendix G provides example incidents of ear and nose insertions.

2. Zinc-Air Hearing Aid Batteries

Staff estimate that at least 9 percent of button cell or coin battery ingestion or insertion incidents involve zinc-air batteries. Zinc-air batteries are primarily used in hearing aids. Zinc-air batteries are typically much smaller than other button cell or coin batteries, and therefore do not present the same risk of choking. Staff did not find any choking incidents in which zinc-air batteries were established to have been the source of choking. Moreover, zinc-air batteries use a technology that needs air in order for the current to flow or voltage to be present on the terminals. If they are swallowed or inserted into the ear or nose, the wet mucosa stops this flow of air and also the voltage, so there are no chemical or hydroxide burns. Zinc-air batteries are sealed with a hydrophobic material, so there is little chance for electrolyte leakage. Lastly, some zinc-air batteries are so small they do not cause pressure against the mucosa. Therefore, there will be little or no pressure necrosis injury. Staff is not aware of zinc-air batteries being used in products other than hearing aids, which are medical devices under the Food and Drug Administration's jurisdiction. Staff recommends that the labeling requirements in the NPR not apply to zinc-air button cell or coin battery packaging, because these batteries do not present an ingestion hazard, meaning they are unlikely to cause choking, chemical burns, chemical leakage, or pressure necrosis. Staff recommends seeking comment in the NPR on whether any consumer products contain zinc-air button cell or coin batteries, and whether the Commission should require ingestion warnings on zinc-air button cell or coin battery packaging.

3. Summary

The medical literature, CPSC data, and data from the NCPC show that button cell and coin batteries cause serious injury and death when ingested, due to impaction in the esophagus. Injuries that occur include esophageal burns and perforations, vocal cord paralysis, and fistulas created by burning through the esophagus and surrounding tissues creating a connection between the esophagus and the trachea or blood vessels. One researcher found that a majority (61.8%) of button cell or coin batteries involved in ingestions over an 18-year period came directly from a consumer product, supporting the position that the battery compartment on consumer products must be strengthened to address the ingestion hazard (Litovitz et al., 2010b).

Staff also found from CPSC data and the medical literature that serious injury results from button cell or coin batteries that are inserted into the nose and ear. Batteries inserted into the nose can be aspirated and ingested, and cause associated ingestion injuries. Insertion injuries also include septal perforation, decreased structural support of the nose, and hearing loss.

F. Hazard Pattern

Based on staff's incident data search, the hazard pattern for button cell or coin battery ingestion scenarios involved initial child access to batteries. Staff identified the primary ways children gain access to button cell or coin batteries before ingesting them:

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

1. Access to the battery from a product's intact battery compartment.
    a. Seventy-nine out of 112 fatal and nonfatal CPSRMS incident narratives identified in Tab A refer to products with button cell and coin battery compartments that are potentially easily accessed by children.[25] Ten of the 79 incident narratives refer to batteries in compartments that appeared easy to open or defeat. These batteries did not accidentally come out of a battery compartment, but appeared easily accessible to children while in a compartment.
2. The battery compartment broke or failed to contain the battery as intended.
    a. Sixty-nine of the 79 fatal and nonfatal CPSRMS incidents involving products describe the batteries coming out of the battery compartment or the product or the battery compartment opening or breaking, often while a child was interacting with the product. In some cases, the battery was found to have come from a product only after a child was diagnosed with having ingested the battery. Eighteen of these incidents specifically describe products with screws that were ineffective, including comments about stripped threads, continuous spinning, screws that were "too short," and compartments that popped open even though there was a screw.
3. Victim removed battery from battery packaging, or battery was loose and not contained within the packaging or product and accessed by victim.
    a. Six out of 112 fatal and nonfatal CPSRMS incident narratives refer to loose batteries or battery packaging hazards, and staff estimates that at least 7 percent of NEISS incidents involve loose batteries or batteries liberated from the packaging.

Section 3 of Reese's Law requires child-resistant packaging for button cell or coin battery packaging. Consistent with Section 2 of Reese's Law, staff concludes the remaining hazards can be addressed with performance requirements for consumer products containing button cell and coin batteries and labeling requirements for such products and for the packaging of button cell or coin batteries by:

1. Reducing children's ability to directly access the battery compartment of these products,
2. Reducing the risk of loose batteries liberated from these products, and
3. Warning caregivers of the battery ingestion hazards to children.

G. Recalls

The Office of Compliance conducted six recalls of consumer products containing button cell or coin batteries related to a battery ingestion hazard between January 1, 2011, and July 31, 2022. The recalled products were responsible for four reported battery ingestion incidents. The recalls affected approximately 823,900 products (including toys). The recalls were processed by Office of Compliance and Field Operations, Fast Track Team. Details of each recall can be found in Tab F.

H. Voluntary Standards

Section 2(d) of Reese's Law states that the Commission shall not promulgate a final rule for consumer products that contain button cell or coin batteries if the Commission determines, with respect to any consumer product, that a voluntary standard that meets the requirements of section 2(a) of Reese's Law is either in effect at the time of the Commission's determination, or will be in effect not later than 180

[25] Out of the 79 products included in this hazard pattern analysis, 77 are consumer products and 2 are household medical devices (body temperature thermometer and toothbrush).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

days after the enactment of Reese's Law (February 12, 2023). Pursuant to section 2(d)(2) of Reese's Law, if the Commission determines that such a voluntary standard exists, the Commission must publish such determination in the *Federal Register*.

CPSC staff reviewed recognized voluntary standards related to child-resistant battery compartments for consumer products to determine whether such standards meet the performance and labeling requirements in section 2(a) of Reese's Law. Staff concludes that no standards contain performance and labeling requirements that would eliminate or adequately reduce the risk of button cell or coin battery ingestion.

1. Standards for Battery Compartment Accessibility in Products Incorporating Button Cell or Coin Batteries

Staff reviewed six voluntary standards, and found four that most directly address hazards associated with button cell and coin battery accessibility, as described in Tab D:[26]

- UL 4200A, *Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies* (UL 4200A)
- ASTM F963 *Standard Consumer Safety Specification for Toy Safety*
- IEC 62368-1 *Audio/video, information and communication technology equipment-Part 1: Safety requirements*
- IEC 62115 *International Standard for Electric Toys – Safety*

This section describes the standards and staff's assessment of the adequacy of the standards in addressing the ingestion hazard associated with child access to button cell or coin batteries in consumer products.

2. Comparison and Assessment of Standards in Addressing Battery Access in Consumer Products

Staff compared the scope, required action to open the battery compartment(s), and abuse testing to simulate foreseeable use and misuse conditions for the listed standards and found that none of the individual standards adequately address the ingestion hazard associated with child access to button cell or coin batteries in consumer products. A detailed analysis of these standards can be found in Tab D. Table 5 summarizes how the above standards address the battery ingestion hazard with requirements that are intended to minimize the risk of children removing batteries from the consumer product.

[26] Staff's assessment in Tab D includes voluntary standards referenced by the Australian standard F2020L01656.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 5. Summary of Voluntary Standards Performance Requirements

Standard	Scope	Action to Open Battery Compartment	Abuse Testing
UL 4200A	Household-type products that incorporate or may use button cell or coin batteries of lithium technologies	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment; screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand.	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times. Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test –74 lbf. over 38 square inches for 10s in positions likely to produce the most adverse results
ASTM F963	Toys intended for use by children under 14 years of age	Coin, screwdriver, or other common household tool required to open battery compartment	(1) Drop test – maximum 10 times at 4.5 ft in random orientation; minimum of 4 times at 3 ft in random orientation (2) Torque test – 2-4 in-lbs. of torque over 10 seconds (3) Tension test – 10-15 lbs. of tension over 10 seconds (4) Tension test for pliable materials – 10-15 lbs. of tension over 10 seconds (5) Compression test – 20-30 lbf over 1 square inch for 10 seconds
IEC 62368-1	Electrical and electronic equipment within the field of audio, video, information and communication	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment,	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Standard	Scope	Action to Open Battery Compartment	Abuse Testing
	technology, and business and office machines with a rated voltage not exceeding 600 V	screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand	(2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test – apply 74 lbf. for 10s in positions likely to produce the most adverse results
IEC 62115	Electric toys being any product designed or intended for use in play by children under 14 years of age	Batteries that fit wholly within the small parts cylinder shall not be removable without the aid of a tool, screw fastener must be captive.	(1) Screw test – Remove/replace screws 10 times with torque applied (2) Drop test – maximum 10 times at 93 cm ± 5 cm (36.6 in.) in random orientation; minimum 4 times at 93 cm ± 5 cm (36.6 in.) in random orientation (3) Impact test – 3 impacts by hammer imparting 0.5-J of energy (4) Tension test – 70 N ± 2 N (15.7 lbs.) of tension over 10 seconds (5) Tension test – 70 N ± 2 N (15.7 lbs.) tension force on a textile seam over 10 seconds

Table 6 summarizes staff's evaluation of whether the standard eliminates or adequately reduces the risk of injury from button cell or coin battery ingestion by children age six or under. Specifically, the table includes the scope of the voluntary standard, and whether the scope includes all relevant battery chemistry types that create an ingestion hazard and associated consumer products, as seen in the incident data; whether the standard's performance requirements for constructing and securing related to the construction of the battery compartment, and the methods to secure the battery compartment, would eliminate or adequately reduce the risk of injury from access to batteries from consumer products and

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

their ingestion, as seen in the incident data; and whether the standard addresses use and abuse testing, and if so, the adequacy of the use and abuse testing to eliminate or adequately reduce ingestion incidents as seen in the data.

Table 6 – Assessment of Existing Voluntary Standards Performance Requirements for Button Cell or Coin Batteries

		UL 4200A	ASTM F963	IEC 62368-1	IEC 62115
Scope	Battery Chemistry Type	Lithium	Any	Any	Any
	Product Type	Any	Toys	Audio/ Visual Equipment	Electronic Toys
Construction	Opens with Tool	A	A	A	A
	Captive screws	I		I	A
	Threaded attachment requirements	A		I	
	Opens with two independent and simultaneous movements	I		I	
	Accessibility	A	A	A	A
Use and Abuse	Pre-conditioning in oven	A		A	
	Open/close and remove/install battery/screw(s) 10 times	A		A	I
	Drop test - based on product weight/type	I	I	I	I
	Drop test - based on age grading		I		
	Impact Test	A		I	I
	Crush Test (big surface area)	A		A	
	Torque Test		A		
	Tension Test		A		A
	Tension Test - Seams		A		A
	Compression Test (little surface area)		A		
	Accessibility Probe Compliance Test	I	I	I	A
	Securement (non-removable batteries)	A			

Blank – Does not address requirements, I – Inadequately addresses requirements, A – Adequately addresses requirements

Staff's assessment is that no existing voluntary standard includes within its scope all battery types and all consumer products that contain button cell or coin batteries as reflected in the incident data. Additionally, no voluntary standard on its own eliminates or adequately reduces the risk of injury, based incidents and consumer products seen in the data. Details of staff's assessment of the construction and use and abuse requirements are below and in Tab D.

.

Construction: Action to Open Battery Compartment

All the above voluntary standards specify similar requirements for a locking mechanism to secure the battery compartment that requires a tool (or coin) to open, to reduce the possibility of children removing the battery. UL 4200A is the only standard that specifies either a minimum torque of 0.5 Nm (4.4 in-lbf) and a minimum angle of rotation of 90 degrees for the battery compartment fastener mechanism or a

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

minimum of two full threads engaged. Younger children may lack the required cognitive ability and fine motor coordination to perform the necessary actions to access the battery compartment, as discussed in Tab C. Incidents involving battery compartments with stripped threads or screws of insufficient length, including incidents involving toys that purportedly met ASTM F963 (which does not contain these requirements for the locking mechanism) indicate these requirements are important to secure the battery compartment. Therefore, based on engineering analysis and testing, staff assesses that the requirements in UL 4200A related to products that use a tool or coin to open the battery compartment, when applied to the full scope of products subject to Reese's Law, are adequate to address these construction elements related to button cell and coin battery ingestion hazard as discussed in Tab C and Tab D.

All the above standards, except ASTM F963-17, include a requirement for captive screws, which are screws that remain in the compartment or cover when unscrewed. Holding the screws captive is intended to ensure that when a consumer changes the battery, the screw is not lost or discarded when the consumer seeks to reclose and secure the compartment. Ensuring that consumers do not lose screws and use them to resecure the battery compartment every time the battery compartment is opened is paramount to the success of this locking mechanism to prevent child access to batteries. If the screw is not captive to the compartment door, consumers can more easily lose the screw or defeat the locking mechanism by removing the screw, potentially for convenience, without appreciating the safety purpose of the screw. Accordingly, the requirement for a captive screw helps to ensure that the screw is maintained and used by consumers each time the battery compartment is opened and reclosed. UL 4200A and IEC 62368-1 include exceptions to the captive screw requirement, such as for a "large panel door" which is not likely to be discarded or left off the equipment. It is unclear to which products this exception would apply; any door to a button cell or coin battery compartment left unsecure because of missing screws could allow a child to access the battery and pose a risk of ingestion.

UL 4200A and IEC 62368-1 also specify an option for the battery compartment door to require a double-action mechanism (requiring at least two independent and simultaneous movements to open the compartment by hand) that the toy standard does not have. Similar requirements are used throughout children's juvenile product standards, as well as standards involving common household items that may be hazardous to children, such as ASTM F1004 – 22 *Standard Consumer Safety Specification for Expansion Gates and Expandable Enclosures.* Younger children may lack the required cognitive ability and fine motor coordination to perform the necessary actions to access battery compartments that incorporate two independent and simultaneous actions, and therefore, the likelihood of opening a battery compartment would be reduced for those children (Tab C). Based on testing and evaluation of certain double-action locking mechanisms, staff concludes that these types of locking mechanisms could be very effective in preventing younger children from opening the battery compartment while permitting flexibility to design effective child resistant battery enclosures, but the wording of the requirement could be misinterpreted (Tab D).

Use and Abuse Testing

The voluntary standards reviewed by staff all specify similar abuse tests designed to test products' durability against reasonable, foreseeable use or misuse. Staff considers the drop test and impact test in UL 4200A adequately simulate use and abuse by subjecting consumer products to simulated drop and impact forces which are likely to be experienced, to a greater extent than the toy standards (ASTM F963-17 and IEC 62115). Staff considers the compression tests, torque tests, and tension tests in the toy standards adequately simulate interactions like a child grasping a part with fingers or teeth and twisting, pulling, or pressing on it. (A detailed assessment of these test methods can be found in Tab D.)

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Therefore, staff recommends that requirements from UL 4200A be used as the basis for the draft proposed rule, adding the compression test, torque test, and tension test methods from ASTM F963. Staff's observations are:

- UL 4200A specifies heat pre-conditioning of plastic components of the product. ASTM F963 and IEC 62115 do not require heat pre-conditioning. Staff's testing demonstrated that heat pre-conditioning of the product will stress plastic components and more realistically simulate the expected condition of the product during normal use.
- UL 4200A specifies mechanical pre-condition of the product by opening and closing the battery compartment and by removing and installing the battery. ASTM F963 and IEC 62115 do not require pre-conditioning by opening and closing the battery compartment. Staff's testing confirmed that mechanical pre-conditioning breaks in the components associated with securing the battery compartment and will address some quality issues, such as stripping of threads.
- UL 4200A specifies portable products be subjected to 3 drops, while hand-held portable products be subjected to 10 drops, each from a height of 3.3 feet in positions likely to produce the maximum force on the battery compartment; these are compared to requirements in ASTM F963 and IEC 62115 that allow for as few as 4 drops from a height of 3 feet in random orientation. The impact energy imparted to the product is more severe when dropped from a higher height. In addition, more drops that are specifically angled to produce the maximum force on the battery compartment are more severe than less drops at random angles. A more severe test is better able to address incidents of breaking consumer products or battery compartments allowing access to button cell or coin batteries, and is therefore more adequate to address the risk of injury.
- UL 4200A requires three impact tests that impart 2-J of energy directly on the battery compartment with a steel ball. ASTM F963 does not specify impact tests on the compartment, IEC 62368-1 varies the required impact energy based on the type of product, and IEC 62115 requires less energy per impact, which does not adequately reduce access to the battery compartment for certain products.
- ASTM F963 specifies torque test and tension test methods to simulate interactions like a child grasping a part with fingers or teeth and twisting, pulling, or pressing on it. These requirements are adequate to test battery compartments in products with pliable materials, such as shirts and greeting cards that light up or make sound using batteries. UL 4200A does not have torque and tension requirements addressing products with pliable materials.
- UL 4200A specifies a compression test of 74.2 pounds (330 N) over a 3.9-inch x 9.8-inch (100mm x250mm) area, which adequately addresses forces from a hand or foot. This is compared to requirements in ASTM F963 and IEC 62115 which specify a concentrated load of 30 pounds (133.5 N) over a 1-square-inch area; these tests subject the products to a crushing load that better addresses children unintentionally opening battery compartments which cannot be impacted directly during the drop test, but which can be pushed open with hands or fingers.
- UL 4200A and IEC 62368-1 have requirements that may exclude products containing non-removable button cell or coin batteries from abuse testing. UL 4200A specifies that if a product has a battery that is not intended to be removed or replaced by the user that is held fully captive by soldering, fasteners, or any equivalent means, that product is not subject to abuse testing and only subject to applicable pre-conditioning tests and secureness testing using a test hook and a force of 4.5 lb. (20 N). Similarly, IEC 62368-1 excludes any products with non-removable

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

batteries from all abuse testing, but it does not require any secureness test. Staff are aware of incidents involving children gaining access to non-removable batteries in products such as computers. Although non-removable batteries may be secured to the product through various mechanical means, it is foreseeable that these products could be used or abused in a way that could potentially dislodge the batteries from the product, and it remains unclear whether the secureness test in UL 4200A will adequately address the secureness of non-removable batteries. Staff requests comment on whether the secureness test in UL 4200A is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries.

Accessibility Test

Each of these four standards relies on a test probe based on a child's finger to verify whether certain components are accessible, but only IEC 62368-1, IEC 62115, and UL 4200A require a force to be applied with their respective probes to verify compliance. The IEC 62368-1 test probe head has a 3.5 mm (0.14 in.) radius, and compliance is verified with a force of 30 N ± 1 N (6.7 lbf ± 0.2 lbf). IEC 62115 and UL 4200A each use Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032. This test probe head has a 4 mm (0.16 in.) radius. Compliance is verified with a force of 50 N in IEC 62115, and a force of 45 N ± 1 N (10.1 lbf ± 0.2 lbf) in UL 4200A. Using Test Probe 11 from IEC 61032 with a force of 50 N (11.2 lbf), per IEC 62115, is adequate to assess a child's ability to get into a battery compartment.

3. Staff testing of products to UL 4200A

Staff tested 83 products to the performance requirements specified in UL 4200A to explore the test methods and evaluate products in the market. The testing included pre-conditioning and the sequential abuse tests, as described in the voluntary standards section above. Details of this testing can be found in Tab D.

Staff's evaluation included the many types of battery compartment closing mechanisms used for the products tested. The different types of locking mechanisms to secure the battery or battery compartment included:

- Single-action mechanism tabs, doors, and covers,
- Multiple- or double-action mechanism tabs, doors, and covers,
- Screws to enclose for the battery compartment or to enclose the entire product,
- Twist-on access covers, and
- Permanent enclosures.

Single-action tabs, doors, and other mechanisms failed the requirements of UL 4200A section 5.3. An example of a single action locking mechanism is shown in Figure 13 below. The battery compartment in the example requires a pull force in a single direction to slide the battery compartment out of the product.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

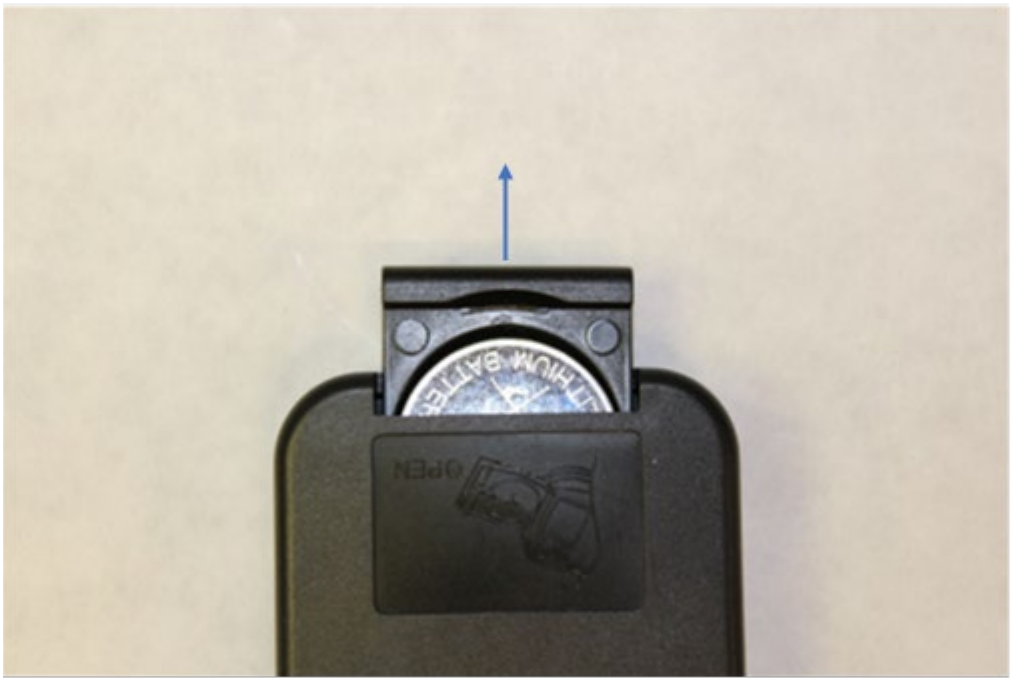


Figure 13. Single-action example

Comparatively, a “double-action” locking mechanism requires two independent and simultaneous movements. Figure 14 below illustrates a double-action locking mechanism.

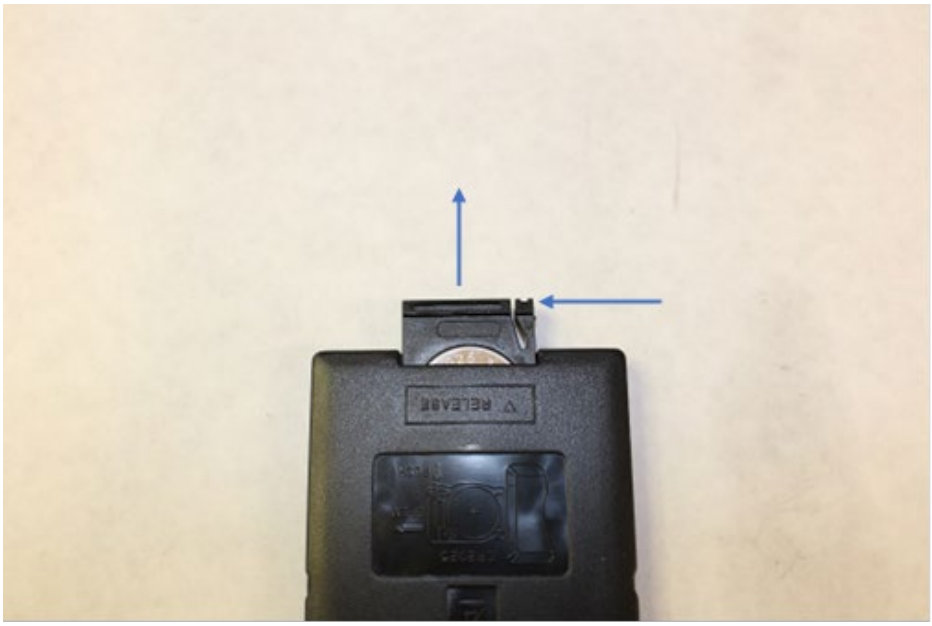


Figure 14. Double action example

Staff was able to open some products with a single action although they were designed as double action. For example, the product shown in Figure 15 was intended to require the consumer to first lift the tab by the grooves and then twist the cover. However, staff was able to apply a single force in a diagonal

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

direction to open the compartment, as shown in Figure 16. Staff considers this battery cover a single-action mechanism; however, it is unclear if this product would fail the double-action requirement in UL 4200A, which staff proposes to modify by requiring that the two actions performed must be independent and cannot be combined into one single action by a single finger or digit.

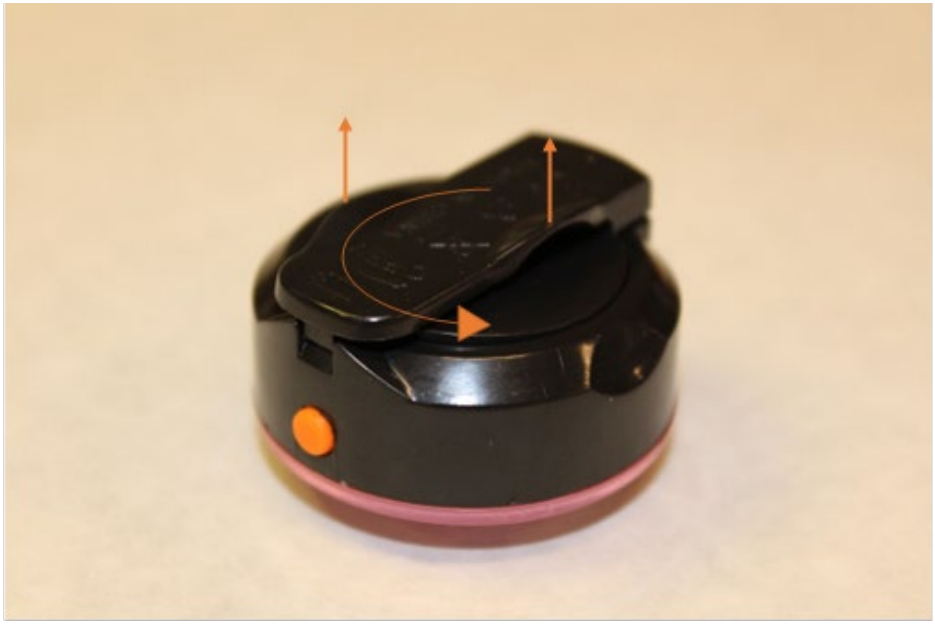


Figure 15. Sample product with intended double-action locking mechanism

Figure 16. Single diagonal force to open battery compartment cover

Four products assessed by staff had twist-on covers that opened at an angle of rotation less than 90 degrees, as shown in Figure 17. Therefore, these products failed the requirements in section 5.5 of UL 4200A to have a minimum of 90 degrees of rotation to open the compartment.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

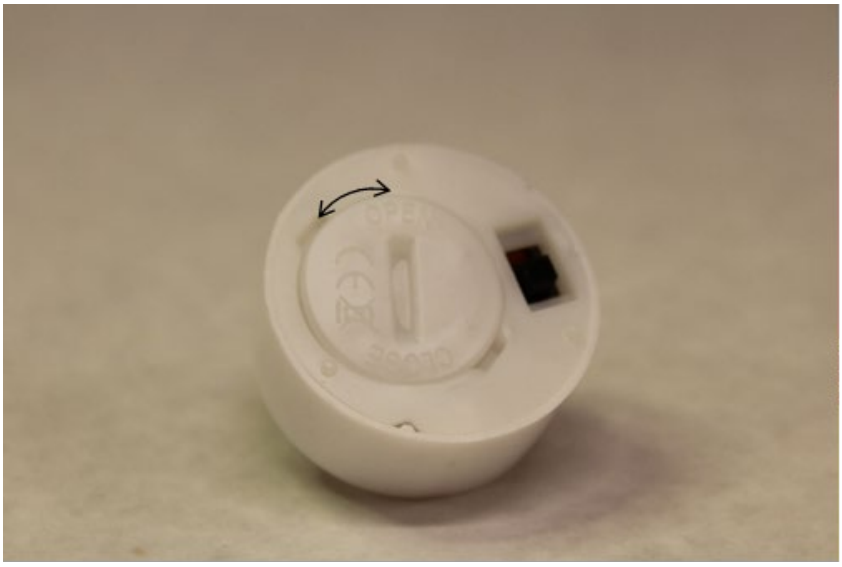


Figure 17. Twist-on cover with less than 90-degree rotation

III. Recommended Performance Requirements

A. Performance Requirements

Staff's review of voluntary standards showed that no one standard contained adequate performance requirements to address a child accessing the battery enclosures in consumer products. Based on a review of the incident data, engineering analysis, and staff's testing of consumer products, staff concluded that general requirements and abuse testing based on elements from UL 4200A, ASTM F963-17, IEC 62368-1, and IEC 62115 would provide adequate requirements to meet Reese's law to promulgate:

(1) a performance standard requiring the button cell or coin battery compartments of a consumer product containing button cell or coin batteries to be secured in a manner that would eliminate or adequately reduce the risk of injury from button or coin cell battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions.

Table 7 and Table 8 summarize staff's proposed performance requirements.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 7. Summary of Proposed Performance Requirements for Consumer Products with Compartments for Replaceable Batteries

Button cell or coin batteries must not become accessible or liberated when tested to these requirements:	
Construction Requirements	
Battery Compartment Construction Options	*Option 1*: Coin, screwdriver, or other household tool. • Captive screws • Two threads engaged or minimum torque + spin angle *Option 2*: Two independent & simultaneous hand movements. • Cannot be combinable to a single movement with a finger or digit.
Accessibility Test	Open or remove any part of the compartment not meeting *Option 1* or *Option 2*. Apply Tension Test for Seams from 16 CFR part 1250 on pliable materials, using a force of 70.0 N (15.7 lbf). Determine whether Test Probe 11 from IEC 61032 can touch the battery.
Preconditioning Requirements	
Preconditioning in Oven	Thermoplastics - 7 hours at 158°F or greater, based on operational temperature.
Simulated Battery Replacement	Open/Close and remove/install battery 10 times.
Use and Abuse Tests	
Drop Test	10 drops from 1 m (39.4 in) on hardwood, in positions likely to produce maximum force.
Impact Test	3 impacts on battery compartment with steel sphere, 2 J (1.5 ft-lbf) of energy.
Crush Test	335 N (75.3 lbf) for 10 s, using 100 by 250 mm (3.9 by 9.8 in) flat surface.
Compression Test	Test from 16 CFR Part 1250, using a force of 136 N (30.6 lbf).
Torque Test	Test from 16 CFR part 1250, using a torque of 0.50 Nm (4.4 in.-lbf).
Tension Test	Test from 16 CFR part 1250, using a force of 72.0 N (16.2 lbf).
Probe for Accessibility	Apply 50 N (11.2 lbf) with Test Probe 11 from IEC 61032 to confirm compliance.

Table 8. Summary of Proposed Performance Requirements for Consumer Products with Compartments for Non-Replaceable Batteries

Option 1 – Not Accessible	Meets the same requirements as battery compartment for replaceable batteries.
Option 2 – Accessible	• Secured with soldering, fasteners such as rivets, or equivalent means. • Applicable preconditioning requirements apply. • Confirmed with secureness test: test hook applies a force of 22 N (4.9 lbf) directed outwards for 10 s, at all possible points. Battery cannot liberate from the product.

Below is a summary of how the recommended requirements differ from UL 4200A, with clarification to the captive screw requirements, double-action lock requirements, additional tests based on the ASTM F963-17 standard, and greater force requirements from IEC 62115.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

1. Captive Screw Requirements

UL 4200A and IEC 62368-1 exclude from the requirement for captive screws any large panel doors leading to button cell or coin battery compartments which are not likely to be discarded or left off the equipment; however, staff are unsure to what products with button cell or coin batteries this exception would apply. Any door to a button cell or coin battery compartment left unsecure because of missing screws could allow a child to access the button cell or coin battery and pose a risk of ingestion. Therefore, staff recommends not including this exception to the captive screw requirements.

2. Double-Action Locks

UL 4200A describes as acceptable, certain locks that require two independent and simultaneous movements by hand, or double-action locks. Staff's testing showed that clarification of a double action is needed to reduce the likelihood of poorly designed double-action mechanisms. Staff found that some products with double-action locking mechanisms were easily opened by combining the two actions into one single action, and therefore, those actions are not truly independent (*e.g.*, the diagonally applied force described previously). This may lead to products with battery enclosure locking mechanisms that can be opened by a child or outside force. Staff recommends using a similar requirement in the draft proposed rule, but clarifying what constitutes an acceptable double-action lock, by requiring that the two actions performed must be independent and cannot be combined into one single action by a single finger or digit.

3. Compression Test

For some products with recessed battery compartments or complex polygonal surfaces, impacts from a drop test or impact test on a flat surface may not directly impact the battery enclosures due to their shape. For example, the product in Figure 18 has a bottom edge and the battery compartment is slightly recessed. Additionally, there are projections or legs that raise the product that may create space that does not allow direct contact between the battery compartment and a flat surface. ASTM F963-17 specifies a compression test that applies a maximum 30.5 lbf (135.7 N) load on a surface approximately 1.125 in. (0.380 mm) in diameter specifically for any areas that are inaccessible to flat surface contact. Staff recommends utilizing this test in the proposed rule to account for potential child access to these surfaces of the product.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

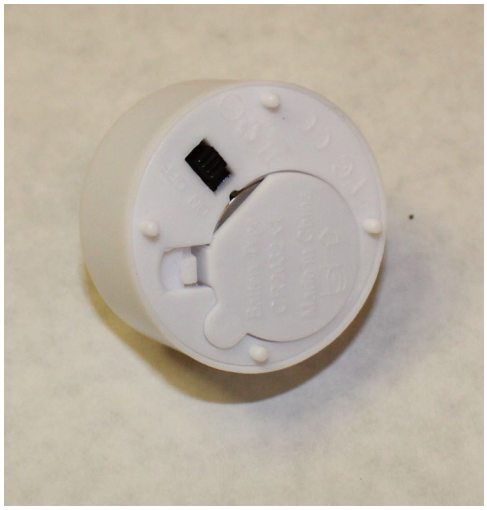


Figure 18. Example of Product with Recessed Battery Enclosure

4. Drop Test

The drop test in UL 4200A specifies that "portable products," defined as products designed to be carried easily with mass not exceeding 18 kg (39.7 lb), be dropped three times, expanding this to 10 times for hand-held products. The term "hand-held" is undefined and subjective, which may lead to a product being subjected to a different number of drops by different testers. To avoid this confusion, and to increase the adequacy of the drop test to address the risk of battery accessibility, staff recommends subjecting all products to 10 drops. Similarly, staff are not aware of any products with mass greater than 18 kg (39.7 lb) with replaceable button cell or coin batteries, and concludes the "portable" distinction is unnecessary and potentially confusing. Therefore, staff recommends removing the term "portable."

5. Torque and Tensile Tests

Many of the non-rigid products, such as light-up clothing and greeting cards, passed abuse tests from UL 4200A because they can absorb the energy from the tests, but the batteries or battery compartments can be accessed easily through other methods not considered in UL 4200A, such as torque or tension loads, which simulate a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth. ASTM F963-17, IEC 62115, and other voluntary standards include torque and tension tests to address this hazard. Therefore, staff recommends torque and tension tests based on ASTM F963-17 (or 16 CFR part 1250) in the proposed rule to appropriately test products made with pliable materials, such as fabric, paper, or textiles, and to adequately account for common child use and misuse interactions.

6. Greater Forces

The maximum force requirements in IEC 62115 for the tensile test and the accessibility probe are greater than those in ASTM F963-17 and UL 4200A, respectively. The use of these greater forces will better address children unintentionally accessing the battery compartment. Therefore, staff recommends basing

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

the minimum force requirements for the tensile test and the accessibility probe on the maximum force requirements in IEC 62115.

B. Summary

Reese's Law requires that the Commission promulgate a final consumer product safety standard which contains:[27]

> (1) a performance standard requiring the button cell or coin battery compartments of a consumer product containing button cell or coin batteries to be secured in a manner that would eliminate or adequately reduce the risk of injury from button cell or coin battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions[.]

Based on a review of the incident data, engineering analysis, and staff's testing of consumer products, staff concludes that a rule based on the requirements in UL 4200A and sections of ASTM F963-17, with modifications, would meet the requirements in section 2(a)(1) of Reese's Law. Such a rule would result in consumer products with child-resistant battery enclosures that would adequately reduce the risk of injury from button cell or coin battery ingestion by children who are 6 years of age or younger during reasonably foreseeable use or misuse conditions. UL 4200A requires the use of tools or a double-action lock to open the battery compartment. The standard also specifies preconditioning tests to simulate use and drop, impact and compression tests to simulate abuse. Staff recommends modifications to the scope of UL 4200A to include products using button cell batteries and coin batteries regardless of the chemistry. As outlined above, staff recommends additional requirements based on ASTM F963-17 for compression test applied directly to the battery compartment and torque and tension tests to simulate a child grabbing and twisting on the battery enclosure or tearing apart batteries contained in soft goods. TAB G is staff's draft recommended regulatory text based on requirements in UL4200A and applicable requirements in ASTM F963-17.

IV. Recommended Marking and Labeling Requirements

Reese's Law requires that warning labels be included:

(1) On the packaging of button cell or coin batteries and the packaging of consumer products containing such batteries;
(2) In any literature accompanying consumer products containing button cell or coin batteries (such as a user manual); and
(3) As practicable, directly on a consumer product containing button cell or coin batteries, in a manner that is visible to the consumer upon installation or replacement of the battery, or if the battery is not intended to be replaced or installed by the consumer, in a manner that is visible to

[27] 15 U.S.C.§ 2056e(a)(1).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

the consumer upon access to the battery compartment.
   a. If it is impracticable to label the product, this information is placed on the packaging or instructions.

In addition, Reese's Law requires that the warning labels do the following:[28]

(1) Clearly identify the hazard of ingestion; and
(2) Instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice.

Tab C details ESHF staff's review of warning label requirements in existing voluntary standards, and Table 9 and Table 10 below summarize staff's assessment. Staff does not conclude any one standard adequately addresses the requirements for warning labels in Reese's Law. However, when requirements of various standards are combined, they present succinct warnings to address the ingestion hazard associated with button cell or coin batteries.

Table 9. Summary of Staff's Assessment of Labeling Requirements in Standards for Consumer Products Containing Button Cell or Coin Batteries

		ASTM F963	UL 4200A	ASTM F2999-19	ASTM F2923-20	IEC 62115
Scope	Battery Chemistry Type	All	Lithium	All	All	All
	Product Type	Toys	All	Jewelry	Children's Jewelry	Toys
Labeling	On Consumer Product Packaging	I				I
	In instructions or accompanying literature	I	I			I
	On consumer product		I			

Blank – Does not address requirements, I – Inadequately addresses requirements, A – Adequately addresses requirements

Table 10. Summary of Staff's Assessment of Labeling Requirements in Standards for Batteries

		ANSI C18.1M	ANSI C18.3M	UL 1642	IEC 60086-4	IEC 60086-5
Scope	Battery Chemistry Type	Aqueous	Lithium	Lithium	Lithium	Aqueous
Labeling	On batteries*	I	I		I	I
	On battery packaging	I	I	I	I	I
	In instructions or accompanying literature		I			

Blank – Does not address requirements, I – Inadequately addresses requirements, A – Adequately addresses requirements
*Not directly addressed by Reese's Law

Additionally, staff recommends requiring performance and technical data associated with button cell or coin batteries at the point of sale, to inform consumers and to better address the risk of serious injury and death associated with the ingestion of button batteries. Accordingly, in addition to the required warnings

[28] 15 U.S.C.§ 2056e(b). Note: Reese's Law exempts compliant toy products and, in reference to section 3(a) for child-resistant packaging, "shall not apply with respect to button cell or coin batteries that are in compliance with the marking and packaging provisions of the ANSI Safety Standard for Portable Lithium Primary Cells and Batteries (ANSI C18.3M)." The proposed warning label requirements for button cell or coin battery packaging in accordance with Section 2 are additive to ANSI C18.3M.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

specified in Reese's Law, staff has recommendations for labeling to improve safety communication to consumers. Section 27(e) of the CPSA allows the Commission to require any manufacturer of consumer products to provide to the Commission performance and technical data related to performance and safety as may be required to carry out the purposes of the CPSA, and to give notification of such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser of such product for purposes other than resale, as it determines necessary to carry out the purposes of the CPSA. One of the purposes of the CPSA listed in section 2 of the CPSA is to protect the public against unreasonable risks of injury associated with consumer products. Including staff's recommended information at the point of sale, as additional labeling on packaging or products (when visible in the packaging), would help carry out this purpose of the CPSA.

Therefore, in accordance with Reese's Law and section 27(e) of the CPSA, staff recommends the following requirements for the warning labels:

A. Warning Label Format Requirements

All recommended warning labels follow requirements found in ANSI Z535.4, American National Standard Product Safety Signs and Labels, which is the primary voluntary consensus standard providing guidelines for the design of safety signs and labels for application to consumer products. The standard includes recommendations for the design, application, use, and placement of warning labels, such as having the signal word "WARNING" and the safety alert symbol of an equilateral triangle surrounding an exclamation mark. Staff recommends the following generic requirements to apply to all warning labels:

Generic Format Requirements for the Recommended Warning Labels:

1. All warnings must be clearly visible, prominent, legible, and permanently marked.
2. Warning must be in contrasting color to the background onto which it is printed.
3. Warnings must be in English.
4. The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.
5. The signal word "WARNING" must be in black letters on an orange background. The signal word must appear in sans serif letters in upper case only.
6. Certain text in the message panel must be in bold and in capital letters, as shown in the example warning labels, to get the attention of the reader.
7. For labels that are provided on a sticker, hangtag, instructions, or manual, the safety alert symbol and the signal word "WARNING" must be at least 0.2 in. (5 mm) high. The remainder of the text must be in characters whose upper case must be at least 0.1 in. (2.5 mm), except where otherwise specified.
8. For labels that are required to be on the packaging of button cell and coin batteries, the packaging of consumer products containing such batteries, and directly on consumer products, text size must be dependent on the area of the principal display panel. Text size must be determined based on Table 11, which is based on the information found in 16 CFR part 1500.19(d)(7).
    a. The "principal display panel" is defined as the display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.

b. The "product display panel" means the surface area on, near, or in the battery compartment. For consumer products with replaceable button cell or coin batteries, the product display panel must be visible while a consumer installs or replaces the button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel must be visible upon access to the battery compartment.

c. The "secondary display panel" means a display panel for a retail package of a button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

Table 11. Letter size for recommended warning labels.

Letter size measurements in inches								
Display Area: Inches²	*0–2*	*+2–5*	*+5–10*	*+10–15*	*+15–30*	*+30–100*	*+100–400*	*+400*
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display Area: cm²	*0-13*	*+13-32*	*+32-65*	*+65-97*	*+97-194*	*+194-645*	*+645-2,581*	*+2,581*
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397

B. Battery Packaging

1. Staff developed an example of the recommended warning for the principal display of the battery packaging, shown in Figure 19. The icon incorporated with the warning must be at least 8 mm in diameter.

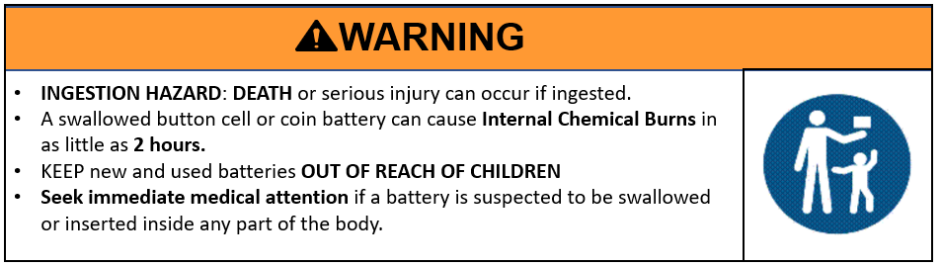


Figure 19. Proposed warning of ingestion hazard for battery packaging.

Staff recommends requiring the following wording in the warning label for button cell and coin battery packaging and offers the following rationale for each statement:

- **INGESTION HAZARD: DEATH** or serious injury can occur if ingested.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

This sentence identifies the hazard and severity as required by Reese's law.

- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.

This sentence provides warning label requirements as stated in Reese's Law – an effective warning should have an explanation of how and why ingestion of a button cell or coin battery is hazardous.

- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.

This sentence describes how to prevent the hazard. The sentence informs the consumer that both new and used batteries are hazardous, as required by Reese's law. Used batteries are hazardous because they may not have been fully discharged.

- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.

This sentence informs the consumer what actions should be taken if the battery is ingested or inserted into any part of the body. Staff recommends including a warning regarding "insertion" on this warning, because insertions into the nose can be aspirated and lead to ingestion, with the same risk of injury associated with oral ingestions.

Staff recommends use of the icon recognized for keeping the item out of children's reach to quickly convey the safety message and direct the reader's attention to the label. The icon incorporated with the warning must be at least 8 mm (0.31 in.) in diameter. Text size must be calculated per Table 11.

If space prohibits (See Table 11) the full warning with the icon shown in Figure 19, staff recommends placing the "Keep out of Reach" icon (Figure 20) on the principal display panel and placing the warning text (Figure 21) on the secondary display panel. The icon must be at least 20 mm (0.79 in.) in diameter for visibility.

Figure 20. "Keep out of Reach" icon

⚠WARNING INGESTION HAZARD ● DEATH or serious injury can occur ● A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours** ● KEEP new and used batteries **OUT OF REACH OF CHILDREN** ● **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 21. Warning text without icon.

Button cell or coin batteries included separately with the consumer product (but not yet installed in the product) must contain the warning label in Figure 19 on the principal display panel. If space prohibits the full warning, the icon shown in Figure 20 must be placed on the principal display panel with the text shown in Figure 21 on the secondary display panel, and the icon must be at least 20 mm in diameter for visibility. Once the product packaging is opened, spare batteries need to be stored out of reach of

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

children. The goal is to ensure consumers have the opportunity to see the appropriate safety related warning information and take appropriate action to store spare batteries until needed.

C. Consumer Products Packaging

Reese's Law requires warning labels on the packaging of consumer products containing button cell or coin batteries. Staff recommends the warning label must contain the same wording and icon as the battery packaging, except to add the following sentence after "INGESTION HAZARD:"

- This product contains a button cell or coin battery.

An example of the full warning is shown in Figure 22. Staff recommends the warning must be on the principal display panel of the consumer product packaging. Staff recommends requiring that consumer products that do not include packaging have the warning affixed to the product with a hang tag or sticker label.

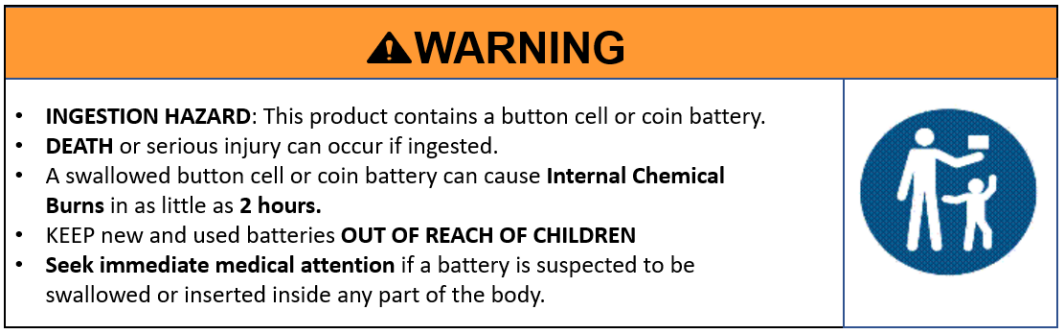


Figure 22. Example of the proposed full warning to indicate the presence of button or coin battery and the ingestion hazard for consumer product packaging. The icon must be at least 8 mm (0.31 in.) in diameter.

Staff recommends product packaging that does not have the space to permit the full warning (see Table 7) must include an abbreviated warning on the principal display panel, with the remaining statements ("KEEP new and used batteries **OUT OF REACH OF CHILDREN"** and "Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body") placed on the secondary display panel, as shown in Figure 23. The icon must be at least 8 mm (0.31 in.) in diameter. Text size must be calculated per Table 11.

Figure 23. Example abbreviated warning, if the consumer product packaging does not have space for the full warning on the front. The icon must be at least 8 mm in diameter.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

D. Directly on Product

Reese's Law requires, as practicable, warnings directly on the consumer product. Staff recommends that a consumer product must be permanently marked with an ingestion warning on the product display panel. The following warning must be used (Figure 24):

Figure 24. Proposed on-product warning label.

If space on the product does not allow the full warning text shown in Figure 24 (refer to Table 11), staff recommends the internationally recognized "Warning: contains coin battery" icon, as shown in Figure 25 be permitted without text. The icon must be at least 7 mm (0.28 in.) in width and 9 mm (0.35 in.) in height and must be on the product display panel and must be in yellow with black outlines as shown in Figure 25. The icon must be defined in accompanying printed materials, such as instructions, manual, insert, or hangtag.

Figure 25. Internationally recognized safety alert symbol to indicate "Warning: Contains coin battery."

Figure 26 demonstrates the scaled version of the above icon on a product containing a battery that has a 20 mm (0.79 in.) diameter, as well as a product containing a 5 mm (0.20 in.) battery. Staff concludes that most consumer products can accommodate the icon.

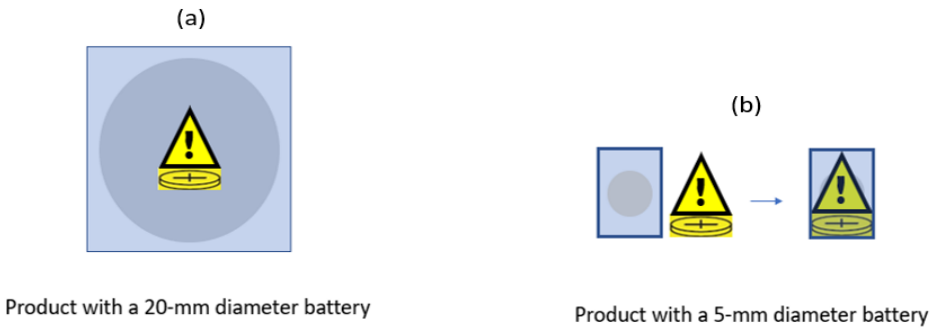


Figure 26. (a) consumer product with 20mm diameter battery and icon, (b) consumer product containing a 5 mm (0.20 in.) battery and icon

However, if the product itself is too small (see Table 11) to include the warning in Figure 24 or the icon alone (Figure 25), staff recommends requiring either:

1. To have packaging containing the warning (see requirements for consumer product packaging), or
2. To have a hangtag or sticker label with the full warnings as shown in Figure 22.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

E. Instructions/Manuals Accompanying Consumer Products

Staff recommends requiring that instructions and manuals, if applicable, contain the full warning label text required for the packaging (example shown in Figure 22).

F. Point of Sale Safety Information

In addition to the required warnings specified in Reese's Law, staff has the following recommendations pursuant to section 27(e) of the CPSA to improve safety communication to consumers. To protect the public against the unreasonable risk of injury and death to children 6 years old and younger from button cell and coin battery ingestion, staff recommends the following performance and technical data be required at the point of sale pursuant to section 27(e) of the CPSA.

1. Websites or Apps that enable consumers to purchase products online

Given the increasing number of online sales, staff assesses that point of purchase includes online sales, and consumers should be able to view safety information while purchasing products online. Consumer products containing button cell or coin batteries offered for sale online must include the applicable warnings[29] discussed above on the website or app of a manufacturer or importer, that enables consumers to purchase a product. Otherwise, consumers are not exposed to the warnings until they receive the physical product, and knowing the hazard associated with button cell or coin batteries may influence their purchasing decision or the actions they may take to avoid the hazard. Consistent with the Commission's authority under section 27(e) of the CPSA, this recommended requirement would be required for manufacturer (or importer) websites that allow for consumer purchase of the product.

Online sales and advertising must include the warning in Figure 19 for purchases of button cell or coin batteries, and the warning in Figure 22 for purchases of consumer products containing button cell or coin batteries. The warning must be clearly visible, prominent, and legible next to the product description or near the product image or near the product price so that consumers will notice it.

2. Request for Comment on Requiring a Warning Icon on Button Cell or Coin Batteries

Reese's Law does not require marking or labeling regarding the ingestion hazard directly on button cell or coin batteries. However, the voluntary standard ANSI C18.3M advises to durably and indelibly mark coin cells with the "Keep Out of Reach" icon, with a minimum icon size of 6 mm in diameter. In accordance with Reese's Law, staff recommends the "Keep Out of Reach" icon be used in conjunction with warning labels on battery and consumer product packaging to quickly convey the required message and direct the reader's attention to the warning label. Requiring button cell or coin batteries that are visible within the packaging at the point of sale to have the "Keep Out of Reach" icon will further remind the consumer of the ingestion hazard, and direct attention to the icon and warning label on the battery packaging. Additionally, placing the "Keep Out of Reach" icon on button cell or coin batteries would continue to inform consumers of the ingestion hazard posed by the battery at all stages of its lifecycle, including while it is in battery packaging, when placed in a consumer product, or when loose. Staff requests comment on whether the rule should require button cell or coin batteries to be durably and indelibly marked with the "Keep Out of Reach" icon where size permits, at a minimum size of 6 mm in

[29] For the sale of button cell or coin batteries, the applicable warnings are those for the battery packaging. For the sale of consumer products, the applicable warnings are those for the consumer product packaging.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

diameter, and if so, is the appropriate legal authority Reese's Law, section 27(e) of the CPSA, or another statute. Figure 27 shows an example of durable and indelibly marked coin battery with the icon etched into the battery.

Figure 27. "Keep Out of Reach" icon etched onto battery

G. Other Battery Safety Information

In addition to the ingestion hazard warning, staff recommends requiring that the following information be placed on the battery packaging and consumer product packaging. Consumers must be aware of safe handling and use of batteries to reduce battery leakage, fire and/or explosion hazards that could lead to personal injury. Staff recommends the following additional safety information pursuant to Reese's Law and Section 27(e) of the CPSA:

1. Battery packaging

The principal display panel or secondary display panel of the battery packaging must include the following:

- "Keep in original package until ready to use."

This statement intends to instruct consumers to leave batteries in child resistant packaging as a specific means of keeping new batteries out of the reach of children.

- "Immediately dispose of used batteries and keep away from children. Do NOT dispose of used batteries in household trash."

This statement instructs consumers how to prevent ingestion hazards from used batteries, by keeping used batteries out of reach of children, including out of household trash.

- "Call a local poison control center for treatment information."

This sentence makes more actionable the guidance to "immediately seek medical attention" and provides consumers with a resource for obtaining medical advice suitable to their situation.

- Battery type (*e.g.* LR44, CR2032)
- Battery chemistry (e.g. silver oxide button or lithium)
- Nominal voltage

Having battery type, chemistry, and voltage on the packaging constitutes performance and technical data that may help identify the battery if an ingestion is suspected. For example, lithium button cell or coin batteries are associated with a higher likelihood of injury or death, in part because they have a

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

greater voltage than other button cell or coin batteries. If a button cell or coin battery is ingested, knowing this information could assist medical providers to assess the severity of the risk of injury, and to treat the patient accordingly. The compatible battery type and voltage information on the product packaging will also help consumers avoid any hazards associated with using incompatible batteries, such as leakage, fire and/or explosion hazards, and reduce the risk of a loose batteries resulting from selection of the wrong battery. There have been incidents of children ingesting loose battery cells.

- Year and month or week of manufacture or expiration date
- Name or trademark of the manufacturer or supplier

Identification of manufacture date and other manufacturer information is technical data that may facilitate recalls resulting from ingestion of button or coin batteries.

- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."

This statement is intended to reduce the chance of consumers mixing batteries as described; mixing batteries can contribute to battery leakage, fire and/or explosion hazards that could lead to personal injury. The statement will better inform the consumer to use the correct type of battery cell that is called for use in the product to minimize loose cells, such as the consumer taking a battery cell from the battery packaging and then realizing that it is the incorrect brand or type of battery. There have been incidents of children ingesting loose battery cells.

- "Ensure the batteries are installed correctly according to polarity (+ and -)."

The reminder statement is to inform the consumer that installing the battery cells with the correct polarity will properly operate the product. Incorrect installation may result in the consumer removing the battery cells (loose cells) to install another set of battery cells. There have been incidents of children ingesting loose battery cells. Batteries installed with the wrong polarity can leak or explode.

- "Remove and immediately discard batteries from equipment not used for an extended period of time."

This statement is intended to ensure consumers immediately dispose of batteries in unused products, because if left for an extended amount of time these batteries can leak, discharge, or explode unexpectedly. Used battery cells still have sufficient energy to cause damage if ingested. There have been incidents of children ingesting loose battery cells.

- "Non-rechargeable batteries are not to be recharged."

This statement enhances safety because placing non-rechargeable batteries in a charger can cause battery leakage, fire and/or exploding hazards. This statement is intended to ensure consumers do not leave out or attempt to recharge non-rechargeable batteries. There have been incidents of children ingesting loose battery cells.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

This statement explains how the improper operation of a battery may result in injuries from chemical burns. Damaged battery cells may leak toxic chemicals that poses a risk when ingested.

2. Consumer product packaging or accompanying hang tag or sticker label.

The principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must include the following:

- Products with non-replaceable batteries must include a statement indicating the product contains non-replaceable batteries.

  If a consumer attempts to replace a non-replaceable battery, this action may damage the consumer product or the battery, and contribute to battery leakage, fire and/or explosion hazards. This may also cause the original or the replacement battery to become accessible, contributing to the ingestion hazard.

The following requirements were previously described for battery packaging, and are also required on either the principal display panel or secondary display panel of the consumer product packaging, or in the absence of consumer product packaging, the accompanying sticker or hangtag:

- Battery type (*e.g.* LR44, CR2032)
- Nominal voltage

3. Instructions and manuals:

Instructions and manuals, when provided with consumer products, must include the following additional battery safety-related information that is also required on the battery packaging:

- "Remove and immediately dispose of used batteries."
- "Even used batteries may cause severe injury or death."
- "Call a local poison control center for treatment information."
- Battery type (e.g. LR44, CR2032)
- Nominal voltage
- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."
- "Remove and immediately discard batteries from equipment not used for an extended period of time."
- "Non-rechargeable batteries are not to be recharged."
- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

If instructions or manuals are not provided with the consumer product, this information must be present on the principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label. This ensures the consumer has the opportunity to see the appropriate safety-related information, whether the consumer product is supplied with a button cell or coin battery or not.

V. Effective Date

Staff recommends that a final rule containing (1) performance and warning label requirements for consumer products containing button cell or coin batteries, and (2) warning label requirements for button cell or coin battery packaging, become effective 180 days after publication of a final rule in the *Federal Register*. Accordingly, products manufactured or imported 180 days after publication of a final rule must comply with the rule. A substantial number of consumer products containing button cell or coin batteries do not meet the requirements in UL 4200A, and many affected industries will be unfamiliar with all or part of the draft proposed requirements. Additionally, staff's recommended warning label requirements include specific language that would require manufacturers to revise or reprint all existing packaging. A 180-day effective date also reflects similar language in Reese's Law, which in section 3(a) sets a 180-day effective date for the child-resistant packaging requirements. Staff concludes that a 180-day effective date is likely to give affected businesses enough time to design, manufacture, and test consumer products with battery enclosures meeting the rule's requirements.

VI. Certification and Notice of Requirements

A rule for consumer products containing button cell or coin batteries would be a consumer product safety rule that requires testing and certification under section 14(a) of the CPSA. Additionally, as applied to (non-toy) children's products containing button cell or coin batteries, the rule would be a children's product safety rule that requires third party testing by a CPSC-accepted laboratory, and certification of compliance to the standard. See 16 CFR parts 1110 and 1107.

The Commission published Requirements Pertaining to Third Party Conformity Assessment Bodies, 16 CFR part 1112, which establishes the requirements for accreditation of third-party testing laboratories to test for compliance with a children's product safety rule. For consumer products containing button cell or coin batteries that are children's products, staff recommends that the Commission propose to amend part 1112 to include consumer products containing button cell or coin batteries.

VII. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. §§ 601 – 612) requires that the agency prepare an initial regulatory flexibility analysis that describes the impact that the rule would have on small businesses and other entities, unless the rule will not have a significant economic impact on a substantial number of small entities.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

A. Costs and Impact of Draft Rule for Small Manufacturers

Button cell or coin battery-powered products may require redesign to accommodate the tool lock or a double-action lock required by the draft proposed rule. Button cell or coin battery-powered product manufacturers would most likely adopt a tool lock secured with a screw for affected products that currently do not conform to the proposed rule requirements. The potential costs of this rule are, therefore, the incremental cost to incorporate a screw lock, and the one-time research/development and retooling costs associated with the changes to battery compartments. For products that incorporate a double-action lock to secure the compartment, staff expects the only cost incurred would be the redesign of the compartment to accommodate the change.

Estimates of the incremental costs to modify a battery compartment for a screw lock range from $0.02 to $0.04 per product, based on an ESMC staff estimate. The estimate of possible research/development and retooling costs equates to a maximum $15,400 per firm. Firms that choose to meet the requirement using a double-action lock are only expected to incur research and development costs.

Manufacturers would likely incur additional costs to certify that their button cell or coin battery-powered products meet the requirements of the draft proposed rule, as required by Section 14 of the CPSA. For general use products, the certification must be based on a test of each product or a reasonable testing program. Manufacturers may complete the testing themselves or use a testing laboratory. Certification of children's products, however, must be completed by a CPSC-accepted, third party conformity assessment body (third party laboratory). Based on quotes from testing laboratory services for consumer products, the cost of certification testing will range from $150 to $350 per product sample. These third-party testing costs should be considered as a possible maximum testing cost of the draft proposed rule. Note that the requirement to certify compliance with all product safety rules is a requirement of the CPSA and not of the draft proposed rule. Certificate content requirements are set forth in section 14(g) of the CPSA and codified in 16 CFR part 1110. A reasonable testing program performed by the manufacturer would meet the requirements for general use (non-children's) products, but children's products are required to be tested and certified based on the third-party testing requirements in 16 CFR part 1107.

To comply with the draft proposed rule, small manufacturers would incur a one-time redesign and continuous incremental component costs, described above, for some product lines that currently do not meet the requirements. Staff does not expect most small manufacturers to suffer a disproportionate cost effect from the draft proposed rule; but firms that heavily rely on the production of small unique/novel electronic products or high volume-low price products could be adversely affected. Retail prices for button battery-powered products vary widely, with the least expensive on a per-unit basis being mini flashlights at $1.00.[30] A small manufacturer could incur costs that exceed 1 percent of annual revenue if the firm only produced these high-volume low-price or novel electronic products. Also, smaller manufacturers with under $1,540,000 in annual revenue could incur one-time costs that exceed 1 percent of annual revenue, based on CPSC staff's estimate of the potential research and development costs, which ranged from $7,700 to $15,400 per firm.

Generally, staff considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. CPSC staff expects a potentially significant impact on some small firms which manufacture button battery powered products. Staff assesses that most small firms would not incur costs that exceed 1 percent of annual revenues and therefore not be significantly impacted by the proposed rule.

[30] Based on staff's review of product offerings on retailer websites and in-store locations.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

B. Alternatives for Reducing the Adverse Impact on Small Entities

Under section 603(c) of the Regulatory Flexibility Act, an initial regulatory flexibility analysis should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." CPSC staff assessed that the broad scope of Reese's Law does not allow for a significant alternative that would reduce impacts to small businesses, as methods for reducing impacts to small firms, such as limiting scope, providing exemptions, and consumer education in lieu of regulatory action, would not meet the applicable statute. To reduce impact of the rule on small firms, CPSC could remove the additional labeling requirements under section 27(e) of the CPSA, as recommended by staff, that are not required by Reese's Law. However, removing additional labeling is expected to reduce burden by an inconsequential amount as firms would still have to conform to the other labeling provisions. The *incremental* increase in burden from staff's additional labeling requirements is insignificant.

VIII. Request for Comment

Staff recommends requesting comments on all aspects of the staff recommendations, and specifically on the following items:

Performance Requirements

- Whether any consumer products contain zinc-air button cell or coin batteries (as opposed to medical devices such as hearing aids), and whether such products should be required to meet the performance requirements for battery compartments on consumer products;
- Whether any voluntary standard meets the performance and labeling requirements of Reese's Law;
- Whether the requirements should incorporate test methods commonly used on toy products, such as the torque and tensile tests for parts of the product that can be gripped by a child's fingers or teeth, or a tensile test for pliable materials;
- For consumer products that use button cell or coin batteries and have large panel doors, what consumer products have such doors, and should the Commission exclude large panel doors from the requirement for captive screws; why or why not (i.e., why does a large panel door represent a different risk of injury from battery access without using captive screws than a smaller battery compartment door does?);
- Whether a double-action locking mechanism used to secure battery compartment enclosures, meaning those mechanism that rely on two independent and simultaneous hand movements to open (versus a screw, for example), should be allowed to secure button cell or coin battery compartments;
- Whether Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032, is adequate to verify accessibility of the battery in the compartment;
- Whether the secureness test in UL 4200A is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries;

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- Whether there are any additional performance requirements that should be considered, either for specific types of products, or in general;
- Whether one or more performance requirements should be based on IEC 62368-1, in addition to, or instead of, performance requirements based on UL 4200A; and
- Whether the proposed performance requirements are needed and are likely to eliminate or adequately reduce the ingestion hazard associated with access to button cell or coin batteries from consumer products.

Marking and Labeling Requirements

- Whether the Commission should require ingestion warnings on the packaging for zinc-air button cell or coin batteries;
- Whether all button cell and coin battery packaging should include the warning on the principal display panel;
- Whether the requirement for the "Keep Out of Reach" icon to be 20 mm for visibility purposes, when alone on the front of battery packaging, provides sufficient warning of the ingestion hazard;
- Whether the content included for other battery safety information is sufficient to address ingestion and other hazards associated with button cell or coin batteries;
- For technical and performance data related to the safety of button cell or coin batteries required at the time of purchase, whether the proposed warnings' content and location requirements are adequate to advise consumers who purchase a product online or in-store about the hazards associated with these batteries;
- Whether staff's assessment that virtually all consumer products can accommodate either the full warning or one of the scaled icons is accurate;
- Whether the rule should require button cell or coin batteries to be durably and indelibly marked with the "Keep Out of Reach" icon where size permits, at a minimum size of 6 mm in diameter, and if so, whether the appropriate legal authority is Reese's Law, section 27(e) of the CPSA, or another statute; and
- Whether the internationally recognized safety alert symbol as shown in yellow color indicating the presence of a coin cell should be required on consumer products containing button cell or coin batteries; and

Initial Regulatory Flexibility Analysis and Other Comments

- Whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and to provide specific information to support such a later or an earlier effective date; and
- The number of small firms impacted and expected cost impact on small firms (as a percentage of annual revenue) of the draft proposed rule.

IX. Conclusion

CPSC staff estimates that between 2011-2021, there were approximately 54,300 emergency room visits associated with ingestion, impaction, or insertion of button cell or coin batteries. The data show that these incidents occur most often with children aged 4 years or younger. Ingestion of a button battery has

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

caused severe injuries and deaths. Children access button batteries from consumer products that are powered by the batteries, either directly from the battery compartment, or because the batteries have escaped from the compartments.

In accordance with Reese's Law, CPSC staff recommends a draft proposed rule to address the button cell and coin battery ingestion hazards to children. The draft proposed rule contains:

1) Performance requirements for consumer products containing button cell or coin batteries that require the battery to be secured in a manner that would eliminate or adequately reduce the risk of injury from the ingestion hazard to children during reasonably foreseeable use or misuse conditions. Staff's draft proposed rule is based on UL 4200A, which staff concludes to be adequate to address the risk of injury based on staff's engineering analysis and testing of consumer products, with the following modifications:

    - A wider scope to match the scope of products covered by Reese's Law;
    - Clarification that a locking mechanism requiring two simultaneous and independent actions does not include actions that can be combined into one single action by a single finger or digit, to address poor locking mechanism designs observed in testing;
    - The addition of the compression test from the toy standard, 16 CFR part 1250 (ASTM F963-17), to address children pressing on areas of the battery compartment not directly impacted by the drop test;
    - The requirement that all products, including products weighing more than 18 kg, be subjected to 10 drops, rather than just hand-held products, to reduce subjectivity in the test method based on the term "hand-held" being undefined;
    - The addition of the torque and tensile tests from the toy standard, 16 CFR part 1250 (ASTM F963-17), to address a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth.

2) Warning label requirements for:

    - The packaging of button cell or coin batteries and the packaging of consumer products containing button cell or coin batteries;
    - Accompanying literature; and
    - Consumer products, as practicable.

Staff did not conclude any one standard adequately addresses the warning label requirements in Reese's Law. The recommended requirements follow the format requirements in ANSI Z535.4 and are based on warnings found in ANSI C18.3M, ASTM F963, UL 4200A, and other standards.

Staff additionally recommends point-of-sale warnings of the ingestion hazard and other battery safety information under section 27(e) of the CPSA to improve safety communication to consumers to address the unreasonable risk of injury and death to children from ingesting or inserting button cell or coin batteries into the body, and other hazards.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TAB A

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Daniel Taxier, Project Manager
Division of Mechanical and Combustion Engineering

DATE: November 22, 2022

THROUGH: Risana Chowdhury,
Division Director
Division of Hazard Analysis

FROM: John Topping
Mathematical Statistician
Division of Hazard Analysis

SUBJECT: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Deaths, Injuries, and non-Injury Incidents Associated with Hazards of Button Cell or Coin Battery Ingestion

---

I. Introduction

Per Reese's Law, Public Law No. 117-171, a "button cell or coin battery" includes a single-cell battery with a diameter greater than the height of the battery. This memorandum provides incident data associated with button cell or coin batteries ingested by mouth, or inserted into the nose or ears. This memorandum uses the abbreviation "BCCB" to cover the combination of Button Cell or Coin Batteries and focuses on BCCBs entering the body through any of three specific orifices (mouth, nose, or ears), regardless of victim age and intent. However, this memorandum does *not* include any count or assessment of insertions (of which some may result in impactions) in the rectum or genitals.

The combination of threats of impaction from BCCBs in the digestive tract (from ingestion), impaction directly by mouth or impaction or insertion into the nose or ears is abbreviated in this memo using the term "III" (for impactions, ingestion, or insertion via the mouth, nose, or ears), which is combined with a previously defined term as "BCCB-III." Furthermore, all BCCB-III *estimates* in this memorandum refer specifically to estimates of related U.S. hospital emergency room visits and do *not* include incidents that may have gone untreated or were treated in some other setting.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

II. BCCB-III Estimates Derived from National Electronic Injury Surveillance System (NEISS)[1]

Over the entire 11-year period from 2011-2021, an estimated 54,300 BCCB-III occurred, with medical professionals able to determine ingestion, impaction, or insertion into the mouth, nose, or ears of a battery consistent with characteristics of a button cell or coin battery. This estimate is derived from a sample of 2,183 cases CPSC staff found to have sufficient information to imply such a conclusion and *excludes* cases indicating uncertainty of BCCB-III, other than for the use of several inferential assumptions. Staff interpreted the words "disc" and "coin" as sufficient to conclude BCCB without necessarily requiring a more explicit battery type descriptor, such as "button cell" or "coin cell." Given that the types of batteries used with watches and the types of batteries used with hearing aids are overwhelmingly BCCB, references to batteries for or from a watch, or for or from a hearing aid, were interpreted as indicating BCCB if there was no other information to the contrary. Although indications that a battery was "small" would not necessarily suffice to establish BCCB, in some contexts, staff considered small battery size indicative of BCCB, such as in some contexts implying very flat or very small battery size and in some other contexts that, in combination with other contextually indicative characteristics–appeared to be descriptive of BCCB for example, "SWALLOWED A SMALL ROUND LITHIUM BATTERY," indicating a size, shape, and chemistry suggesting BCCB ingestion. This assessment *excludes* many cases, however, establishing ingestion (or insertion) of a battery in which the type of battery is not indicated or implied. Cases indicating only suspected or possible ingestion, without subsequent confirmation of insertion, were also excluded. Staff's assessment generally relied upon the final diagnosis as recorded in short text summaries from medical professionals. The lack of detection of a battery as a foreign body does not necessarily contraindicate battery presence (which may sometimes be missed by x-ray scans). Consequently, these estimates of BCCB-III may likely underestimate the actual number of BCCB-III occurrences.

Table 1 provides the number of cases and corresponding estimates of BCCB-III for every year during the 11-year period 2011 through 2021.

[1] NEISS Injury estimates and counts of reported deaths are assessed for the entire period from 2011-2021, based on data available as of May 2022. However, nonfatal incidents reported via CPSRMS (which may include non-injury incidents and reports of concern without incident in addition to reports of actual injuries) are assessed only for the more recent period of 2016-2021. Although NEISS is complete for 2011-2021, and thus, the injury estimates are final, additional reporting of deaths and other incidents is particularly expected for the most recent years 2020-2021.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 1. Estimated Number of BCCB-III Cases Treated in Hospital Emergency Departments, 2011-2021.

Year	Estimate	N	CV
2011	4,600	170	0.20
2012	4,500	179	0.18
2013	5,000	178	0.21
2014	5,500	177	0.19
2015	3,500	163	0.15
2016	6,500	237	0.15
2017	5,400	196	0.20
2018	4,500	200	0.17
2019	4,200	178	0.26
2020	5,500	270	0.14
2021	5,200	235	0.18
Total	**54,300**	**2,183**	**0.15**

Source: NEISS, CPSC.
Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample. Estimates spanning periods of multiple years (such as the 11 years from 2011 to 2021) are total estimates, and *not* annual averages.

Table 2 provides estimates of disposition associated with BCCB-III. An estimated 8,800 (16%) were hospitalized or transferred to another hospital. An estimated 44,500 (82%) were treated and released. In comparison, among all consumer product-related emergency room visits in the same period (regardless of relationship to batteries), only an estimated 9 percent result in hospitalization or transfer to another hospital with an estimated 89 percent treated and released. This comparison suggests BCCB-III cases are relatively more severe than average.

Table 2. Estimated Number of BCCB-III by Victim Disposition, 2011-2021.

Victim Disposition	Estimate	Estimated Percent	N	CV
Hospitalized/Transferred	8,800	16%	418	0.17
Treated and Released	44,500	82%	1,722	0.16
Other *	**	2%	43	**
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.
*Dispositions observed among the "other" category in the sample cases include "Held for observation (includes admitted for observation)" and "Left without being seen/Left against medical advice."
**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.

The majority of the victims, an estimated 31,400 (58%) of BCCB-III were identified as male, with an estimated 22,900 (42%) identified as female.

Table 3 provides estimates of victim age at the time of initial treatment associated with BCCB-III. An estimated 16,100 (30%) of the victims were young children under the age of 2 years, and an estimated 26,900 (50%) were children between the ages of 2 and 6. In total, an estimated 43,000 (79%) BCCB-III were associated with children *under* 7 years of age. The remaining estimated 11,300 (21%) are associated with victims ages 7 years and older (including adults). Although young children appear to be at significantly higher risk than older populations, elderly adults appear to be at

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

greater risk than younger adults. Adult and elderly ingestions can be related to loose BCCB being confused with medication and ingested under the mistaken belief that the BCCB are pills.

Table 3. Estimated Number of BCCB-III by Victim Age (or Age Range), 2011-2021.

Victim Age (or Age Range)	Estimate	Estimated Percent	N	CV
0-11 months	2,900	5%	129	0.27
12-23 months	13,200	24%	513	0.21
2 years	8,700	16%	378	0.19
3 years	7,100	13%	315	0.19
4 years	5,500	10%	220	0.12
5 years	3,200	6%	146	0.17
6 years	2,400	4%	84	0.18
7 years	1,900	4%	71	0.20
8 years	1,500	3%	59	0.24
9 to 14 years	2,900	5%	141	0.16
15-24 years	*	2%	33	*
25-34 years	*	1%	8	*
35-44 years	*	<1%	5	*
45-54 years	*	<1%	1	*
55-64 years	*	<1%	6	*
65-74 years	*	1%	17	*
75-84 years	*	2%	21	*
85+ years	1,500	3%	36	0.22
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.
*This estimate does not meet NEISS reporting criteria.

Table 4 provides the distribution of BCCB-III based on the orifice through which the batteries entered the body. Insertions in the mouth generally resulted in ingestion, whether impacted in the digestive tract, or passing through without impaction. Staff assessed all of the mouth insertions as "ingestions"; however, it is possible a small proportion may have involved impaction in the mouth, without necessarily reaching further into the digestive tract. Insertions in the nose overwhelmingly resulted in impaction. However, a very small proportion of nose insertions ultimately resulted in ingestion with batteries subsequently getting into the stomach or digestive tract (*e.g.*, after aspiration through the nose). All of the ear insertions were assessed as impactions in the ears. These estimates in Table 4 simply present BCCB-III based upon the orifice through which batteries entered the victim's body, regardless of the eventual outcome.

Table 4. Estimated Number of BCCB-III by Victim Orifice Inserted, 2011-2021.

Victim Orifice Inserted	Estimate	Estimated Percent	N	CV
Mouth	48,000	88%	1,915	0.16
Nose	3,400	6%	161	0.18
Ear	2,900	5%	107	0.17
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Note that BCCB-III by definition excludes instance of batteries entering the body through other orifices, such as the rectum or genitals, which staff concluded typically involves activity by adults or adolescents with other or unknown battery types that this package cannot address.

With an estimated 97 percent of victims ingesting or inserting batteries with size classified as "Unknown," and staff only being able to classify size range for slightly more than 2 percent, staff is unable to report estimates of BCCB-III differentiated by battery size.

A substantial majority of the data (an estimated 86%) were classified "Unknown" regarding battery chemistry. Staff was able to conclude an estimated 1,600 (3%) as Lithium and 5,000 (9%) as Zinc-air. The estimate associated with alkaline chemistry does not satisfy NEISS reporting requirements. The conclusion of zinc-air battery chemistry was substantially assisted from the assumption that "hearing aid" type batteries could be inferred to have zinc-air battery chemistry. Other battery chemistries could not generally be established on the basis of comparable associated product type derived inferences. The actual numbers and percentage for each of these battery chemistries are very likely higher (and potentially considerably higher) than these unadjusted estimates suggest. However, as some chemistries may be more likely to be detectable than others in this assessment, the battery chemistry breakout should not be assumed to be the same among the 14 percent specifying chemistry and the 86 percent with unknown chemistry.

Table 5 provides estimates based on staff classification of the source of the batteries. For the majority, an estimated 38,900 (72%) of BCCB-III, staff had insufficient information to establish clearly whether the batteries were found loose by the victim, removed from packaging, or directly removed from a product. An estimated 3,100 (6%) were determined to have been found loose by victim (*e.g.*, victim found BCCB on the ground or floor from an undetermined source or victim found BCCB stored loosely in a drawer) prior to ingestion or insertion. Staff determined an estimated 11,900 (22%) to have been removed or accidentally liberated from some kind of product. Staff cannot report an estimate of BCCB-III involving batteries taken directly from battery packaging.

Table 5. Estimated Number of BCCB-III by Battery Source Classification, 2011-2021.

Battery Source Classification	Estimate	Estimated Percent	N	CV
Loose	3,100	6%	131	0.19
Packaging	*	1%	23	*
Product	11,900	22%	496	0.14
Unknown Source	38,900	72%	1,533	0.17
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.
*This estimate does not meet NEISS reporting criteria.

Table 6, which follows, is only applicable to the estimated 11,900 (22% of 54,300) BCCB-III established to have come specifically from some product and classifies that subset based on the type of product for which the battery was a source. As this excludes BCCB-III from an unknown source category, these estimates likely substantially under-estimate the actual number of BCCB-III sourced from each respective product type. The estimate of 5,100 (42% of 11,900) "Consumer Product (excluding toys/games and key fobs)" type BCCB-III includes any product determined not to be a children's toy, key fob, car remote, or medical device (such as a hearing aid or thermometer). Such products included lights (flash lights, pen lights, laser lights, and book/reading lights), remote controls, watches, calculators, decorations and ornaments, electronic candles and tea lights, clocks and timers, electronic sound making books, pens, guitar tuners, and other consumer products. The estimate of 4,400 (37% of 11,900) "toys/games" product type of BCCB-III includes children's toys

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

and games. The data are not sufficient to provide an estimate for car remotes and key fobs, some of which may not be consumer products within the scope of the draft proposed rule. Medical devices, including hearing aids (13%) and other medical devices (5%), are associated with a total estimated 18 percent of the product battery source associated BCCB-III.

Table 6. Estimated Number of Product Battery Source Classified BCCB-III Only by Battery Source Product Type, 2011-2021.

	Product Battery Source Classified Only			
Battery Source Product Type	**Estimate**	**Estimated Percent**	**N**	**CV**
Consumer Product (excluding toys/games and key fobs)	5,100	42%	237	0.17
Toys/games	4,400	37%	176	0.17
Car remotes and key fobs	*	2%	11	*
Hearing aid	1,600	13%	52	0.21
Other Medical Device (excluding hearing aid)	*	5%	16	*
Unknown Product Type**	*	<1%	4	*
Total	**11,900**	**100%**	**496**	**0.14**

Source: NEISS, CPSC.

*This estimate does not meet NEISS reporting criteria.

**For a small proportion of cases, although it could be determined that the batteries were neither loose or from packaging and came from *some* product or device, it could not be determined which *type* of product or device. Therefore for a small proportion of the cases categorized in the Table 5 as known to have come from a *product*, in this table it remains unknown as to *type* of product functioning as battery source.

III. Fatal BCCB Ingestions Reported in Consumer Product Safety Risk Management System (CPSRMS)

Staff is aware of 25 reported BCCB-III-related *deaths* in the United States for the period 2011-2021. All involve ingestion of BCCB by mouth, and therefore, qualify as BCCB-III. This assessment does not generally cover incidents prior to 2011; however, a late 2010 incident from which a child initially survived until death in 2013 due to the resulting complications is included (as one of 6 deaths in 2013). The remaining 24 decedents covered by this assessment died within the same year when they first ingested BCCB. Reporting is particularly incomplete for the most recent years 2020-2021. Among the reported BCCB-III deaths of which staff is aware during this 11-year period, 15 (60%) involved death *before* 2016, and 10 (40%) involved death in or *after* 2016.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table 7. Reported Number of BCCB-III Deaths by Year, 2011-2021.

Year	Deaths	Percent
2011	3	12%
2012	2	8%
2013	6	24%
2014	1	4%
2015	3	12%
2016	0	0%
2017	3	12%
2018	2	8%
2019	0	0%
2020	*4*	*16%*
2021	*1*	*4%*
Total	**25**	**100%**

Source: CPSRMS, CPSC.
Note: Reporting is particularly incomplete for the years 2020-2021, and counts for those years may increase as additional death certificates are received.

A majority of reported decedents (16 or 64%) were indicated as female. A minority of reported decedents (9 or 36%) were indicated as male.

Table 8 presents all 25 BCCB ingestion fatalities by initial victim age (*i.e.*, at the time of ingestion). All were under the age of 5 years. For a small number of these incidents, the decedent survived long enough to reach an older age classification than when first ingesting BCCB. Therefore, initial victim age presented in Table 8 may be younger than the decedent's final age upon death. One (4% of 25) indicated initial victim age as 10 months, although that particular child survived until 3 years of age before death from resulting complications. A majority of reported deaths, 14 out of 25 (56%), involved BCCB ingested by 1-year-old victims (*i.e.*, 12 months to 23 months at time of ingestion). Six (24%) decedents were 2 years old at the time of ingestion. No decedents were reported as 3 years old at the time of initial BCCB ingestion. Four (16%) decedents were age 4 years old at the time of ingestion and death. No decedents were identified *over* the age of 4 years (either upon ingestion or upon death).

Table 8. Reported Number of BCCB-III Deaths by Initial Victim Age, 2011-2021.

Initial Victim Age	Deaths	Percent
0-11 months	1	4%
12-23 months	14	56%
2 years	6	24%
3 years	0	0%
4 years	4	16%
Total	**25**	**100%**

Source: CPSRMS, CPSC.

Battery chemistry was unknown for almost half (48%) of reported deaths. Lithium was determined to be the chemistry for at least 13 (52%) of the deaths. An explicit indication of precise battery type (*e.g.*, CR2032) allowed staff to infer the battery chemistry to be lithium. No other chemistries were indicated or inferred.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Eleven (44%) of the deaths involved batteries of unknown diameter or size. The smallest specified diameter applicable to at least one of the deaths was 18 mm. A diameter of specifically 20 mm was determined for 11 (44%) of the deaths. One incident indicated medical professionals describing an ingested battery as "about the size of a quarter." Although the size of that battery was not precisely indicated, the size of an actual U.S. quarter would be approximately 24.26 mm. A separate death specifically indicated a 25 mm battery. Combining the above observations, we can conclude that at least a majority or 13 (52%) reported deaths involved "Large"-size batteries (20 mm or larger diameter). Only one (the 18 mm battery) could be determined "Medium" size (10 mm to 19.9 mm diameter). None of the batteries could be determined "Small" size (under 10 mm diameter). However, it should be noted that the battery size determinations were often assisted by specific reference to exact battery type (*e.g.*, CR2025 or CR2032), which may be easier to determine for larger extracted battery sizes. It is possible battery size may be more likely to be indicated explicitly or implicitly among deaths involving larger size batteries. Conversely, smaller battery size related BCCB deaths could be less likely to be reported in such a way as to indicate the diameter or size classification of the involved battery. For these and other possible reasons, the 11 deaths related to BCCB of unknown diameter or size classification should *not* be assumed to have a comparable distribution as observed among the 14 deaths for which battery diameter or size classification could be determined.

For the majority (72%) of BCCB-III deaths there was not enough information to classify whether the victim found the batteries loose (*e.g.*, stored loosely), from packaging, or removed or liberated from a product. One fatality is inferred to involve a battery found loose by the victim prior to ingestion (if there was an initial product or packaging source, such was unknown).[2] Another is inferred (unwitnessed) to have involved batteries taken from packaging. Five (20%) deaths were concluded or inferred to have involved batteries removed or liberated from some product prior to ingestion.

Among the five fatalities classified to be from a "Product" battery source, two deaths were determined to involve batteries extracted from remote controls. One death occurred after a dog chewed a dog collar tracking tag in such a way as to liberate a 20 mm BCCB that fell to the floor undetected before ingestion by a child. In another death, a child was determined to have ingested a battery that came from a tracking device. One death is inferred to have involved a battery from an electronic toy.

IV. Nonfatal Incidents of BCCB Ingestion or Hazard of BCCB-III as Reported in Consumer Product Safety Risk Management System (CPSRMS)

Table 9 presents the nonfatal incidents by year from 2016-2021. Assessment of nonfatal reported incidents was limited to the more recent 6-year timeframe of 2016 (as opposed to the entire 11-year timeframe covered for the death and NEISS injury analyses) due to resource constraints. During this 2016-2021 timeframe, staff determined 43 reported incidents to indicate clearly BCCB ingestion and 44 incidents describing or exhibiting hazards possibly related to BCCB without any indication of an ingestion, impaction, or insertion having actually occurred in these instances. This assessment

[2] The incident narrative describes a button cell or coin battery swept up with other debris and left on the floor.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

excludes six ingestions, within the same period, of unknown type batteries due to uncertainty as to whether they actually involved BCCB. No reported incidents were found to specifically indicate nose or ear impaction or insertion.

Table 9. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Year of Incident, 2016-2021.

Year	Nonfatal Ingestion	Hazard Only	Total	Total Percent
2016	4	5	**9**	10%
2017	12	5	**17**	20%
2018	5	8	**13**	15%
2019	4	4	**8**	9%
2020	*5*	*7*	**12**	14%
2021	*13*	*15*	**28**	32%
Total	**43**	**44**	**87**	**100%**

Source: CPSRMS, CPSC.
Reporting of nonfatal incidents in 2020-2021 are considered more incomplete than prior years and are likely to increase with additional future reporting.

Among the nonfatal *ingestions* only, 51 percent indicated males, and 40 percent indicated females, with the remaining 9 percent not reporting the gender of the victim.

Table 10 presents the distribution of nonfatal BCCB-III by victim age at the time of ingestion. Unlike with the fatal incidents, some of the victims (12 percent of ingestions and 34 percent of the combined nonfatal total) are of unknown age. The majority of the reported victims or possible victims were *under* age 5 (57% of all 87 combined nonfatal incidents or 81% of the 43 nonfatal ingestions). Three children, age 5, were exposed to the hazard of ingestion of BCCB, but as reported by parent or grandparent, no ingestion occurred. These included BCCB falling on the floor after child played with balloon, an exposed battery in a candy dispensing toy, and another unrelated incident in which a child put a flashing toy ring into his mouth at a store, which a parent observed to have BCCB that were not screwed securely and presented the appearance of candy. Only two incidents (both BCCB ingestions) indicate older children. An 8-year-old ingested BCCB from a light-up fidget spinner that fell apart when dropped and liberated the battery. A 9-year-old also ingested BCCB from a lighted fidget spinner when he attempted to remove the BCCB by pulling on an access tab with his teeth. One adult BCCB ingestion involved a consumer with an intellectual or developmental disability (age 25) who removed three BCCB from a telescoping sword toy. One “hazard” incident was reported by a 72-year-old who reported receiving a cut when trying to open BCCB packaging. Although that injury does not itself involve BCCB-III or the hazard thereof, because the hazard may arise from packaging intended to mitigate BCCB-III incidents, it is still classified as a relevant “hazard” incident. This incident, however, was not representative of most of the 44 “hazard” reported incidents, which were generally concerned with children exposed to the risk of ingestion, even if such did not occur.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 10. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Victim Age, 2016-2021.

Victim Age	Nonfatal Ingestion	Hazard Only	Total	Total Percent
0-11 months	3	0	**3**	3%
12-23 months	18	1	**19**	22%
2 years	6	7	**13**	15%
3 years	6	3	**9**	10%
4 years	2	4	**6**	7%
5 years	0	3	**3**	3%
8 years	1	0	**1**	1%
9 years	1	0	**1**	1%
25 years	1	0	**1**	1%
72 years	0	1	**1**	1%
Unspecified*	5	25	**30**	34%
Total	**43**	**44**	**87**	**100%**

Source: CPSRMS, CPSC.
*Age may not necessarily be applicable for some Hazard incidents observing a broad risk of exposure to all children or others without necessarily a particular victim in mind.

Similar to the fatal incidents, battery chemistry was unknown for almost half of the nonfatal incidents. Alkaline and lithium chemistries are both indicated with comparable frequency. Among all nonfatal incidents, alkaline is reported to be involved more frequently (31% alkaline compared with 22% lithium). However, when we consider only the 43 nonfatal ingestion incidents, lithium is more frequently indicated (21% alkaline compared with 30% lithium). Within that same ingestion subset, only one other incident indicates another battery chemistry, in particular a "Silver Oxide" BCCB (from an unknown source). Zinc-air chemistry was only determined to be involved in two "Hazard" incidents, both concerning ingestion hazards due to the *packaging* of hearing aid batteries. Staff did not identify any actual ingestions to have involved zinc-air batteries among the reported incidents.

Battery size is unknown or undetermined for almost half (44%) of all nonfatal incidents. Batteries could be determined to have diameters under 10 mm, and therefore, be classified "Small" for only 1 BCCB-III and 6 hazard incidents. This "Small" battery diameter size category was the least frequently reported. In contrast "Medium" (with battery diameter sizes ranging between 10 mm and 19.9 mm), was the most frequently determined size category applicable to at least 31 percent of the nonfatal total or 33 percent of the ingestion subset. Among nonfatal incidents, "Large" size batteries (with diameters 20 mm or over) were the second most frequently indicated range--16 percent of all nonfatal incidents or 28 percent of the ingestion subset.

Table 11 presents the distribution of reported nonfatal incidents by battery source. No reported nonfatal *incidents* were determined or inferred to involve "Loose" batteries. Although no nonfatal ingestions were determined or inferred related to Packaging, 4 reports indicated relevant packaging hazards. This includes the one previously discussed concern of a 72-year-old injured while trying to open plastic packaging. The remaining three "Hazard" incidents related to "Packaging" involve concerns of *ingestion hazards*, for three very distinct reasons. One reported a product package the consumer purchased stating incorrectly that "Lithium batteries are harmless to the human body." The other two both involved hearing aid battery *packaging;* one is concerned that the adults need to use their mouth to open the packaging (therefore exposing *adults* to an ingestion hazard) whereas the other is concerned that multiple batteries fall out when the packaging is opened (therefore exposing any nearby young *children* to an ingestion hazard). Among reported incidents, the majority were determined or inferred to have batteries removed from or contained in some product (85% of all reported nonfatal incidents or 79% of the ingestion subset).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 11. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Battery Source Classification, 2016-2021.

Battery Source Classification	Nonfatal Ingestion	Hazard Only	Total	Total Percent
Loose	0	0	**0**	0%
Packaging	0	4	**4**	5%
Product	34	40	**74**	85%
Unknown Source	9	0	**9**	10%
Total	**43**	**44**	**87**	**100%**

Source: CPSRMS, CPSC.

Table 12 presents the product type indicated among the 74 nonfatal incidents determined to involve a battery or batteries from some product in Table 14. "Non-toy consumer product" includes BCCB ingestions associated with clothing and accessories, a cup, decorations, a pen, a teether, a headlamp, and a bicycle bell. Balloon lights, electronic books, guitar tuners, *pet* toys, and food accessories are not indicated among the actual ingestions but are indicated among some of the hazard incidents classified under "Consumer Product (excluding toys/games)."

Table 12. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Battery Source Product Type, 2016-2021.

Battery Source Classification	Nonfatal Ingestion	Hazard Only	Total	Total Percent
Consumer Product (excluding toys/games)	13	16	**29**	39%
Toys/games	20	23	**43**	58%
Medical Device	1	1	**2**	3%
Total	**34**	**40**	**74**	**100%**

Source: CPSRMS, CPSC.
Note: No nonfatal incidents were determined indicative of BCCB from a car remote or key fob so that category is omitted. Hazards related to *packaging of batteries* are not relevant to this table even if the type of batteries involved may be closely affiliated with a particular class of product. Consequently, hazard reports concerned with the *packaging of batteries* made primarily for use in hearing aids are not covered by this table, because the observed hazard was not related to the batteries coming out of a product.

V. Conclusion

In the 11 years spanning 2011-2021, at least 25 reported deaths occurred and an estimated 54,300 emergency room visits were associated with ingested or inserted button cell or coin batteries. Due to the exclusion of cases for which a BCCB-III determination was inconclusive, this may under estimate the actual number of BCCB-III cases treated in U.S. emergency departments during that period. On average, annually, two to three deaths occurred and an estimated 4,900 BCCB-III cases were treated in U.S. emergency rooms in that period. An estimated 16 percent of BCCB-III resulted in hospitalization (including transfer to another hospital). Young children appear to be at the greatest risk. Four years of age was the maximum age observed among all 25 decedents who had ingested BCCB. A majority of BCCB-III (an estimated 59%) involved children *under* 4 years of age, while an estimated 79 percent of BCCB-III treated in U.S. emergency rooms involved children *under* 7 years. However, victims were observed in all age groups, so the hazards do not appear exclusive to young children.

Among all *reported* incidents *(e.g., excluding NEISS),* batteries from out of a product or device were determined to comprise the majority of incidents (when combining reported nonfatal

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

incidents with reported deaths). Among reported ingestions of BCCB, whether fatal or nonfatal, at least a majority (57% or 39 out of 68) involved BCCB removed or liberated from some product battery source.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Appendix A: Additional Tabulations of Possible Interest

Tables A1-A3 provide additional support to the analysis of estimates based upon NEISS data.

Table A1. Estimated Number of BCCB-III by Victim Sex, 2011-2021.

Victim Sex	Estimate	Estimated Percent	N	CV
Female	22,900	42%	890	0.15
Male	31,400	58%	1,293	0.15
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.

Table A2. Estimated Number of BCCB-III by Battery Diameter Size Range, 2011-2021.

Battery Diameter Size Range	Estimate	Estimated Percent	N	CV
Small (under 10 mm diameter)	*	1%	13	*
Medium (10 mm - 19.9 mm diameter)	*	2%	20	*
Large (20 mm or larger diameter)	*	1%	17	*
Unknown Size (unknown diameter)	52,600	97%	2,133	0.15
Total	**54,300**	**100%**	**2,183**	0.15

Source: NEISS, CPSC.
*This estimate does not meet NEISS reporting criteria.

Table A3. Estimated Number of BCCB-III by Battery Chemistry, 2011-2021.

Battery Chemistry	Estimate	Estimated Percent	N	CV
Alkaline	*	2%	21	*
Lithium	1,600	3%	48	0.24
Zinc air	5,000	9%	156	0.17
Unknown Chemistry	46,900	86%	1,958	0.15
Total	**54,300**	**100%**	**2,183**	**0.15**

Source: NEISS, CPSC.
*This estimate does not meet NEISS reporting criteria.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

VI. Appendix (continued, deaths)

Tables A4-A7 provide additional support to analysis discussed regarding CPSRMS reported deaths.

Table A4. Reported Number of BCCB-III Deaths by Victim Sex, 2011-2021

Victim Sex	Deaths	Percent
Female	**16**	64%
Male	**9**	36%
Total	**25**	**100%**

Source: CPSRMS, CPSC.

Table A5. Reported Number of BCCB-III Deaths by Battery Diameter or Size, 2011-2021.

Battery Diameter	Deaths	Percent
18 mm	1	4%
20 mm	11	44%
25 mm or "about the size of a quarter"	2	8%
Unknown Diameter	11	44%
Total	**25**	**100%**

Source: CPSRMS, CPSC.

Table A6. Reported Number of BCCB-III Deaths by Battery Chemistry, 2011-2021.

Battery Chemistry	Deaths	Percent
Lithium	13	52%
Unknown Chemistry	12	48%
Total	**25**	**100%**

Source: CPSRMS, CPSC.

Table A7. Reported Number of BCCB-III Deaths by Battery Source Classification, 2011-2021.

Battery Source Classification	Deaths	Percent
Loose	1	4%
Packaging	1	4%
Product	5	20%
Unknown Source	18	72%
Total	**25**	**100%**

Source: CPSRMS, CPSC.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

VI. Appendix (continued, reported nonfatal incidents)

Tables A8-A10 provide additional support to analysis discussed regarding CPSRMS reported nonfatal incidents.

Table A8. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Victim Sex, 2016-2021.

Victim Sex	Nonfatal Ingestion	Hazard Only	Total	Total Percent
Female	17	9	**26**	30%
Male	22	11	**33**	38%
Unspecified**	4	24	**28**	32%
Total	**43**	**44**	**87**	**100%**

Source: CPSRMS, CPSC.
**Sex may not necessarily be applicable for some Hazard incidents suggesting only generalized risks (such as to children in general).

Table A9. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Battery Diameter Size Range, 2016-2021.

Battery Diameter Size Range	Nonfatal Ingestion	Hazard Only	Total	Total Percent
Small (under 10 mm diameter)	1	6	**7**	8%
Medium (10 mm – 19.9 mm diameter)	14	13	**27**	31%
Large (20 mm or larger diameter)	12	3	**15**	17%
Unknown Diameter	16	22	**38**	44%
Total	**43**	**44**	**87**	**100%**

Source: CPSRMS, CPSC.

Table A10. Reported Number of Nonfatal Incidents of BCCB Ingestion or Hazard by Battery Chemistry, 2016-2021.

Battery Chemistry	Nonfatal Ingestion	Hazard Only	Total	Total Percent
Alkaline	9	18	**27**	31%
Lithium	13	6	**19**	22%
Silver Oxide	1	0	**1**	1%
Zinc Air	0	2	**2**	2%
Unknown Chemistry	20	18	**38**	44%
Total	**43**	**44**	**87**	**100%**

Source: CPSRMS, CPSC.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

TAB B

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Daniel Taxier, Project Manager, Battery Regulation **DATE:** January 11, 2023

THROUGH: Mary Kelleher, AED, HS
Stefanie Marques Ph.D. Division Director, HSPP

FROM: Cheryl Scorpio, Ph.D. Pharmacologist, HSPP

SUBJECT: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Toxicity of Batteries

I. Introduction

This memorandum from the Directorate for Health Sciences (HS) supports staff's draft proposed rule (NPR) to establish a safety standard and notification requirements for button cell or coin batteries and consumer products containing such batteries. The draft NPR is required by Reese's Law, Public Law No. 117-171. Reese's Law defines a "button cell or coin battery" as a single cell battery having a diameter greater than its height. This memorandum discusses the injury data from button/coin batteries in the medical literature, CPSC data, and the National Capital Poison Center or poison.org.

As explained below, research demonstrates that button cell or coin batteries cause serious injury and death when ingested due to impaction (or becoming wedged) in the esophagus, including esophageal burns and perforations, vocal cord paralysis, and fistulas created by burning through the esophagus and surrounding tissues creating a connection between the esophagus and the trachea or blood vessels. Serious injury can also result from button cell or coin batteries inserted into the nose and ear, including septal perforation, decreased structural support of the nose, and hearing loss.

II. Medical Literature

A. Button cell or coin batteries

1. Esophagus

Most ingested button cell or coin batteries pass spontaneously without any complications, especially beyond the stomach; complications usually occur from button cell or coin batteries that are stuck in the esophagus (Sigalet et al., 1988). Researchers have determined various mechanisms of injury to explain the tissue damage created by button cell or coin batteries stuck in the esophagus. Researchers have found that the primary way injury occurs with a button

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

battery impacted in the esophagus is by the transmission of electric current eliciting the production of sodium hydroxide (NaOH) and hydrochloric acid (HCl) in tissues adjacent to the cathode and anode terminals, respectively (Hamilton 2009). After only a few hours of contact with a button battery, tissue pH on either side of the battery increases, causing substantial tissue injury. The erosive and perforating effects of esophageal impaction may also continue even after removing the battery (Gao et al., 2020). Another mechanism of injury determined by researchers involves an electrical burn created by electric current passing between the anode and the cathode.

A mechanism of injury associated with alkaline batteries is the leakage of the battery electrolyte solution due to an imperfectly sealed battery. The large concentration of potassium hydroxide (KOH) in the electrolyte solution is particularly corrosive to human tissue. Alkalis penetrate deeply into the tissue layers, and this results in extensive tissue damage. Another mechanism of injury common to any foreign body impaction is pressure necrosis, which creates ischemic, blackened areas of tissue damage (Alvi et al., 1997). Impaction of a button cell or coin battery in the esophagus leads to a burn of the esophagus in as little as 2 hours. A burn in the esophagus may cause a perforation of the esophagus or an esophageal stricture, or a narrowing of the esophagus. Perforation or stricture of the esophagus can make feeding difficult and require a feeding tube in the stomach or dilations of the esophagus to expand the stricture to allow normal swallowing.

A button battery that burns through the esophagus can also burn through nearby tissues, leading to communication between the esophagus and the other surrounding tissues, creating what is called a fistula. Common to the esophageal area are fistulas created with the trachea (tracheoesophageal fistulas or TEF) and with the aorta (aortoesophageal fistulas or AEF). Both of these fistulas are life threatening injuries because they can lead to an open artery and exsanguination or bleeding out of the patient. Researchers report that esophageal burns and fistulas sometimes required multiple surgeries to repair (Slamon et al., 2008). The treatment of these injuries could take weeks in the hospital (Liao et al., 2015; Kimball et al., 2010).

Diagnosing an ingested button cell or coin battery requires an x-ray, because physical examination after ingesting a button cell or coin battery presents with non-specific complaints. Children who have ingested button cell or coin batteries can present to medical providers in respiratory distress. Sometimes the symptoms of button cell or coin battery ingestion are mistaken for other ailments, such as an asthma attack (Takahashi et al., 2009). The child may have unexplained fever, or the physical examination can also be entirely normal, complicating the diagnosis (Cruz and Patel 2012).

Unlike lithium and alkaline button cell or coin batteries, zinc-air hearing aid batteries use a technology that needs air in order for the current to flow or voltage to be present on the terminals. If they are swallowed or inserted into the ear or nose, the wet mucosa generally stops this flow of air and also the voltage, so there are generally no chemical or hydroxide burns. Secondly, the hearing aid batteries are sealed with a hydrophobic material, so there is little chance for electrolyte leakage. And lastly, some hearing aid batteries are so small as to not cause pressure against the mucosa therefore there will be little or no pressure necrosis injury.

In the literature, as summarized in Appendix A, staff found 167 incidents of impacted button cell or coin batteries in the esophagus, of these, 126 incidents occurred in children (age range from 16 days to 9 years). In 11 cases the product was listed that the battery came from: fidget spinner, handheld game, garage door opener, hair dryer, pedometer, personal organizer, toy (3) and watch. Esophageal damage such as burns, perforations, and strictures occurred in 71 cases. Vocal cord paralysis leading to the child not being able to speak occurred in 5 cases. TEFs occurred in 59 cases and AEFs occurred in 19 cases, including 11 cases where the child

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

died. In 21 cases, the impaction of button cell or coin batteries in the esophagus led to death of the child. The range of time the battery was impacted was as little as 2 hours, resulting in vocal cord paralysis in two cases. After 4 weeks, the initial injuries resulted in a TEF and esophageal perforation with a stricture (Nagao et. al. 2007, Vaishnav and Spitz 1989, Kimball et.al. 2010).

In 2010, Toby Litovitz (Litovitz et. al. 2010a) performed a review of 65,246 battery ingestions between 1985 and 2009. The study reported a 6.7-fold increase in major outcomes occurring between the first and final 3 years of the reviewed period without an increase in number of ingestions (See Figure 1). The study found this increase in major outcomes is consistent with increasing number of lithium battery ingestion incidents (up 1.3 to 24 percent), and with the increasing number of ingestion incidents of batteries 20-25 mm in diameter (up 1 to 18 percent). Increases in major outcomes reflects increased use of button cell or coin batteries in home electronics. The report identified that 93.9 percent of major or fatal outcomes involved button cell or coin batteries greater than or equal to 20 mm in diameter. Staff concluded that these larger diameter batteries were likely lithium coin batteries.

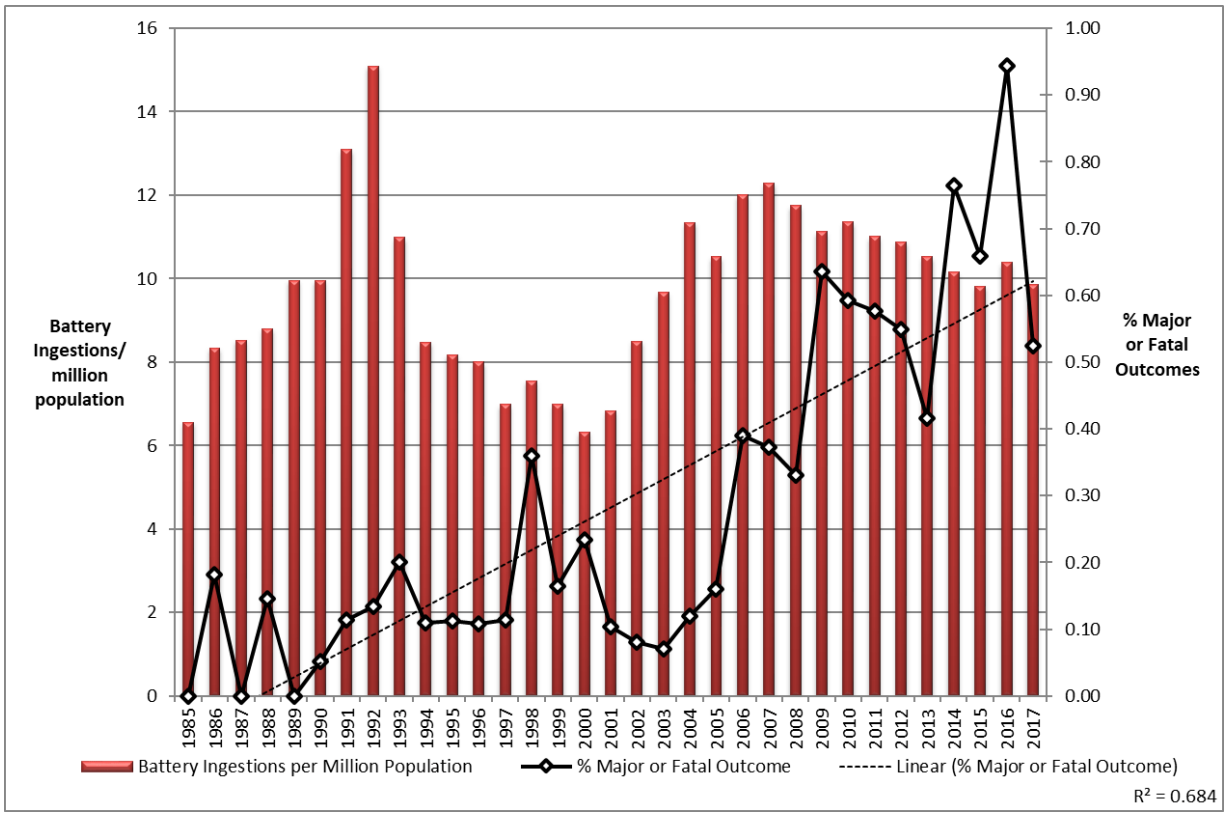


Figure 1: National Poison Data System (NPDS) and National Battery Ingestion Hotline (NBIH) Button Battery Ingestions Frequency and Severity for Major and Fatal Outcomes 1985-2017 (originally published in Litovitz et. al 2010a)

Dawe et. al. 2013 made several points about lithium button cell or coin battery ingestions. Lithium button cell or coin battery ingestion has escalated with their increased use in household products. Also, lithium batteries generate a relatively high voltage, causing rapid local injury, even in a partially discharged state. Therefore, even used or partially discharged batteries can cause life-threatening injuries. The window of opportunity for injury-free removal of an esophageal battery is less than 2 hours (Gao et. al. 2020).

Also, in 2010, Toby Litovitz (Litovitz *et. al*. 2010b) reported on over 8,000 ingestion cases reported to the National Battery Ingestion Hotline over a period of 18 years, the source of the

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

button cell or coin batteries was from a product in 61.8% of button cell or coin battery incidents involving a child under the age of 6. The batteries ingested were loose 29.8 percent of the time, and directly from the packaging 8.2 percent of the time. Remote controls were the highest source of button cell or coin battery incidents involving products, occurring in 37.3 percent of ingestions (Litovitz et al., 2010).

2. Nose

Like ingestion, impaction of button cell or coin batteries in the nose should be removed immediately. Button cell or coin batteries impacted in the nose can lead to severe damage to the endonasal mucous membranes. Nasal insertion can lead to necrosis (tissue death) of the nasal septum cartilage and to nasal septum (the tissue that separated the nasals) perforation (Bachmann 2009). The damage to surrounding structures can occur within minutes and most of the children generally experience long-term effects, such as saddle nose which is a flattening of the nose due to lack of the nasal septum. This requires reconstructive surgery to correct. Development of complications depends on the duration of impact, type of button cell or coin battery (and in which part of the nasal cavity the battery gets lodged. Septum perforation complications can result in lifelong consequences such as facial deformity, and it is advisable to keep these patients on regular follow-up (Bakshi et al., 2016). Dislodgement of a nasal button cell or coin battery can lead to ingestion and the dangers of ingestion described above (Alvi et al., 1997). Animal studies conducted show that when a button cell or coin battery is inserted into the nasal cavity of anesthetized rabbits, full thickness necrosis of nasal septal cartilage occurs in as short as 15 minutes (Chua and Tan 2005).

Appendix B shows 56 cases of nasal insertion with button cell or coin batteries, from 1985 to 2015, that staff found in the literature. The most severe injury is septal perforation, which is caused by the battery burning a hole in the tissue that separates the left and right nostril. Sometimes the battery remained lodged in the nose for long periods of time, sometimes for months leading to extensive damage to the nose (Fosarelli et al., 1988). Sometimes an impaction occurred for only a couple of hours and led to septal perforation of the nose (Liao et al., 2015).

3. Ear

Injury associated with button cell or coin batteries as foreign bodies in the ear occurs when the button cell or coin battery becomes impacted. In the external auditory canal, a button cell or coin battery may cause tympanic membrane perforation or destruction, marked erosion of the ear canal with exposed bone, hearing impairment, facial nerve paralysis, and destruction of the small bones in the middle ear (Bhisitkul and Dunham 1992).

Appendix C shows 10 cases from the medical literature of insertion of button cell or coin batteries into the ear and the damage that occurred. The most severe damage that occurred after insertion of a button cell or coin battery in the ear for 3 weeks resulted in tympanic membrane perforation with erosion of the skin and bone (Premachandra and McRae 1990).

B. Cylindrical Batteries

The most important factor contributing to morbidity and mortality following cylindrical battery ingestion is corrosion of the battery with leakage of contents into the gastrointestinal tract (Levine et al., 1984). Several reports in the literature have described esophageal erosion, perforation, and gastrointestinal hemorrhage. Leakage of the battery contents can result in metal toxicity and hypersensitivity as well as liquefaction necrosis (Dunphy et al., 2015). The ingestion of a cylindrical-type battery that passes into the stomach is not an indication for acute extraction as

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

long as it is not causing symptoms. A follow-up radiograph after a 4-day interval is considered to be sufficient (Cyrany et al., 2014)

Appendix D shows 15 cases of ingestion of cylindrical batteries. A rare case occurred when a AAA battery impacted in the esophagus and caused two fistulas, esophagus to aorta and esophagus to pulmonary artery. The child died from the injuries (Poison.org). Another case involved a child who sucked on a cylindrical battery leading to esophageal erosions from the battery acid (Untersweg et al., 1996). Moreover, swallowing cylindrical batteries can give an artificial abnormal EKG[33] reading but reverts to normal after the batteries are removed (Chang et. al. 2011). Another incident involving cylindrical batteries in the stomach caused deep ulcers in the stomach wall. The ulcers were treated successfully with an over-the-counter acid reducer with no lasting effect (Kim et al., 2006). Two cases involving cylindrical batteries required surgery but had no long-lasting effects (Ribakovs and Uzoigwe 2011; Pararoupa and Bruns-Toepler 2017).

III. National Capital Poison Center or Poison.org

A. Fatal Cases

The National Capital Poison Center, or Poison.org, a private company, has kept track of button cell or coin battery ingestions that have occurred from 1977 to present. References for these incidents come from the news, medical literature, or from the National Battery Ingestion Hotline.[34] According to the Fatal Button Ingestions, a table online at poison.org, 69 deaths occurred due to button cell or coin battery ingestion from 1977 to the present (June 2022).[35] Of these cases, 44 were due to lithium batteries, two to manganese dioxide chemistry, and one alkaline button battery. One death was due to a AAA battery impacting in the esophagus. The sources of these batteries were a movie camera, camera flash, watch (2), camera (2), remote control (8), garage door opener, electric candle, toy (4), remote car alarm, torch, tea light (spare battery), 3D TV glasses, key fob, and loose (battery fed to child by older brother). The button cell or coin battery size ranged from 10 mm to 25 mm. Seven deaths involved reported symptoms after a button cell or coin battery ingestion that appeared as a cold or upper respiratory infection, which led to misdiagnosis as an infection or croup, or just missed altogether. Misdiagnosis of ingestion increases the time to battery removal and increases the chances of a fatal outcome. In 13 deaths, the first symptom was vomiting blood or blood coming from the nose, followed by death. Two deaths were caused by sepsis[36] after removal of the battery. Most of the deaths, 50, were due to the battery burning through the esophagus and creating a fistula, or connection with adjoining tissues, such as the trachea or arteries.

B. Severe Cases

In the Table Nonfatal Button Ingestions with Severe Esophageal or Airway Injury from Poison.org, there were 267 cases with severe injury from 1982 to June 2022.[37] Nine injuries were from manganese dioxide batteries, two were from mercuric oxide, two were from alkaline,

[33] An electrocardiogram (EKG) records the electrical signals in the heart.
[34] Poison Control Center (batteryingestionhotline.com)
[35] Fatal Cases (poison.org)
[36] An infection of the blood stream resulting in a cluster of symptoms such as drop in a blood pressure, increase in heart rate and fever.
[37] Severe Cases (poison.org)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

one was from silver oxide, and 182 were from lithium batteries. Sources of the batteries were camera (7), watch (7), portable CD player, hair dryer, handheld computer game (2), calculator (5), toy (13), sole of shoe (2), ab belt (exerciser), personal digital organizer, talking book, digital ear thermometer (2), remote control (26), flashlight (2), bicycle computer, computer, scale (7), singing card, battery package (3), key fob (7), loose, guitar tuner, night light, baby monitor, lighted tweezers, book light, video camera, keychain, 3D TV glasses, portable speaker, lighted ring, and glucometer. Most of the batteries were 20 mm in diameter, and the battery size range was from 11.6 mm to 24.6 mm. In 132 cases, impaction of the button battery in the esophagus led to damage due to burning of the esophagus. In 22 cases, damage in the esophagus also damaged the vocal cords and led to bilateral vocal cord paralysis. Also, in 10 cases, an esophageal stricture, or narrowing of the esophagus, formed due to the esophageal damage and the time needed to regain normal feeding, in some cases between 2-5 years. Like the fatalities, much of the damage led to burning through the esophagus into adjoining tissues in 110 cases. Surgery to repair this damage was required in 80 cases. In one case, a child required esophageal reconstruction, and the child didn't regain normal feeding for 7 years.

IV. CPSC Data

A. Esophagus

In the CPSC data, injuries occurred with a mechanism of injury similar to what is seen in the medical literature and from the National Capital Poison Center. The following are samples of cases where the button cell or coin battery impacted in the esophagus and had to be removed. There were severe consequences in some cases. Examples of these cases are in Appendix E.

There were 25 fatalities reported in the CPSC data (Tab A – EPI memo). The cases shadow the mechanism of death seen in the medical literature and from the National Capital Poison Center. Examples are given in Appendix F that show impaction in the esophagus, damage to the esophagus, and possible fistula formation leading to death.

B. Nose and Ear

CPSC data mirrored the medical literature in showing that children insert button cell or coin batteries into the nose and ear. There were an estimated 6,300 cases of insertion into the ear or nose from NEISS data (Tab A – EPI memo). Some examples are given in Appendix G.

VI. Summary

The medical literature, CPSC data, and data from the National Capital Poison Center show that button cell or coin batteries cause serious injury and death when ingested due to impaction in the esophagus. Injuries that occur include esophageal burns and perforations, vocal cord paralysis and fistulas created by burning through the esophagus and surrounding tissues creating a connection between the esophagus and the trachea or blood vessels. Toby Litovitz found that a majority (61.8%) of button cell or coin battery ingestions over a period of 18 years came from children removing batteries from products (Litovitz et al., 2010b).

CPSC data and the medical literature also support serious injury resulting from button cell or coin batteries that are inserted into the nose and ear. Injuries include septal perforation, decreased structural support of the nose, and hearing loss.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Staff concluded that other batteries, as defined in Section B, where the diameter is less than the height, as defined, such as AAA cylindrical batteries, do not pose a significant ingestion hazard. Staff is aware that consumers have ingested cylindrical batteries; however, the medical literature shows that injury or death due to ingestion of a cylindrical battery is rare.

References

Abdulkareem I, Sabir OM, Elamin A. Button battery induced traumatic tracheoesophageal fistula. Case report and review of literature. Sudan J Paediatr 2011:11(2):43-49.

Alkan m, Buyukyavuz L, Dogru D, Yalcin E, Karnak L. Tracheoesophageal Fistula Due to Disc-Battery Ingestion. Eur J Pediatr Surg. 2004; 14:274-278.

Alletag MJ, Jacobson D, Santucci K, Riera A. Nasal Disc Battery Removal, A novel technique using a magnetic device. Pediatric Emergency Care & Volume 30, Number 7, July 2014.

Alreheili KM, Almutairi M, Alsaadi A, Ahmed G, Ahejaili A, AlKhatrawi T. A 2-year-old boy who developed an aortoesophageal fistula after swallowing a button battery, managed using a novel procedure with vascular plug device as a bridge to definitive surgical repair. Am J Case Rep, 2021; 22:e931013.

Alvi A, Bereliani A, Zahtz GN. Miniature disc battery in the nose: a dangerous foreign body. Clin Pediatr (Phila). 1997 Jul;36(7):427-9.

Bachmann J, Niewels A, Henschke F, Folz B. A dangerous nasal foreign body: the button battery. Laryngo-Rhino-Otol 2009; 88: 116–118.

Baeza Herrera C, Cortes Garcia R, Velasco Soria L, Velazquez Pino H. Aorto-esophageal fistula due to ingestion of button battery. Cir Pediatr 2010; 23: 126-129.

Bakshi SS, Coumare VN, Priya M, Kumar S. Long-term complications of button batteries in the nose. The Journal of Emergency Medicine, Vol. 50, No. 3, pp. 485–487, 2016.

Bakshi SS. Button battery ingestion. Balkan Med J 2018;35:212-3.

Bakshi SS. A button battery in the nose. Internal and Emergency Medicine (2019) 14:185–186.

Banerjee R, Rao GV, Sriram PVJ, Pavan Reddy KS, Nageshwar Reddy D. Button battery ingestion. Indian J Pedlatr 2005; 72 (2):173-174.

Barabino AV, Gandullia P, Vignola S, Arrigo S, Zannini L, DiPietro P. Lithium battery lodged in the oesophagus: A report of three paediatric cases. Digestive and Liver Disease 47 (2015) 984–986.

Barros AAB, Barros EA. Mercury battery ingestion. BRITISH MEDICAL JOURNAL 5 May 1979 pg 1218.

Bartkevics M, Stankovic Z, Schibli S, Fluri S, Berger S, Schmidli, Kadner A. A near miss and slavage management of aortoesophageal fistula secondary to cell battery ingestion. 2019. https:/doi.org/10.1177/2150135119880549.

Bass DH and Millar AJR. Mercury absorption following button battery ingestion. Journal of Pedatric Surgery, Vol 27, No 12 (December), 1992: pp 1541.1542.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Bekhof J, Nortruis O, Scheenstra R, Dikkers F, deLangen R, de Weerd W. Babies and batteries. Lancet 2004; 364: 708.

Bekhof J, Norbruin OF, Scheenstra R, de Weerd W. Active management of children after ingestion of a button battery. NEDERLANDS TIJDSCHRIFT VOOR GENEESKUNDE. 2005 Jun 25;149(26):1429-33.

Bhisitkul DM and Dunham MD. An unsuspected alkaline battery foreign body presenting as malignant otitis external. Pediatric Emergency Care. Vol 8 No 3. 141-142. 1992.

Blatnik D, Toohill RJ, Lehman RH. Fatal complication from an alkaline battery foreign body in the esophagus. Ann Otol 86:1977. 611-615.

Brandt LJ. Corrosive esophageal injury by a button battery. GASTROINTESTINAL ENDOSCOPY Volume 78, No. 4: 2013: 654-655.

Brown CRS. Intranasal button battery causing septal perforation: a case report. The Journal of Laryngology and Otology. July 1994, Vol. 108, pp. 589-590.

Bum Rim C, Ho Song K. Impaction of coin battery in the appendix. Korean J Gastroenterol 2019;74:51-56).

Capo JM and Lucente FE. Alkaline battery foreign bodies of the ear and nose. Arch Otolaryngol Head Neck Srg. Vol 112. May 1986. 562-563.

Chang H, Hu SC, Tsai MJ. Cylindrical battery ingestion with electrocardiogram mimicking ST-Segment elevation myocardial infarction. Journal of the American College of Cardiology Vol. 59, No. 25, 2012.

Cheng SY and Shih CP. Button battery insertion in nose manifested as infraorbital cellulitis. ENT-Ear, Nose & Throat Journal September 2018. 274.

Chessman R, et al. BMJ Case Rep 2017. doi:10.1136/bcr-2017-219331.

Chian MC and Chen YS. Tracheoesophageal fistula secondary to disc battery ingestion. American Journal of Otolaryngology, Vol 21, No 5 (September-October), 2000: pp 333-336

Chua DYK and Tan HKK. Repair of nasal septal perforations using auricular conchal cartilage graft in children: Report on three cases and literature review. International Journal of Pediatric Otorhinolaryngology (2006) 70, 1219—1224.

Clute J, Frey T, Reed J. Button versus battery: foreign body ingestions in pediatrics. Pediatrics in Review. Vol. 40 No. 11 NOVEMBER 2019 e38-41. 2019.

(CPSC, 1992). CPSC (1992) Final Report Study of Aversive Agents.

Cyrany Jiri et al. Ingestion of battery by a 1-year-old baby. Endoscopy 2014; 46: E543–E544.

Dane et al. A truly emergent problem: button battery in the nose. ACADEMIC EMERGENCY MEDICINE • February 2000, Volume 7, Number 2. 204-206.

Dawe N, Puvanendran M, flood L. Unwitnessed lithium ion disc battery ingestion: case report and review of best practice management of an increasing clinical concern. The Journal of Laryngology & Otology (2013), 127, 84–87.

Dunphy L, Maatouk M, Raja M, O'Hara R. Ingested cylindrical batteries in an incarcerated male: a caustic tale! BMJ Case Rep 2015. doi:10.1136/bcr-2014-208922.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Eliason MJ, Melzer JM, Winters JR, Gallagher TQ. Identifying predictive factors for long-term complications following button battery impactions: a case series and literature review. International Journal of Pediatric Otorhinolaryngology 87 (2016) 198e202.

Eshaghi H, Norouzi S, Heidari-Bateni G, Mamishi. Spondylodiscitis: A rare complication of button battery ingestion in a 10-month-old boy. Pediatric Emergency Care & Volume 29, Number 3, March 2013. 368-370.

Eynon-Lewis NJ, Spraggs PDR. Button Batteries. The Journal of Laryngology and Otology May 1995, Vol. 109, pp. 472.

Fernando P. Perforation of nasal septum due to button battery lodging in nose. British Medical Journal Volume 294 21 March 1987. 742-743.

Fosarelli P, Feigelman S, Pearson E, Calimano-Diaz A. An unusual intranasal foreign body. Pediatric Emergency Care. Vol 4 No 2. 1988.117-118.

Fundakowski CE, Moon S, Torres L. The snare technique: a novel atraumatic method for the removal of difficult nasal foreign bodies. The Journal of Emergency Medicine, Vol. 44, No. 1, pp. 104–106, 2013.

Gao Y, Wang J, Ma J, Gao Y, Zhang T, Lei P, Xiong X. Management of button batteries in the upper gastrointestinal tract of children. Medicine (2020) 99:42.

Garcia-Fernandez FJ, Leon-Montanes RL, Bozada-Garcia JM. Caustic esophageal injury by impaction of cell batteries. Rev Esp Enferm Dig 2016, Vol. 108, N.º 12, pp. 811-812.

Gibbs H, Sethia R, McConnell PI, Aldrink JH, Sinoka T, Williams K, Jatana KR. Survival of toddler with aortoesophageal fistula after button battery ingestion. Case Reports in Otolaryngology Volume 2021, Article ID 5557054, 7 pages https://doi.org/10.1155/2021/5557054

Gohil R, Culshaw J, Jackson P, Singh S. Accidental button battery ingestion presenting as croup. The Journal of Laryngology & Otology (2014), 128, 292–295.

Gomes CC, Sakano E, Lucchezi MC, Porto PRC. Button battery as a foreign body in the nasal cavities. Special aspects. Rhinology. 32, 98-100, 1994.

Gordon AC, Gough MH. Oesophageal perforation after button battery ingestion. Annals of The Royal College of Surgeons of England (1993) vol. 75, 362-364.

Goussard P, Morrison J, Nel E, Mfingwana L, Andronikou S, Blokland R, Mukhtar, Loock JW, de Bruyn GHM. Bilateral vocal fold palsy due to ingested battery in the postcricoid area/proximal esophagus. 2021. DOI: 10.1002/ppul.25366.

Granata A, Gandolfo C, Aciemo C, Plazza M, Burgio G, Traina M. Button battery removed from the stomach resulting in a missed aortoesophageal fistula – a multidisciplinary approach to rescuing a very young patient: a case report. 2018. https://doi.org/10.1186/s13256-018-1818-5

Griffin K, Brent R, Vollenhoven B, Swanson AE. Vaginal burn form alkaline battery in an 8-year-old. J Pediatr Adolesc Gynecol 28 (2015) e99-e100.

Gruner Melissa et al. ESD closure of a tracheoesophageal fistula in a child… Endoscopy 2017; 49: E212–E214.

Guinet T, Gaulier JM, Moesch C, Bagur J, Malicier D, Maujean G. Sudden death following accidental ingestion of a button battery by a 17-month-old child: a case study. Int J Legal Med (2016) 130:1291–1297.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Hamilton JM, Schraff SA, Notrica DM. Severe injuries from coin cell battery ingestions: 2 case reports. Journal of Pediatric Surgery (2009) 44, 644–647.

Hammad TA, Alastal Y, Bawany MZ, Nawras A, Hammad M, Alaradi O. Cylindrical batteries in the stomach: should we wait 48 hours for removal? ACG Case Reports Journal. Volume 3. Issue 1. 2015. 3-4.

Hammami MB, Alkaade S, Piraka C, Taylor JR. Endoscopic retrieval vs observation in cylindrical battery ingestion. Ochsner Journal 19:157–165, 2019.

Hammond P, Jaffray B, Hamilton L. Tracheoesophageal fistula secondary to disk battery ingestion: a case report of gastric interposition and tracheal patch. Journal of Pediatric Surgery (2007) 42, E39–E41.

Harjai MM, Ramalingam WVBS, Chitkara G, Kattyar A. Corrosive trachea-esophageal fistula following button battery ingestion. Indian Pediatrica. Vol 49 (2012) 145-146.

Hofmeyr R, Bester K, Willms A, Hewitson J, Byhahn C. Tracheoesophageal fistula following button battery ingestion in an infant. Airway management considerations. Anaesthesist 2019 68:777–779.

Hong D, Chu YF, Tong KM, Hsiao CJ. Button batteries as foreign bodies in the nasal cavities. International Journal of Pediatric Otorhinolaryngology, 14 (1987) 15-19.

Houas Y, Sahli S, Fitouri F, Ben Salah M, Hamazaoui M. Spontaneous resolution of a tracheoesophageal fistula caused by button battery ingestion. JAMA Otolaryngoloy-Head & Neck Surgery. (2016) Vol 142 No 6. 609-610.

Imamoglu M, Cay A, Kosucu P, Ahmetoglu A, Sariham H. Acquired trachea-esophageal fistulas caused by button battery lodged in esophagus. Pediatr Surg Int (2004) 20: 292–294.

Ing RJ, Kramer RE, Darst J, Mayes LM, Twite MD. Button battery ingestion in children: a role for angiography? Can J Anesth/J Can Anesth (2017) 64:321–322.

Janarthanan V, Moorthi K, Shaha KK. Fatality due to button battery lodgment in the upper digestive tract of a neonate. An unusual presentation. Am J Forensic Med Pathol 2019. 1-4.

Johannsen LK, Grundtvig N. A button battery in the ear as cause of acute hearing loss and confusion in an elderly patient. Ugeskr Laeger. 2013 Dec 2;175(49):3024-5.

Janik JS, Burrington JD, Wayne ER, Foley LC. Alkaline battery ingestion. Colorado Medicine. December 1982. 404-405.

Jarugula R and Dorofaeff T. Oesophageal button battery injuries: Think again. Emergency Medicine Australasia (2011) 23, 220–223.

Kalyanshettar SS, Patil SV, Upadhye G. Button battery ingestion-case report and review. Journal of Clinical and Diagnostic Research. 2014 Sep, Vol-8(9): PD01-PD02.

Karnecki K, Piesniak D, Jankowski Z, Gos T, Kaliszan M. Fatal haemorrhage from an aortoesophageal fistula secondary to button battery ingestion in a 15-month-old child. Case report and literature review. Legal Medicine. 45 (2020)101707. 1-4.

Khalaf RT, Gurevich Y, Marwan AI, Miller AL, Kramer RE, Sahn B. Button battery powered fidget spinners: A potentially deadly new ingestion hazard for children. JPGN 2018;66: 595–597.

Kim SH, Keum B, Chun HJ. Drooling, irritability, and refusal to eat in a 22-month-old child. http://dx.doi.org/10.1053/j.gastro.2015.04.046.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Kim JK, Kaltenbach TR, Sirinian E, Marcus SN. Endoscopic removal of two leaking alkaline batteries. 2006. Endoscopic Retrieval vs Observation in Cylindrical Battery Ingestion - PMC (nih.gov).

Kimball SJ, Park AH, Rollins II MD, Grimmer JF, Muntz H. A review of esophageal disc battery ingestions and a protocol for management. Arch Otolaryngology Head Neck Surg/Vol 136 (NO. 9), SEP 2010. 866-871.

LaFrance DR, Traylor JG, Jin L. Aspiration pneumonia and esophageotracheal fistula secondary to button battery ingestion. Forensic Sci Med Pathol (2011) 7:283–286.

Landry GL and Edmonson MB. Attractive method for battery removal. JAMA. Dec 26, 1986. Vol 256 No 24. 3351.

Lavon O, Lurie Y, Abbou B, Bishara B, Israelit SH, Bentur Y. Surgical removal of cylindrical batteries 6 years after ingestion. IMAJ 2008;10:799–801.

Levine MJ, Jacob H, Rubin M. Battery ingestions: a potential form of alkaline injury to the gastrointestinal tract. Annals of Emergency Medicine 13:2 February 143-145. 1984.

Liao AY and McDonald D. Oesophageal complication from button battery ingestion in an infant. 2011. doi:10.1111/j.1440-1754.2012.02511.x.

Liao W, Wen G, Zhang X. Button battery intake as foreign body in Chinese children. Review of case reports and the literature. Pediatr Emer Care 2015;31: 412-415.

Lin VYW, Daniel SJ, Papsin BC. Button batteries in the ear, nose and upper aerodigestive tract. International Journal of Pediatric Otorhinolaryngology (2004) 68, 473—479.

Litovitz T, Whitaker N, Clark L, White N, Marsolek M. Emerging battery-ingestion hazard: clinical implications. 2010a. DOI:10.1542/peds.2009-3037.

Litovitz T, Whitaker, N, Clark L. Preventing battery ingestions: An analysis of 8648 cases. Pediatrics 2010b; 125:1178-1183.

Loh WS, Leong J-L, Tan HKK. Hazardous foreign bodies: complications and management of button batteries in nose. Ann Otol Rhinol Laryngol. 2003 Apr;112(4):379-83.

Loots DP Toit-Prinsloo LD Saayman G. Disk battery ingestion: a rear cause of perforation of the brachiocephalic artery. Forensic Sci Med Pathol (2015) 11:614–617.

Mahajan S, Jaswal V, Thingnam SKS, Dora N. Successful surgical management of an aorto-oesophageal fistula caused by a button battery ingestion. European Journal of Cardio-Thoracic Surgery 55 (2019) 790–791.

Malliwal RS, Bhattacharya S. Durable cell: a case of multiple AA battery ingestion as a mode of deliberate self-harm. J R Soc Med Sh Rep 2013; 4:28. DOI 10.1177/2042533313476681.

Martines Criado Y, Lopez AM, Valladares JC, De Agustin Asensio JC. Impactación esofágica de pilas de botón en la infancia.¡Cómo evitar la tragedia! Cir Pediatr 2013; 26: 142-145.

Maves MD, Carithers JS, Birck HG. Esophageal burns secondary to disc battery ingestion. Ann Otol Rhinol Laryngol 93:1984.

McCombe AW, Ramadan MF. Nasal Button Battery. Otolaryngol Head Neck Surg. 1992 Mar;106(3):317.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

McLarty JD, Krishman M, Rowe MR. Disk battery aspiration in a young child. ARCH OTOLARYNGOL HEAD NECK SURG/VOL 138 (NO. 7), JULY 2012.

Mercer RW, Schwartz MC, Stephany J, Donnelly LF, Franciosi JP, Epelman. Vascular ring complicates accidental button battery ingestion. 2015. http://dx.doi.org/10.1016/j.clinimag.2015.01.009.

Metterlein T, Haubner F, Knoppke B, Graf B, Zausig Y. An unexpected ferromagnetic foreign body detected during emergency magnetic resonance imaging: a case report. BMC Research Notes 2014, 7:808.

Mortensen A, Hansen NF, Schiodt OM. Cardiac arrest in child caused by button battery in the oesophagus and complicated by aorto-oseophageal fistula. Ugeskr Laeger. 2009 Oct 19;171(43):3098-9.

Mortensen A. Fatal aortoesophageal fistula caused by button battery ingestion in a 1-year-old child. American Journal of Emergency Medicine (2010) 28, 984.e5–984.e6.

Nagao N, Kaneko T, Hikawa Y, Yanagihara S. Laryngeal edema and vocal cord paralysis due to lithium battery ingestion; a case report. MASUI. THE JAPANESE JOURNAL OF ANESTHESIOLOGY. 2007 Aug;56(8):956-8.

Neverman EM and Geyer B. Acquired tracheoesophageal fistula due to battery ingestion. doi:10.7556/jaoa.2016.037.

Nguyen LN, Ramanathan S, Vahabzadeh-Monshie HR, Borders JC, de Armendi AJ. Battery swallow-induced tracheoesophageal fistula in a pediatric patient. DOI: 10.1002/ccr3.3887.

(NIDCD, 2010).Global Variation in Sensitivity to Bitter-Tasting Substances (PTC or PROP) | NIDCD (nih.gov).

(NIDCD, 2019). Quick Statistics About Taste and Smell | NIDCD (nih.gov).

Nisse P, Lampin ME, Aubry E, Cixou E, Mathieu-Nolf M. Fatal aorto-esophageal fistula due to accidental ingestion of button battery. Algorithm for management of disk-battery ingestion in patients younger than 6 years old. 2016. http://dx.doi.org/10.1016/j.lpm.2016.07.016.

Nivatvongs W, Ghabour M, Dhanasekar G. Difficult button battery ear foreign body removal: the magnetic solution. The Journal of Laryngology & Otology (2015), 129, 93–94.

Nuri Kosar M, Gorgulu O. Ingestion of cylindrical battery and medical treatment. 2021 doi: https://doi.org/10.12669/pjms.37.2.3225.

Obateru OA, Durowaye MO, Olokoba AB, Olaiyi OK. Endoscopic removal of impacted oseophageal foreign body: A case report and a review of literature. DOI:10.4103/0189-6725.181706.

Okuyama H, Kubota A, Oue T, Kuroda S, Nara K, Takahashi T. Primary repair of tracheoesophageal fistula secondary to disc battery ingestion: A case report. Journal of Pediatric Surgery, Vol 39, No 2 (February), 2004: pp 243-244.

Olivera CA and Julca AO. Clindrical Battery in the Stomach in the Instituto Nacional de Salud del Niño, Lima, Peru. Rev Gatroenterol Peru. 2013;33(2):153-6.

Ordoobadi AJ, Allar BG, Orhurhu V, Keith S, Cocchi MN. ST segment elevation caused by artifact from aylindrical battery ingestion. The Journal of Emergency Medicine, Vol. 58, No. 4, pp. 673–676, 2020.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Ott KC, Harris JC, Barsness KA, Arseneau J, Ghadersohi S, Raval MV. Management of broncho-esophageal fistula after button battery ingestion. Journal of Surgical Case Reports, 2021;10, 1–4.

Oyewole M, Ajayi O, Hilger A. Oesophageal foreign body: an unusual presentation. The Journal of Laryngology & Otology (2013), 127, 1242–1243.

Pae SJ, Habte SH, McCloskey JJ, Schwartz AJ. Battery ingestion resulting in aortoesophageal fistula. Anesthesiology V 117, No 6 (2012) 1354.

Palmer O, Natarajan B, Johnstone A, Sheikh S. Button battery in the nose – an unusual foreign body. *The Journal of Laryngology and Otology* October 1994, Vol." 108**,** pp. 871-872.

Pandey V, Gangopadhyay AN, Gupta DK, Sharma SP, Kumar V. Novel technique of repair of large tracheo-esophageal fistula following battery ingestion in children: review of two cases. Pediatr Surg Int (2014) 30:537–539 DOI 10.1007/s00383-014-3498-6.

Panella NJ, Kirse DJ, Pranikoff T, Evans AK. Disk battery ingestion: Case series with assessment of clinical and financial impact of a preventable disease. Pediatric Emergency Care & Volume 29, Number 2, February 2013: 165-169.

Pantazopoulos I, Mavrovounis G, Mermiri M, Adamou A, Gourgoulianis K. Intentional ingestion of batteries and razor blades by a prisoner: a true emergency? DOI 10.1108/IJPH-06-2021-0054.

Paparoupa M and Bruns-Toepler M. Case report: Foreign body moves retrograde through ileocecal valve during colonoscopy. https://doi.org/10.1155/2017/8707959.

Parker K, Visram S, Hodges S. An incidental finding of a long-standing button battery in the floor of the nose during a routine orthodontic examination. Journal of Orthodontics, Vol. 43, 2016, 147–150.

Parray T, Siddiqui SM, Hughs M, Shah S. Tension pneumothorax and subcutaneous emphysema during retrieval of an ingested lithium button battery. J Anesth (2010) 24:469–471 DOI 10.1007/s00540-010-0908-3.

Patel SA, Hillel AD, Perkins J. Battery ingestion leading to bilateral vocal cord paresis. *JAMA Otolaryngol Head Neck Surg.* 2013;139(3):304-306.

Peralta MG, Fadda BC, Contreras LR. Tracheoesophageal fistula secondary to ingestion of a button battery. Rev. Chil. Pediatr. 62(6):378-381. 1991.

Petri NM, Mestrovic J, Andric D, Drzelj V, Stipancevic H. Esophagotracheal fistula after lithium disc battery ingestion successfully treated with hyperbaric oxygen therapy. International Journal of Pediatric Otorhinolaryngology (2003) 67, 921-926.

(PLOS One, 2015).Clinical Features of Reported Ethylene Glycol Exposures in the United States (plos.org).

Premachandra DJ and McRae D. Severe tissue destruction in the ear caused by alkaline button batteries. Postgrad Med J (1990) 66, 52-53.

Raboei EH, Syed SS, Maglrabi M, El Beely S. Management of button battery stricture in 22-day-old neonate. Eur J Pediatr Surg 2009; 19: 130‑131.

Ramasamy V and Nadarajah S. The hazards of impacted alkaline battery in the nose. DOI**:**10.4103/jfmpc.jfmpc_47_18.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Ribakovs A and Uzoigwe C. From cylindrical battery ingestion to right hemicolectomy. The American Surgeon. June 2011, E103-E104.

Rivera EA and Maves MD. Neutralizing agents and disc battery burns. Ann *Otol Rhinol Laryngol* 96:1987.

Ruhl DS, Cable BB, Rieth KKS. Emergent treatment of button batteries in the esophagus: Evolution of management and need for close second-look esophagoscopy. Annals of Otology, Rhinology & Laryngology 2014, Vol. 123(3) 206–213.

Russell RT, Cohen M, Billmire DF. Tracheoesophageal fistula following button battery ingestion: Successful non-operative management. Journal of Pediatric Surgery (2013) 48, 441–444.

Sahni JK, Singh GB, Verma R, Dhanda SK. A rare cae of lithium battery ingestion in a neonate with no complications. Pediatr Emer Care 2012;28: 705-706.

Samad L, Ali M, Ramzi H. Button battery ingestion: Hazards of esophageal impaction. J Pediatr Surg 34:1527-1531.

Sato Y, Obtsuki K, Ohtani I, Ouchi J, Toyomasu K, Kohno H, Imaizumi H, Takatori T, Kodama N. Three cases of the foreign bodies of button batteries in the nasal cavity. Oto-Rhino-Laryngological Society of Japa Tokyo :1985 Jul;88(7):920-5.

Senthilkumaran G, Crankson S, Yousef M. Spontaneous closure of acquired trachea-oesophageal fistula. *The Journal of Laryngology and Otology* July 1996, Vol. 110**,** pp. 685-687.

Shakir NT, Pollock AN. Battery ingestion. Pediatric Emergency Care & Volume 30, Number 1, January 2014. 72-73.

Shen XF, Wang Y, Li Q, Chen WB. A case of esophageal tracheal fistula caused by button cell. Doi:10.13201/j.issn.1001-1781.2018.20.014.

Shepherd M, Hamill JK, Barker R. Button battery injury in children – a primary care issue? J Prim Healthcare. 2014:6(1);69-72.

Shibuya S, Azuma T, Lane GJ, Okawada M, Yamataka A. Successful strategy for the conservative management of acquired tracheoesophageal fistula due to lithium button battery ingestion. Eur J Pediatr Surg Rep 2020;8:e18–e22.

Sigalet D, Laes G, Tracheo-esophageal injury secondary to disc battery ingestion, American Journal of Otolaryngology 23 (1988) 996–998.

Simonin M, D'Agostino I, Lebreton M, Jughon O, Hamza J, Oualha M. Bilateral vocal palsy following coin cell lithium battery ingestion: a case report and review. Eur J Pediatr (2013) 172:991–993.

Sindi E, Bahadur A, AlRajhi H, Yousef Y. Disc battery ingestion: a single event with different outcomes. International Journal of Pediatrics and Adolescent Medicine 4 (2017) 87-90.

Singh G, Sharma S, Khurade S, Gooptu S. Ingested foreign bodies in children: A report of two cases. DOI**:**10.4103/2249-4863.148148.

Skinner DW and Chui P. The hazards of 'button-sized' batteries as foreign bodies in the nose and ear. The journal of Laryngology and Otology. November 1986. Vol 100. Pp 1315-1318.

Slamon NB, Hertzog JH, Penfil SH, Raphaely RC, Pizarro C, Derby CD. An unusual case of button battery-induced traumatic tracheoesophageal fistula. Pediatric Emergency Care. Volume 24, Number 5, May 2008.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Soerdjbalie-Maikoe V, van Rijn RR. A case of fatal coin battery ingestion in a 2-year-old child. Forensic Science International 198 (2010) e19–e22.

Soong WJ, Yuh YS. Ingested button battery retrieved by a modified magnet endoscope. *Chin Med Assoc* 2007;70(3):132–135.

Spiers A, Jamil S, Whan E, Forbes D, Gollow I, Andrews D. Survival of patient after aorto-oesophageal fistula following button battery ingestion. doi: 10.1111/j.1445-2197.2011.05984.x.

Sudhakar PJ, Al-Dossary J, Malik N. Spondylodiscitis complicated by the ingestion of a button battery: a case report. (2008). DOI:10.3348/kjr.2008.9.6.555.

Szaflarska-Poplawska A, Poplawski C, Romanczuk B, Parzecka. Endoscopic removal of a battery that was lodged in the oesophagus of a two-year-old boy for an extremely long time. Prz Gastroenterol 2015; 10 (2):122–126.

Tabari AK, Mirshemirani A, Rowrokh M, Seyyedi J, Tabari NK, Razavi S, Talebian M. Tracheoesophageal fistula following disc battery ingestion and foreign body impaction. Caspian J Intern Med 2011; 2(4): 336-339.

Takahashi T, Teramoto Y, Aoyama T, Sahakibara H, Hara M, Maseki M. Yamaguchi S. Anesthetic management of a child with an esophageal foreign body with was misdiagnosed as asthma. MASUI. THE JAPANESE JOURNAL OF ANESTHESIOLOGY. 2009 Feb;58(2):199-201. 199-201.

Takesaki NA, dos Reis MC, de Miranda MLF, Baracat CE. Hemorrhagic shock secondary to button battery ingestion. DOI**:** 10.1590/1516-3180.2014.1323697.

Tan A, Wolfram S, Birmingham M, Dayes N, Garrow E, Zehtabchi S. Neck pain and stiffness in a toddler with history of button battery ingestion. The Journal of Emergency Medicine, Vol. 41, No. 2, pp. 157–160, 2011.

Tanigawa T, Shibata R, Katahira N, Ueda H. Battery ingestion: The importance of careful radiographic assessment. Intern Med 51: 2663-2664, 2012.

(TechWorm, 2020). Why gamers are licking the new Nintendo Switch game cartridges » TechWorm.

Thatcher A, DiPaola F, Zopf D. Complication of button battery ingestion. https://doi.org/10.1053/j.gastro.2017.03.061.

Tibballs J, Wall R, Velandy Koottayi S, Stokes KB, Cochrane A, Barnes R, Kimber C. Tracheo-oesophageal fistula caused by electrolysis of a button battery impacted in the oesophagus. J. Paediatr. Child Health (2002) 38, 201–203.

Tuang GJ, Hussin NRN, Abidin ZAZ. Unilateral rhinorrhoea and button battery: a case report. Fam Med Com Health 2019;7:e000137. doi:10.1136/fmch-2019-000137.

Untersweg U, Mayr J, Schmidt. Oesophageal burn caused by sucking a 1.5 volt battery. Acta Paediatr 85. 1382-3. 1996.

Vaishnav A and Spitz L. Alkaline battery-induced trachea-oesophageal fistula. Br. J. Surg. 1989, Vol. 76, October,1045.

Ventura F, Candosin S, Barranco R, Bonsignore A, Andrello L, Tajana L, Osculati A. A fatal case of coin battery ingestion in an 18-month-old child. Am J Forensic Med Pathol 2017;38: 43–46.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Vottlter TP, Nash JC, Rutlidge JC. The hazard of ingested alkaline disk batteries in children. JAMA 1983;249:2504-2506.

Wakimoto M, Willer BL, McKee C, Nafiu OO, Tobias JD. Successful management of an aorto-esophageal fistula following button battery ingestion: A case report and review of the literature. DOI:10.4103/sja.sja_1040_20.

Wall SJ, Nadel DM, Handler SD. Airway compromise caused by disk battery ingestion. Otolaryngology–Head and Neck Surgery Volume 121 Number 3. 1999. 302-303.

Walton JM, Darr A, George A. An unusual case of an oesophageal foreign body presenting as torticollis. Ann R Coll Surg Engl 2016; 98: e40–e42.

Watanabe K-I, Hatano G-Y, Aoki H, Okubo K. The necessity of simple X-ray examination: A case report of button battery migration into the nasal cavity. Pediatr Emer Care 2013;29: 209Y211.

White N.C., Litovitz T., White M.K., Watson W.A., Benson B.E., Horowitz B.Z., Marr-Lyon L. (2008) The impact of bittering agents on suicidal ingestions of antifreeze; Clin. Toxicol. (Phila); 46(6):507-514.

White N.C., Litovitz T., Benson B.E., Horowitz B.Z., Marr-Lyon L., White M.K. (2009) The impact of bittering agents on pediatric ingestions of antifreeze; Clin. Toxicol. (Phila); 48(9):913-921.

Wurzel DF, Masters IB, Choo KL, Isles AF. A case for early borchoscopic airway assessment after disc battery ingestion. Pediatric Pulmonology 49:E72–E74 (2014).

Yardeni D, Yardeni H, Coran AG, Golladay ES. Severe esophageal damage due to button battery ingestion: can it be prevented. Pediatr Surg Int (2004) 20: 496–501.

Zhang Z, Ma J, Liu S, Liu X, Yan X, Niu T, Li C, Li Q, Wang C, Meng C. Fully-covered metallic stenting in an infant with tracheoesophageal fistula due to button battery ingestion. International Journal of Pediatric Otorhinolaryngology 95 (2017) 80-83.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

APPENDIX A

Case Studies of Button/coin batteries Impaction in the Esophagus (Deaths are highlighted)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
No Injury				
14 mo	Button/coin battery	Unknown	Uncomplicated spontaneous passage	Bekhof et al., 2005
10 yr	Button/coin battery	Unknown	Uncomplicated spontaneous passage	Bekhof et al., 2005
1 yr	Quarter-sized button/coin battery	5.5 hrs	No esophageal injury	Kimball et al., 2010
2 yr	Button/coin battery	3 days	No symptoms	Liao et al., 2015
8 yr	10 mm button/coin battery	1 hrs	No mucosal injury	Gao et al., 2020
Esophageal Injury				
10 mo	1.35 V mercury camera button/coin battery	18-22 hrs	Severe burn of the esophagus	Maves et al., 1984
3 yr	23mm 1.5 V button/coin battery	48 hrs	Circumferential burn of the cervical esophagus. Stricture.	Rivera and Maves 1987
1 yr	Button/coin battery	3 hrs	Circumferential burns of the esophagus. Respiratory compromise.	Wall et al., 1999
7 yr	20 mm 3V button/coin battery from Gameboy-like device	4.5 hrs	Esophageal narrowing	Yardeni et al., 2004
10 mo	20 mm button/coin battery from personal digital organizer	6 hours	Esophageal perforation	Lin et al., 2004
3 yr	CR2032 3V lithium	48 hours	Esophageal ulceration	Banerjee et al., 2005
11 mo	Button/coin battery	Unknown	Development of severe complications: stricture of the esophagus	Bekhof et al 2005
8 yr	20 mm 3V button/coin battery from TV remote	2 hrs	Vocal cord paralysis	Nagao et al., 2007
1 yr	12 mm button/coin battery	2 days	Mild erosion of mucosa	Soong and Yuh 2007
1 yr	Button/coin battery	Unknown	Mediastinitis and spondylodiscitis.	Sudhakar et al., 2008

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
22 day	12 mm Button/coin battery	18 hours	Esophageal perforation, stricture	Raboei et al., 2009
9 mo	Button/coin battery	Unknown	Esophageal eschar[38], vocal cord paralysis	Hamilton et al., 2009
1 yr	Button/coin battery	Unknown	Airway stenosis[39]	Tahakashi et al., 2009
< 1 yr	21mm Button/coin battery	30 days	Presented with cough, dysphagia, stridor for 30 days. Found erosion into esophageal muscle with perforation. Outcome was esophageal stricture with single dilation at 3.5 months.	Kimball et al., 2010
< 1yr	Quarter sized button/coin battery	3.5 hrs	Superficial esophageal injury, esophageal stricture	Kimball et al., 2010
9 yr	23 mm button/coin battery	3 hrs	Erosion into esophageal muscle.	Kimball et al., 2010
1 yr	Button/coin battery	Unknown	Erosion into esophageal muscle	Kimball et al., 2010
4 yr	Button/coin battery	3 hrs	Erosion into esophageal muscle	Kimball et al., 2010
3 yr	Button/coin battery	6 hrs	Erosion into esophageal muscle	Kimball et al., 2010
5 yr	Button/coin battery	12 hrs	Erosion into esophageal muscle	Kimball et al., 2010
4 yr	Button/coin battery	4.5 hrs	Superficial esophageal injury	Kimball et al., 2010
4 yr	Button/coin battery	24 hrs	Esophageal perforation, emphysema[40], tension pneumothorax[41], pneumomediastinum[42], mediastinitis[43]	Parray et. al. 2010
9 yr	Button/coin battery	Unknown	Perforation in the esophagus	Wu et. al. 2011
7 mo	20 mm 3V button/coin battery	Unknown	Esophageal perforation and stricture	Liao and McDonald 2011
1 yr	20 mm 3V button/coin battery	2 weeks	Spondylodiscitis[44]	Tan et. al. 2011
5 mo	Button/coin battery	24 hrs	Severe esophageal stricture	Jarugula and Dorofaeff 2011

[38] An eschar is a slough or piece of dead tissue that is cast off from the surface of the skin, particularly after a burn injury.
[39] Abnormal narrowing.
[40] A lung disease that results in shortness of breath due to destruction and dilation of the alveoli.
[41] A collapsed lung that occurs when air enters into the pleural cavity.
[42] Air in the mediastinum. The mediastinum is the space in the middle of the chest, between the lung and around the heart.
[43] A swelling and irritation (inflammation) of the chest area between the lungs. A life-threatening condition that carries an extremely high mortality if unrecognized or treated improperly.
[44] Spondylodiscitis, also referred to as discitis-osteomyelitis, is characterized by infection involving the intervertebral disc and adjacent vertebrae.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION
CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
17 day	Button/coin battery	17 days	Slight redness and edema at site of battery.	Sahni et. al. 2012
1 yr	20 mm button/coin battery	Unknown	Esophageal erosion.	Cruz and Patel 2012
2 yr	Lithium button/coin battery	Several hours	Superficial erosion in the esophagus	Tanigawa et al., 2012
52 yr	2 3v 2 cm lithium button/coin batteries removed from a pedometer	2.5 hours	Partial thickness corrosive injury	Walker and Caldera 2013
1 yr	CR2032 lithium button/coin battery	>48 hours	Bilateral vocal paralysis	Simonin et al., 2013
3 yr	Button/coin	14 hours	Inflammation and necrosis of esophageal mucosa	Martinez-Criado et al., 2013
5 yr	Button/coin battery	12 hpurs	Inflammation and necrosis of esophageal mucosa	Martinez-Criado et al., 2013
9 yr	Button/coin battery	9 hours	Inflammation and necrosis of esophageal mucosa	Martinez-Criado et al., 2013
3 yr	20mm lithium button/coin battery	10 hours	Esophageal mucosal burn injury	Dawe et al., 2013
10 mo	Button/coin battery	1 month	Infectious spondylodiscitis[45]	Eshagi et al., 2013
1 yr	20 mm Button/coin battery	7 months	Irregular mucosa around battery. No obvious stricture or perforation.	Oyewole et al., 2013
10 mo	Button/coin battery	14 hours	Full circumference, extensive mucosal damage	Panella et al., 2013
3 yr	Button/coin battery	48 hours	Circumferential injury, extensive mucosal injury	Panella et al., 2013
1 yr	21 mm button/coin battery	48 hours	Non circumferential mucosal damage	Panella et al., 2013
8 mo	20 mm button/coin battery	>72 hours	Full-thickness burn with exposed muscle, esophageal perforation with neck abscess	Panella et al., 2013

[45] Infectious spondylodiscitis is a rare but serious disease of the intervertebral disc, which may also involve peri-vertebral structures and may lead to extensive destruction and general symptoms and neurological deficits. Patients present with a variety of symptoms, including back pain, fever, nausea, and weight loss.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
34 mo	20 mm button/coin battery	24 hours	Extensive corrosive burn, TEF	Panella et al., 2013
1 yr	23 mm button/coin battery	24 hours	Circumferential burn with significant eschar	Panella et al., 2013
1 yr	20 mm 3V lithium button/coin battery	5 hours	Vocal Cord Paresis[46]	Patel et al., 2013
1 yr	CR2016 20 mm 3V lithium button/coin battery	3 months	Esophageal mucosal swelling	Gohil et al., 2014
1 yr	20 mm button/coin battery	6 hours	Superficial ulceration, erosions[47], friability[48], blisters, exudates[49], hemorrhages[50], whitish membranes, no perforation	Ruhl et al., 2014
11 mo	22 mm button/coin battery	12 hours	Superficial ulceration, erosions, friability, blisters, exudates hemorrhages, whitish membranes, no perforation	Ruhl et al., 2014
13 mo	20 mm button/coin battery	4 days	Superficial ulceration, erosions, friability, blisters, exudates hemorrhages, whitish membranes, no stricture or perforation	Ruhl et al., 2014
1 yr	20 mm button/coin battery	6 hours	Sloughing of tissues with deep ulcerations or necrosis[51], no perforation	Ruhl et al., 2014
1 yr	Button/coin battery	4 months	Sloughing of tissues with deep ulcerations or necrosis, severe esophageal stricture	Ruhl et al., 2014
8 yr	20 mm 3V Button/coin battery	1 days	Esophageal ulceration	Kalyanshettar et al., 2014
5 yr	CR2032 lithium	3 days	Esophageal perforation	Barabino et al., 2015
18 mo	CR2032 lithium	3 hours	Esophageal ulceration	Barabino et al., 2015
2 yr	20 mm 3V CR2032 lithium button/coin battery	6 months	Esophageal stricture	Szaflarska-Poplawska et al., 2015
1 yr	20 mm 3V Lithium Button/coin battery	Unknown	Mild esophageal stricture	Kim et al., 2015

[46] Muscle weakness.

[47] A shallow or superficial ulceration.

[48] Tissue that tears, sloughs, and bleeds more easily when touched.

[49] A liquid or semisolid that has been discharged through the tissues to the surface or into a cavity.

[50] An abnormal escape of blood from an artery, a vein, an arteriole, a venule or a capillary network.

[51] The death of living cells or tissues.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
1 yr	Button/coin battery	Unknown	Esophageal burn	Shepherd et al., 2014
2 yr	Button/coin battery	5 weeks	Esophageal thickening and stricture	Walton et al., 2016
5 yr	15 mm button/coin battery from a toy	15 hours	Corrosion of esophageal mucosa	Singh et al., 2014
7 yr	Lithium button/coin battery	10 hours	Inflammatory changes and superficial ulcers at the point of impaction in the esophagus.	Obateru et al., 2016
1 yr	Button/coin battery	6 hours	Esophageal ulcer, vocal cord paralysis	Thatcher et al., 2017
2 yr	Button/coin battery	2 days	Circumferential burn with moderate to severe inflammatory changes in the mucosa. Pneumomediastinum.	Sindi et al., 2017
1 yr	Button/coin battery	2 days	Esophageal ulceration	Ing et al., 2017
39 mo	2 Button/coin batteries approximately 20 mm	10 hours	Esophageal ulcerations	Garcia-Fernandez et al., 2016
9 yr	Button/coin battery	2 hours	Esophageal erythema[52], swelling and slough at site of impaction	Bakshi, 2018
3 yr	Button/coin battery	2-4 hours	Esophageal ulceration	Clute et al., 2019
2 yr	15 mm button/coin battery	9 hours	Esophageal injury	Gao et al., 2020
1 yr	20 mm button/coin battery	34 hours	Esophageal injury	Gao et al., 2020
1 yr	22 mm button/coin battery	17 hours	Esophageal injury	Gao et al., 2020
1 yr	18 mm button/coin battery	5 hours	Esophageal injury	Gao et al., 2020
1 yr	13 mm button/coin battery	9 hours	Esophageal injury	Gao et al., 2020
2 yr	22 mm button/coin battery	12 hours	Esophageal injury	Gao et al., 2020
11 mo	15 mm button/coin battery	24 hours	Esophageal injury	Gao et al., 2020
9 mo	22 mm button/coin battery	31 hours	Esophageal injury	Gao et al., 2020

[52] Superficial reddening of the skin, usually in patches, as a result of injury or irritation causing dilatation of the blood capillaries.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
9 mo	22 mm button/coin battery	15 hours	Esophageal injury	Gao et al., 2020
7 yr	21 mm button/coin battery	13 hours	Esophageal injury	Gao et al., 2020
1 yr	20 mm button/coin battery	4 hours	Esophageal injury	Gao et al., 2020
1 yr	CR2032 3V lithium button/coin battery from a glucometer	8 hours	Reduced vocal fold movement, esophageal severe burn wounds and necrosis. No improvement in vocal cord function.	Goussard et al., 2021
Fistula Formation/Death				
2.5 yr	Button/coin battery, camera battery	24 hours	Tracheoesophageal fistula (TEF)[53], bloody Vomit, cardiac Arrest, death	Blatnik et al., 1977
1 yr	22 mm button/coin battery	4 days	Aortoesophageal fistula (AEF[54]), death	Shabino et al., 1979
2 yr	Alkaline camera button/coin battery	2 weeks	TEF	Janik et al., 1982
3 yr	Button/coin battery, camera battery	5 days	TEF	Volleler et al., 1983
4 mo	12 mm button/coin battery	30 hours	TEF	Sigalet and Lees 1988
1 yr	10 mm alkaline button/coin battery	4 weeks	TEF	Vaishnav and Spitz 1989
11 mo	Button/coin battery from a watch	30 hours	TEF, death	Peralta et al., 1991
1 yr	Button/coin battery from hair dryer	3 days	TEF, esophageal stricture	Gordon and Gough 1993
5 mo	22 mm Button/coin battery	12 days	TEF	Senthilkumaran et al., 1996
4 yr	20 mm 3V lithium	36 hours	TEF	Samad et al., 1999

[53] Tracheoesophageal fistula is a life-threatening condition in which there is an abnormal connection between the esophagus and trachea (windpipe).
[54] An aortoesophageal fistula is a life-threatening cause of gastrointestinal bleeding, where an abnormal communication between the esophagus and the aorta may result from a thoracic aortic aneurysm, foreign body ingestion, esophageal malignancy, or postoperative complications.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
	CR2032 button/coin battery			
5 yr	20 mm 3V lithium button/coin battery	5 hours	Small TEF	Samad et al., 1999
1 yr	23 mm Maxell CR2032 3V lithium battery	3 days	TEF	Chiang and Chen 2000
3 yr	21mm button/coin battery	10 days	TEF	Anand et al., 2002
11 mo	Button/coin battery	9 hours	TEF	Tibbals et al., 2002
1 yr	23mm Button/coin battery	Unknown	TEF	Petri et al., 2003
6 week	Alkaline button/coin batteries	Unknown	TEF	Bekhof et al., 2004
1 yr	20 mm button/coin battery	7 days	TEF	Okuyama et al., 2004
2 yr	22 mm MnO_2 button/coin battery	17 days	Infection, TEF	Imamoglu et al., 2004
1 yr	23 mm MnO_2 button/coin battery	1 day	Death secondary to massive TEF	Imamoglu et al., 2004
2 yr	23 mm MnO_2 button/coin battery	5 days	TEF, Cardiac Arrest, Survived	Imamoglu et al., 2004
10 mo	15.6 mm HgO button/coin battery	22 hours	TEF, esophageal stricture	Imamoglu et al., 2004
9 mo	16 mm HgO button/coin battery	7 days	TEF, esophageal stricture	Imamoglu et al., 2004
4 mo	12 mm ZnO_2 button/coin battery	30 hours	TEF	Imamoglu et al., 2004
1 yr	20 mm button/coin battery	28 days	TEF	Imamoglu et al., 2004
5 mo	22 mm button/coin battery	12 days	TEF	Imamoglu et al., 2004
2 yr	22 mm MnO_2 button/coin battery	17 days	TEF	Imamoglu et al., 2004
16 mo	23 mm CR2032 3V lithium	3 days	TEF	Alkan et al., 2004

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
6 weeks	Button/coin battery	Unknown	TEF	Bekhof et., al., 2005
1 yr	22 mm Lithium button/coin battery	1 week	TEF, esophageal stricture	Hammond et al., 2007
1 yr	20mm button/coin battery	Several hours	Traumatic erosive TEF	Slamon et al., 2008
1 yr	2 button/coin batteries from garage door opener	1 day	AEF, death	Hamilton et al., 2009
1 yr	Lithium Button/coin battery	Unknown	AEF, death	Mortensen et al., 2009
1 yr	Lithium button/coin battery	7 days	TEF	Kimball et al., 2010
2 yr	Button/coin battery	9 days	Haematothorax[55], esophageal perforation, perforated arteria lusoria (subclavian artery), death	Soerdjbalie-Maikoe and Rijn 2010
3 yr	20 mm button/coin battery	Unknown	AEF, death	Baeza Herrera et al., 2010
1 yr	CR2032 3V button/coin battery	10 days	AEF, death	Mortensen 2010
3 yr	20 mm	3 weeks	TEF, tracheal stricture and recurrent chest infections	Abdulkareem et al., 2011
9 mo	5 mm button/coin battery	5 days	TEF	Tabari et al., 2011
2 yr	Button/coin battery	8 months	TEF	Tabari et. al., 2011
2 yr	Button/coin battery	8 days	TEF	Tabari et al., 2011
3 yr	Button/coin battery	1.5 months	TEF	Tabari et al., 2011
3 yr	20mm CR2032 3V Button/coin battery	Unknown	TEF, death	LaFrance et al., 2011
1 yr	Button/coin battery	19 hours	TEF	Jarugula and Dorofaeff 2011
1 yr	1.5 cm button/coin battery from a toy harmonium	10 days	TEF	Harjai et al., 2012
4 yr	23 mm Button/coin battery	Unknown	AEF, death	Pae et al., 2012

[55] A hemothorax is an accumulation of blood within the pleural cavity.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
10 mo	Button/coin battery	Unknown	AEF	Spiers et al., 2012
1 yr	20 mm button/coin battery	4-6 hours	TEF	Russell et al., 2013
5 yr	Button/coin battery	10 days	Deep ulcerated lesion in the esophagus. Cardiorespiratory arrest, death	Takesaki et al., 2014
2 yr	Button/coin battery lithium	5 days	TEF	Pandey et al., 2014
3 yr	22 mm lithium button/coin battery	Unknown	TEF	Pandey et al., 2014
1 yr	21 mm Button/coin battery	>2 days	TEF	Shakir et. al., 2014
1 yr	Lithium 3V button/coin battery	23 hours	TEF	Wurzel et al., 2014
4 yr	23 mm button/coin battery	Unknown	Death	Shakir et al., 2014
2 yr	20 mm button/coin battery	2 weeks	Esophageal perforation to the brachiocephalic artery, death	Loots et al., 2015
1 yr	CR2032 lithium button/coin battery	Unknown	AEF, death	Barabino et al., 2015
4 yr	CR2032 button/coin battery	2 days	Esophageal erosion, vasculoesophageal[56] fistula, death	Mercer et al., 2015
11 mo	Button/coin battery	7 days	TEF	Liao et al., 2015
3 yr	Button/coin battery	4 days	TEF	Liao et al., 2015
3 yr	Button/coin battery	5 days	TEF	Liao et al., 2015
1 yr	Button/coin battery	48 hours	TEF	Houas et al., 2016
1 yr	3V CR20 20 mm button/coin battery	Unknown	Complete rupture of the esophageal wall, death	Guinet et al., 2016
2 yr	3V lithium Button/coin battery (CR2032)	Unknown	vocal fold immobility, TEF, esophageal stricture	Eliason MJ et al., 2016
1 yr	20 mm Button/coin battery	5 days	TEF	Neverman and Geyer 2016

[56] A fistula that formed at a vascular ring. A vascular ring occurs when the aorta or its branches form a complete ring around the trachea.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
4 yr	Lithium button/coin battery	Unknown	AEF, death	Nisse et al., 2016
1 yr	20 mm button/coin battery	7 days	TEF	Chessman et al., 2017
10 mo	Button/coin battery	>15 days	TEF	Zhang et al., 2017
1 yr	20 mm CR2032 3V button/coin battery	Unknown	AEF, death	Ventura et al., 2017
1 yr	Button/coin battery	1 weeks	TEF	Sindi et al., 2017
3 yr	Button/coin battery	Unknown	TEF	Gruner et al., 2017
3 yr	CR 2025 lithium button/coin battery	>6 hours	AEF	Granata et al., 2018
Unknown	20 mm button/coin battery/coin	Unknown	TEF	Shen et al., 2018
3 yr	21 mm button/coin battery from a fidget spinner	7 hours	AEF	Khalaf et al., 2018
1 yr	20mm Lithium button/coin battery	36 hours	AEF	Bartkevics et al., 2019
3 yr	Button/coin battery	36 hours	AEF	Mahajan et al., 2019
16 day	11.4 mm Button/coin battery from an unsecured toy	1 week	TEF, death	Janarthanan et al., 2019
1 yr	21 mm button/coin battery	3 weeks	TEF	Hofmeyr et al., 2019
1 yr	22 mm button/coin battery	52 hours	TEF	Gao et al., 2020
3 yr	21 mm button/coin battery	76 hours	AEF, death	Gao et al., 2020
1 yr	Lithium button/coin battery	5 days	TEF	Shibuya et al., 2020
1 yr	CR2025 3V Lithium button/coin battery	Unknown	AEF, death	Karnecki et al., 2020

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
2 yr	Button/coin battery	16 hours	AEF	Alreheili et al., 2021
1 yr	Button/coin battery	2 weeks	AEF	Gibbs et al., 2021
1 yr	Button/coin battery	Unknown	TEF	Nguyen et al., 2021
1 yr	3V 20 mm button/coin battery	4 days	Broncho-esophageal fistula[57]	Ott et al., 2021
1 yr	23.5 mm button/coin battery	>10 days	AEF	Wakimoto et al., 2021

[57] A broncho-esophageal fistula refers to an abnormal communication between a bronchus and the esophagus. Bronchus is a part of the lungs.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

APPENDIX B

Case Studies of Button/Coin Batteries Impacted in the Nose

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
No Injury				
5 yr	Button/coin battery	Unknown	No complications	Sato et al., 1985
3 yr	Button/coin battery from an electronic game	3 hours	No damage	Gomes et al., 1994
Nasal Injury				
2 yr	Alkaline Button/coin battery	Unknown	Septal perforation	Sato et al., 1985
2 yr	Alkaline Button/coin battery	Unknown	Nasal atresia[58]	Sato et al., 1985
5 yr	Button/coin battery from a camera	1 day	There were extensive buns in the region where the battery was lodged	Capo and Lucente 1986
5 yr	Button/coin battery from a hearing aid	3 days	Inferior turbinate blackened and necrotic, nasal septum blackened.	Skinner and Chui 1986
4 yr	392 Eveready 7-9 mm button/coin battery	24 hours	Small septal perforation	Fernando 1987
6 yr	11.6 mm HgO Alkaline Button/coin battery from a calculator	Unknown	Ulceration of the septum and inferior turbinate found and covered with necrotic tissue	Hong et al., 1987
3 yr	11.6 mm HgO Alkaline Button/coin battery from a toy	1 hour	Nasal mucosa only showed mild inflammation.	Hong et al., 1987
2 yr	Button/coin battery	2-3 months	The septum had a clean anterior perforation approximately 1.5 cm in diameter. She was to be followed for future reconstructive surgery.	Fosarelli et al., 1988
24 yr	Button/coin battery	24 hours	Large mucosal burn of the middle turbinate and adjacent septum.	McCombe et al., 1992
5 yr	10 mm Button/coin battery from an	>5 days	Full thickness septal perforation	Brown 1994

[58]Absence or abnormal narrowing of an opening or passage in the body.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
	electronic game			
6 yr	Button/coin battery from a watch	Unknown	Septal perforation	Palmer et al., 1994
6 yr	Button/coin battery from a watch	3 days	Septal perforation, saddle nose[59]	Palmer et al., 1994
2 yr	Watch battery	12 hours	Moderate bleeding and no ulceration of the mucosa.	Gomes et al., 1994
3 yr	Watch battery	12 hours	Ulcerated lesion of the cartilaginous portion of the nasal septum	Gomes et al., 1994
5 yr	10 mm Button/coin battery	24 hours	Deep ulceration with crusts of the nasal septum	Gomes et al., 1994
4 yr	Button/coin battery from an electronic calculator	12 hours	Crust of the nasal septum with no perforation and hyperaemia[60] of the mucosa.	Gomes et al., 1994
9 yr	Button/coin battery	3 hours	Irregular mucosal changes with discoloration but the septum was intact.	Alvi et al., 1997
4 yr	Button/coin battery	> 34 hours	The inferior turbinate was found to be completely necrotic. The nasal septum was also necrotic and nearly perforated.	Dane et al., 2000
3 yr	Alkaline Button/coin battery	>12 hours	Extensive necrosis of nasal mucosa, no perforation	Loh et al., 2003
4 yr	Alkaline Button/coin battery	>48 hours	Septal perforation, extensive nasal mucosal necrosis	Loh et al., 2003
4 yr	Zinc Oxide Button/coin battery	4 hours	Superficial erosion in inferior turbinate and septum.	Loh et al., 2003
2 yr	Alkaline Button/coin battery	7 hours	Septal perforation and extensive nasal mucosal necrosis.	Loh et al., 2003
3 yr	Alkaline Button/coin battery	3 days	Large septal perforation, extensive nasal mucosal necrosis, right facial cellulitis.	Loh et al., 2003
4 yr	Alkaline Button/coin battery	3 days	Large septal perforation, extensive nasal mucosal erosion and right facial cellulitis.	Loh et al., 2003
4 yr	Button/coin battery	2 days	The mucosa in the right side of the nasal septum was eroded exposing the cartilage. Large central nasal septal perforation 1.2 cm diameter with extensive crusting and granulation tissue was noted in the right side of the nose. Adhesion was also evident over the nasal septum and the lateral wall.	Chua and Tan 2005
4 yr	Button/coin battery	<12 hours	0.5 cm septal perforation	Chua and Tan 2005

[59] Saddle nose is characterized by a loss of height of the nose, because of the collapse of the bridge.
[60] Hyperaemia is the increase of blood flow to different tissues in the body.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
4 yr	Button/coin battery	3 days	Necrotic turbinate tissue in the left anterior nasal space and necrotic cartilage in the right side of the nasal septum. 0.8 cm diameter nasal septal perforation with extensive crusting.	Chua and Tan 2005
4 ½ yr	Button/coin battery	Unknown	Necrosis of mucosal tissue.	Bachmann et al., 2009
4 yr	8 mm Button/coin battery	>2 days	Placed in nose, aspirated to lung, pneumonia, local necrosis and stricture	McLarty et al., 2012
4 yr	15 mm button/coin battery	6 hours	Friable mucosa of the septum, turbinate and nasal floor with no active bleeding.	Fundakowski et al., 2013.
2 yr	11.6 mm button/coin battery from a toy	4 days	Septal perforation, saddle nose	Watanabe et al., 2013
3 yr	Button/coin battery	Unknown	Mucosal damage	Alletag et al., 2014
4 yr	Button/coin battery	>2 days	Large septal perforation	Shepherd et al., 2014
3 yr	Button/coin battery	Unknown	Mucosal lesion	Metterlein et al., 2014
6 yr	Button/coin battery	12 hours	Septal perforation	Liao et al., 2015
2 yr	Button/coin battery	8 hours	Septal perforation	Liao et al., 2015
37 mo	Button/coin battery	2 days	Septal perforation, adhesions between right inferior turbinate and septum	Bakshi et al., 2016
66 mo	Button/coin Battery	2 days	Septal perforation	Bakshi et al., 2016
39 mo	Button/coin battery	4 days	Septal perforation, right chronic maxillary sinusitis[61]	Bakshi et al., 2016
47 mo	Button/coin battery	3 days	Septal perforation, extensive adhesions in bilateral nasal cavities, bilateral chronic maxillary sinusitis	Bakshi et al., 2016
23 mo	Button/coin battery	2 days	Septal perforation, atrophic rhinitis[62] in left nasal cavity	Bakshi et al., 2016
54 mo	Button/coin battery	2 days	Septal perforation, adhesions between left inferior turbinate and septum	Bakshi et al., 2016
64 mo	Button/coin battery	2 days	Septal perforation, saddle nose[63]	Bakshi et al., 2016
50 mo	Button/coin battery	2 days	Septal perforation, extensive adhesions in bilateral nasal cavities, bilateral chronic maxillary sinusitis	Bakshi et al., 2016
28 mo	Button/coin battery	5 days	Septal perforation, granulations[64] over septum surrounding the perforation site	Bakshi et al., 2016
52 mo	Button/coin battery	1 day	Septal perforation, adhesions between nasal septum and right middle turbinate.	Bakshi et al., 2016

[61] A condition in which the sinuses are inflamed causing difficulty in breathing due to nasal blockage.
[62] Atrophic rhinitis is an uncommon and distinct clinical syndrome of progressive atrophy of the nasal mucosa.
[63] Saddle nose is a condition associated with nasal trauma. It is characterized by a loss of height of the nose, because of the collapse of the bridge.
[64]Small, fleshy, beadlike protuberances, consisting of outgrowths of new capillaries, on the surface of a wound that is healing. Also called *granulation tissue*.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
2 yr	Button/coin battery	2 days	3 cm area of necrotic tissue destruction was present on the left along with near complete erosion of the inferior turbinate. Septal perforation	Eliason MJ et al., 2016
13 yr	10 mm Button/coin battery	Unknown	Granulation tissue surrounding battery	Parker et al., 2016
3 yr	Button/coin battery 11-12 mm	3 days	Septal perforation	Chen and Shih 2018
5 yr	Button/coin battery	1 day	Swelling of nose and face. Mucosa of septal cartilage eroded and filled with crust. No perforation.	Ramasamy and Nadarajah 2018
3 yr	Button/coin battery	1 day	Septal perforation	Bakshi 2019
3 yr	Button/coin battery	2 weeks	The right middle turbinate and posterior part of the right inferior turbinate were eroded.	Tuang et al., 2019

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

APPENDIX C

Case Studies of Button/Coin Batteries Impaction in the Ear

Age of Victim	Desc. Of Battery	Impaction Duration	Scenario/Outcome	Reference
Mild Injury				
9 yr	Small watch battery	1 day	Minimal trauma to skin of ear canal. Ear drum intact.	Nivatvongs et al., 2015
More Severe Injury				
8 yr	10 mm button/coin battery from a watch	Unknown	The tympanic membrane was erythematous with a moth-eaten appearance in the area of the battery. Several perforations, separated by thin strands of tympanic membrane noted. Canal skin adjacent to the battery was also ulcerated and friable.	Capo and Lucente 1986
9 yr	Button/coin battery from miniature toy watch	90 min	Moderate erythema[65] of the canal without swelling or erosion.	Landry et al., 1986
12 yr	Button/coin battery from an electronic calculator	8 days	Extensive granulation tissue, perforated tympanic membrane. Conductive hearing loss.	Skinner and Chui 1986
10 yr	Button/coin battery	3 weeks	Tympanic membrane perforation with erosion of skin and bone.	Premachandra and McRae 1990
2 yr	Button/coin battery	24 hours	Tympanic membrane perforation.	Premachandra and McRae 1990
79 yr	Zinc alkaline button/coin battery	3 days	Tympanic membrane perforation.	Premachandra and McRae 1990
13 yr	5mm Button/coin battery	2 days	Presented with 2-day history of left ear pain and symptoms of an upper respiratory tract infection. Pathologic examination of the tissue removed from the ear revealed intense and chronic inflammation with granulation tissue.	Bhisitkul and Dunham 1992
6 yr	2 button/coin batteries from a musical card	Unknown	The deep ear canal skin was severely inflamed and the battery had 'welded' to the tympanic membrane.	Eynon-Lewis et al., 1995
95 yr	Hearing Aid Battery	Unknown	Presented with acute hearing loss and confusion. Foreign Language	Johannsen and Grundtvig 2013

[65]Redness of the skin caused by dilatation and congestion of the capillaries, often a sign of inflammation or infection.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

APPENDIX D

Case Studies of Cylindrical Batteries (deaths are highlighted)

Age of Victim	Desc. Of Battery	Time since ingested	Scenario/Outcome	Reference
No Injury				
38 yr	2 AA batteries	6 year	Batteries were wrapped in a small plastic bag, no damage	Lavon et al., 2008
2 yr	AA battery	2 hrs	No complications	Olivery and Julca 2013
54 yr	5 AA batteries	3 days	No features of obstruction or suggestion of damage to their structural integrity on radiograph. Let batteries pass per rectum	Malliwal and Bhattacharya 2013
36 yr	2 AA batteries	Unknown	No mucosal damage noted in stomach	Hammami et al., 2019
26 yr	AA battery	3 hrs	Passed unremarkable after 3 days	Nuri Kosar and Gorgulu 2021
35 yr	3 cylindrical batteries	13 hrs	Passed unremarkable after 72 hrs.	Pantazopoulos et al., 2021
Injury				
31 yr	Eveready Energizer alkaline c-cell battery	2 weeks	Grand mal seizure, mild diffuse gastritis	Levine et al., 1984
4 yr	1.5 V corroded cylindrical battery	Several min	Sucked on the battery. Esophageal burn	Untersweg et al., 1996
60 yr	2 AA batteries	10 days	Multiple deep ulcers seen throughout the stomach	Kim et al., 2006
36 yr	6 AAA batteries	1 hour	The EKG was abnormal, suggestive of a myocardial infarction. Patient denied chest pain or any other symptoms. Blood levels of cardiac enzymes were all normal. After successful endoscopic removal of the batteries, the EKG was normal again.	Chang et al., 2011
56 yr	AA battery	4 days	Perforation of colon, chemical.	Ribakovs and Uzoigwe 2011
4 yr	AAA battery	4 days	Two fistulas: esophagus to aorta and esophagus to pulmonary artery. Death.	Poison.org[66]
31 yr	5 AAA and 2 AA	>24 hrs	3 deep ulcerations and multiple erosions in stomach	Hammad et al., 2015
37 yr	6 AA and 2 AAA	7 hrs	Superficial mucosal necrosis was clinically evident, but the wall of the stomach appeared viable	Dunphy et al., 2015
30 yr	2 cylindrical batteries	Unknown	Small bowel obstruction, removed surgically	Pararoupa and Bruns-Toepler 2017
51	18 AA batteries	Unknown	ST segment elevations on EKG. No damage to GI. Normal EKG after battery removal	Ordoobadi et al., 2019

[66] Fatal Cases (poison.org)

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

APPENDIX E

Incidences of button/coin batteries impacted in the esophagus.

CPSRMS Case 1724882	21 MOF had swallowed a small coin-sized battery. She was airlifted to the hospital & surgical team examined esophagus and found the battery stuck just above girl's aorta. A pediatric surgeon at the hospital, grasped the battery and pulled it out.
CPSRMS Case 1699426	Guest stated toy fell apart, 4YO son swallowed battery. Guest stated child choked, wasn't breathing, was rushed to ER, had button battery extracted from airway. Guest stated doctor thought toy may be caught in airway/esophagus and operated on child
CPSRMS Case 1712735	My 8 yr old child had a light up fidget spinner. When dropped they fall apart easily. He is special needs and had the light up battery in his mouth and swallowed it. He had surgery to remove the battery as it was lodged in his esophagus in the chest area. The battery caused damage to his tissue in the esophagus.
CPSRMS Case 1761346	1 YOM child was choking and taken to the emergency room. It was discovered that he was choking on a button battery. He was in a coma for 2 months because his vocal chords were damaged and prevented him from breathing on his own.
CPSRMS Case 1787872	On April 17, 2018, [REDACTED]'s little 19-month-old swallowed a button battery that fell out of a knock off [REDACTED] remote. The remote was purchased from [REDACTED] and had no safety features to prevent easy access to the battery. It is believed that the remote was manufactured in China. These and similar dangerous remotes continue to be available for sale on [REDACTED]. The child suffered permanent injuries to her esophagus and continues to treat.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

APPENDIX F

Fatalities with esophagus impaction

CPSRMS Case 1705926	The decedent was a 1-year-old male who on REDACTED DATE, swallowed a button battery. He was admitted to a local hospital and the battery was removed from his esophagus. Erosion from the battery was noted in the esophagus. He was subsequently released home. On REDACTED DATE he was at home and began vomiting blood. After 911 was called, he was transported to a local hospital and died at their Pediatric Emergency Room.
CPSRMS Case 1735478	1 YOF decedent was lethargic and had blood coming from nose. A button battery was found in decedent's stomach. She also had esophageal tear. Surgery was underway and she went into cardiac arrest; was pronounced shortly. COD: complications of foreign body (button battery) ingestion.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

APPENDIX G

Button battery insertions into nose and ear

NEISS Case 110143118	3 YO F SENT OVER FROM DOCTORS OFFICE, PT HAS A BATTERY IN RT EAR. DX FOREIGN BODY RT EAR
NEISS Case 110148166	4YOF HAS FB IN LT NARE/ LT NASAL FB, BUTTON BATTERY
NEISS Case 110210324	7 YOF HAD A SMALL BATTERY IN HER EAR/ FOREIGN BODY TO EAR
NEISS Case 110309448	3YOF STUCK A WATCH BATTERY IN HER NOSE AT HOME. MOM UNABLE TO GET OUT. NO SYMPTOMS. DX FB IN NOSE
NEISS Case 110311747	5 YO FEMALE WITH A BATTERY IN EAR. DX FB EAR
NEISS Case 110419179	4 YO F PUT BUTTON BATTERY UP NOSE-STUCK DX: F.B. (BATTERY) STUCK IN NOSE

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

TAB C

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

DATE: January 11, 2023

TO: Daniel Taxier, Project Manager, Button Batteries Rulemaking
Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences

THROUGH: Rana Balci-Sinha, Ph.D., Director,
Division of Human Factors, Directorate for Engineering Sciences

FROM: Jill Hurley, Engineering Psychologist,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Human Factors Assessment

I. Introduction

In accordance with Reese's Law, CPSC staff recommends that the Commission issue a proposed rule to establish a safety standard that contains performance requirements for consumer products that contain button cell or coin batteries, requiring these batteries be secured in a battery compartment that eliminates or adequately reduces the risk of injury from button cell or coin battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions; and warning label requirements on battery packaging, packaging of a consumer product containing button cell or coin batteries, in accompanying consumer product literature, and directly on the consumer product, as practicable.

For the purposes of this memorandum, button cell and coin batteries are defined as they are in section 5(1) of Reese's Law, "a single cell battery with a diameter greater than the height of the battery." This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), includes the review of incidents to identify product types, child access and interaction with batteries, hazard patterns, why supervision is inadequate to address the hazards, review of warning label requirements in domestic and international standards, and staff's recommendations to address the ingestion hazard associated with button cell and coin batteries.

Staff's recommendations on the format, content, and placement of warning labels align with Reese's Law; in addition, staff recommends additional requirements to inform consumers of the ingestion hazard associated with button cell and coin batteries.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

II. Background

A. Hazard

Button cell and coin batteries present a serious hazard if ingested or inserted into nasal passages or impacted in the ear. Life-threatening and serious injury can occur in as little as 2 hours should a button cell or coin battery lodge in the digestive track, ears, or nose. Battery leakage can cause life threatening burns to the body's internal organs. Symptoms of ingested, inserted, or impacted button cell or coin batteries can mimic common illnesses and often lead to delayed diagnosis (See Tab B, Scorpio, C. 2022).

Over an 11-year period from 2011-2021, staff estimates 54,300 U.S. emergency room visits associated with button cell or coin battery ingestions or insertions into the ear or nose (See Tab A, Topping, J. 2022). Injury and death associated with button cell or coin batteries continues despite efforts to increase public awareness of incidents by the medical community. Injuries and death are compounded, in part, by the rise in household products using button cell and coin batteries as a source of power (Sharpe, 2012, Haddad et al., 2020; Kasture et al., 2020). The number of consumer products that use batteries, especially button cell and/or coin batteries continues to rise. The trend in reducing the size and weight of portable consumer products has increased the demand for smaller and stronger, higher-energy batteries. Staff anticipates child exposures to button cell and coin batteries will continue.

B. Child Behavior

Infants and toddlers are reasonably likely to mouth any object within reach. Mouthing and ingestion of non-food items is a normal part of children's exploratory behavior that contributes to incidents of choking and poisoning (Tulve et al., 2002). This is part of the reason for the ban on small parts for toys intended for children younger than 3 years of age, for example, and the mandatory small-parts warning for toys and games intended for children ages 3 to 6 years. Mouthing of non-food items tends to decrease as the child's age increases; however, it is not uncommon for children over the age 3 years to experience choking or ingestion episodes with objects other than food. (A-Kader, 2010; Orsagh-Yentis et al., 2019; Reilly, 1992; Altman & Ozanne-Smith, 1997).

Unintentional foreign body ingestion is one of the top 5 leading causes for nonfatal emergency department visits in children under the ages of 9 years.[1] Management and treatment for childhood accidental ingestion is well documented in the pediatric medical literature (Kay & Wyllie, 2005; Lee, 2018; Kramer et al., 2015; Conners & Mohseni, 2021). Review of medical literature indicates coins as one of the most common ingested foreign objects by children that are found in the home environment. Coins and batteries share commonality in that they are small, round, shiny, and relatively smooth.

[1] Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS) [Online]. (2003). National Center for Injury Prevention and Control, Centers for Disease Control and Prevention. Available from: URL: www.cdc.gov/ncipc/wisqars. [10/1/2022].

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Children are prone to inserting other small shiny objects into their ears and nose, such as jewelry, BBs or pellets, beads, toy parts, and button batteries (Svider et al. (2015); Heim & Maughan, 2007). See Tab B, Scorpio, C. (2022) for details regarding ear and nasal insertion.

Children develop rapidly in the early phases of life in both physical and cognitive growth. Parents are often surprised by what their child can do. Around the age of 3 months, children begin to grasp objects placed in their hand, and by 6 months of age most children have mastered reaching for and grasping objects within their reach (Frankenburg et al., 1990). Beginning around 8 months, children are learning to stand while supporting themselves on objects, such as toys and furniture. By 9 months, children are working on pulling themselves to a standing position. So, by 9 months, children have learned to reach and grasp items within reach and stand. Around 10 months of age, children are learning to stand without holding on and likely accomplished taking a few steps before 12 months. Between the ages of 12 to 18 months of age, children progress from walking, running, and climbing. Increased mobility, physical strength, and coordination, combined with an inherent predisposition towards curiosity and exploration can lead to dangerous situations as young children have little regard for safety (Richards et al., 2020).

C. Source of Access

According to the National Capital Poison Center, 69 deaths occurred due to ingestion of button/coin batteries from 1997 to June 2022.[2] The sources of these batteries, when reported, included movie camera, camera flash, watch (2), camera (2), remote control (8), garage door opener, electric candle, toy (4), remote car alarm, torch, tea light (spare battery), 3D TV glasses, key fob[3], and loose (battery fed to child by older brother).

Other sources of ingested batteries, when reported, include camera (7), watch (7), portable CD player, hair dryer, handheld computer game (2), calculator (5), toy (13), sole of shoe (2), ab belt (exerciser), personal digital organizer, talking book, digital ear thermometer (2)[4], remote control (26), flashlight (2), bicycle computer, computer, scale (7), singing card, battery package (3), key fob (7), loose, guitar tuner, night light, baby monitor, lighted tweezers, book light, video camera, keychain, 3D TV glasses, portable speaker, lighted ring, and glucometer.

Based on staff's assessment of the incident data from 2011-2021, staff observed the following common hazard patterns for how children were exposed to batteries (see Tab D, deGrano, F. (2022):

- victim removed battery from a consumer product,
- battery compartment broke or failed to contain the battery as intended,
- victim removed battery from battery packaging, or
- battery was loose and accessed by victim.

[2] https://www.poison.org/battery/fatalcases
[3] The data does not distinguish key fobs from consumer product fobs. Vehicle key fobs are regulated by the National Highway Traffic Safety Administration (NHTSA) and do not fall within CPSC jurisdiction.
[4] Body temperature thermometers are medical devices and do not fall within CPSC jurisdiction.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

D. Supervision

Battery ingestion, nasal insertion, and/or ear impaction can occur in a matter of minutes. Many incidents are not witnessed, meaning the caregiver was not directly looking at the child.

Because even young children are left unsupervised for a few minutes or more in a room that is considered safe, such as a bedroom or family room, staff conclude that parental supervision is unlikely to be effective to eliminate or reduce the subject hazard. People cannot be perfectly attentive, particularly over long periods of time, regardless of their desire to do so (Wickens & Hollands, 2000). Caregivers must perform other tasks, may be exposed to more salient stimuli, or may be subject to other stressors, such as being responsible for supervising more than one child. In fact, research by Morrongiello and colleagues (2006) indicates that older toddlers and preschool children (2 through 5 years old) are regularly out of view of a supervising parent for about 20 percent of their awake time at home, and are not within visual range or hearing distance for about 4 percent of awake time in the home. The most common rooms in which children were left alone and unsupervised were the living or family room and the bedroom.

Most caregivers recognize obvious hazards such as a hot stove, cleaners and chemicals, or stairs, and act to guard against through baby gates and cabinet locks. Such action is taken when caregivers perceive danger. Everyday items such as television remotes, clothing, key chains, and toys do not present a high level of concern. Consumers may not be aware of all the products that include button/coin batteries and are unlikely to pay attention to how to get to the battery until it needs to be replaced. Some reported incidents demonstrate that at times the child brings the product with a missing battery to the parent or some parents notice that the product is missing a battery.

E. Addressability of Incidents involving Button and Coin Batteries

In accordance with Reese's Law, staff's recommendations for the performance requirements involving consumer products that contain button cell or coin batteries are described Tab D (deGrano, F. 2022). One of these requirements is to design the battery compartments such that it requires a household tool or coin to open, and the other method requires two independent and simultaneous actions performed by hand, a type of "double-action" release mechanism. Similar requirements are used throughout children's juvenile product standards as well as standards involving common household items that may be hazardous to children. Younger children may lack the required cognitive ability and fine motor coordination to perform the necessary actions to access battery compartments that use either of these designs and therefore the likelihood of opening a battery compartment would be reduced for those children.

In addition, per Reese's Law, battery packaging is required to comply with federal child-resistant packaging regulations, if such batteries are sold separately or included separately with a product.

Both of these requirements directly address three of the four sources of access identified in the incidents: victim removed battery from product's battery compartment, battery compartment failed to contain the battery, or victim removed battery from battery packaging.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

III. Staff Analysis of Applicable Standards

ESHF staff evaluated a number of domestic and international mandatory and voluntary standards associated with button cell or coin batteries and consumer products containing such batteries. See Appendix for a detailed analysis of these standards.

In assessing the warning labels included in mandatory and voluntary standards, ESHF staff took into consideration the factors such as placement, format, and content of warning labels to increase the likelihood that consumers notice, read, understand, and heed the labels. These factors are listed below.

Placement:

- Warnings should first be visible and noticeable. Warnings that are placed directly on the product will have higher noticeability compared to the warnings listed in a "distant" instruction manual (Wogalter et al., 1987). The layout of the environment and the tasks that the user will perform related to the product should be taken into account in determining the location of the warning label (Wogalter and Leonard, 1999). Warnings that are spatially close to the relevant task or situation have a considerable effect on the level of compliance. If a warning label interferes with the task, effectiveness increases significantly (Frantz and Rhoades, 1993; Wogalter et al., 1993). Staff considered the requirements and best practices in the standards regarding the location of the labels.
- Websites or apps that enable consumers to purchase a product online are considered points of sale and the first encounter that consumers face to be adequately informed about potential hazards related to a product. Given the increase in online shopping, consumers are exposed to warnings or other safety information on product packaging only after they receive the delivery of the product, as opposed to while making a purchasing decision in a brick-and-mortar store. To ensure consumers will see the warnings at the time they are making buying decisions online, staff considered whether the standard includes requirements for online warning labels.

Format:

- Users may notice the warning label but not stop to review it. Attention must be maintained on the message for some time so that the meaning could be extracted from the material (Wogalter and Leonard, 1999). If the warning message is brief, the information could be extracted very quickly; however, further design features are needed to keep the attention of the user for longer messages. Conspicuity is essential to getting a warning noticed. Signal words, colors, graphics, and placement all increase conspicuity. The salience of a visual warning can be enhanced using (1) large, bold print, (2) high contrast, (3) color, (4) borders, (5) pictorial symbols, and (6) special effects like flashing lights (Wogalter, Conzola, & Smith-Jackson, 2002). Pictorial symbols increase the notice ability of the warnings because they help to capture user's attention (Wogalter and Leonard 1999). Graphic warnings induce an emotional response, increase memory and awareness of the risks, and reinforce motivations to avoid the risks more than the text warnings do (Hammond et al., 2007). Research has shown that pictorial symbols and icons make warnings more noticeable and easier to detect than warnings without

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

such symbols and icons (Wogalter, Dejoy, & Laughery, 1999). Pictograms are also helpful for users with limited or no English literacy. However, the design of effective graphics can be difficult. To avoid confusing consumers, a warning pictogram should be developed with an empirical study and well tested on the target audience. Staff considered the requirements and best practices about formatting characteristics and pictorial symbols in the standards. The "Keep out of Reach of Children" icon with a small arrow pointing upwards next to the object being held by an adult has been internationally recognized, tested for comprehension and is part of ISO 7010 — Graphical symbols — Safety colours and safety signs, coded as M055.[5]

Content:

- A proper hazard connotation should be used, for example the DANGER word for hazards where serious injury or death will occur or the WARNING panel for serious injuries that might occur, if warning compliance is not followed. According to ANSI Z535.4 (2011), these signal words are to be accompanied by specific colors (red for DANGER, orange for WARNING, and yellow for CAUTION). The warning messages should explain the nature of the hazard, the consequences of the hazard, and give instructions on how to avoid the hazard (Wogalter and Laughery, 2006).
- Providing more explicit or detailed information in a warning has been found to increase warning effectiveness (Laughery & Smith, 2006), by increasing the perception of injury severity and perceived hazard (DeJoy, 1999.). Vividness has been found to increase message salience, which triggers one's motivation to act (Murray-Johnson & Witte, 2003).
- Injury severity is believed to be a more important dimension than the likelihood of injury in precautionary behavior (DeJoy, 1999b and Wogalter et al., 1991). Staff considered the description of the hazard, how to avoid the hazard and consequences if the hazard avoidance behaviors are not followed, while reviewing the standards.

IV. Staff Recommendations for Marking and Labeling

ESHF staff has recommendations for warning labels in accordance with Reese's Law. Warning label requirements specified in Reese's Law include the following:

(A) Warning label to be included on the packaging of button cell or coin batteries and the packaging of a consumer product containing button cell or coin batteries;

(B) Warning label to be included in any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries; and

[5] According to https://nsi.isolutions.iso.org/obp/ui#iso:grs:7010:M055, "test data obtained according to ISO 9186-1 are available from more than one country. Findings from testing showed that the safety sign exceeded the criteria of acceptability. A supplementary text sign may be used to increase comprehension. If the safety sign is supplemented by manuals, instructions or training, a supplementary text sign may not be required."

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

(C) Warning label to be included, as practicable,

(i) directly on a consumer product containing button cell or coin batteries in a manner that is visible to the consumer upon installation or replacement of the button cell or coin battery; or

(ii) in the case of a product for which the battery is not intended to be replaced or installed by the consumer, to be included directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information must be placed on the packaging or instructions.

Reese's Law also states that warning labels must: (1) clearly identify the hazard of ingestion, and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice.

In addition to the required warnings specified in Reese's Law, staff has recommendations to improve safety communication to consumers. Section 27(e) of the CPSA allows the Commission to require any manufacturer of consumer products to provide to the Commission performance and technical data related to performance and safety as may be required to carry out the purposes of the Act, and to give such notification of such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser of such product for purposes other than resale, as it determines necessary to carry out the purposes of this Act. One of the purposes of the CPSA listed in section 2 of the CPSA is to protect the public against unreasonable risks of injury associated with consumer products. Including staff's recommended information at the point of sale, as additional labeling on packaging or products (when visible in the packaging), would help carry out this purpose of the CPSA.

Staff's recommendations for warning labels on battery packaging, packaging of the consumer product, consumer product, and instructions/manuals accompanying the consumer product are listed below. Recommendations include preferable formatting, wording, and placement related specifications that staff concludes are appropriate to include based on warning label research.

A. General Warning Label Requirements

All recommended warning labels follow requirements found in ANSI Z535.4 American National Standard Product Safety Signs and Labels, which is the primary voluntary consensus standard providing guidelines for the design of safety signs and labels for application to products. The standard includes recommendations for the design, application, use, and placement of warning labels, such as having the signal word "WARNING" and the safety alert symbol of an equilateral triangle surrounding an exclamation mark. Staff recommends the following generic requirements to apply to all warning labels.

Generic Format Requirements for the recommended Warning Labels:

1. All warnings must be clearly visible, prominent, legible, and permanently marked.
2. Warnings must be in contrasting color to the background onto which it is printed.
3. Warnings must be in English.
4. The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.

5. The signal word WARNING must be in black letters on an orange background. The signal word must appear in sans serif letters in upper case only.
6. Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels to get the attention of the reader.
7. For labels that are provided on a sticker, hang tag, instructions or manual, the safety alert symbol and the signal word "WARNING" must be at least 0.2 in. (5 mm) high. The remainder of the text must be in characters whose upper case must be at least 0.1 in. (2.5 mm), except where otherwise specified.
8. For labels that are required to be on the packaging of button cell and coin batteries, the packaging of consumer products containing such batteries, and directly on consumer products, text size must be dependent on the area of the principal display panel. Text size must be determined based on Table 1 which is based on the information found in 16 CFR part 1500.19(d)(7).
    a. The "principal display panel" is defined as the display panel for a retail package of button cell or coin batteries or retail package of consumer product containing such batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.
    b. The "product display panel" means the surface area on, near, or in the battery compartment. For consumer products with replaceable button cell or coin batteries, the product display panel must be visible while a consumer installs or replaces the button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel must be visible upon access to the battery compartment.
    c. The "secondary display panel" means a display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

Table 1. Letter size for recommended warning labels: Information based on 16 CFR part 1500.19(d)(7).

Letter size measurements in inches								
Display Area: Inches^2	*0–2*	*+2–5*	*+5–10*	*+10–15*	*+15–30*	*+30–100*	*+100–400*	*+400*
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display Area: cm^2	*0-13*	*+13-32*	*+32-65*	*+65-97*	*+97-194*	*+194-645*	*+645-2,581*	*+2,581*
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397

ESHF staff evaluated several Industry standards and does not conclude any one standard adequately addresses Reese's Law (see Appendix), however, when requirements of various standards are combined, they present succinct warnings to address the ingestion hazard

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

associated with button cell or coin batteries. Therefore, staff developed warning labels and a system for use. Staff recommends consistent statements and placement on product and packaging across battery types. Staff proposed warning language aims to improve safety communication and enhance consumer recognition of warning labels and icons depicting the ingestion hazard and severity associated with button cell and coin batteries.

B. Warning Label Requirements for the Button Cell or Coin Battery Packaging

1. The principal display panel of the packaging must include the warning in Figure 1 as stated. The language included in this label clearly identifies the ingestion hazard and severe consequences. Staff recommends the language pertaining to internal chemical burns to inform consumers that this is not simply an instance where the battery can pass through the body but has a much more severe outcome in a short amount of time. If not fully discharged, used batteries may still present a severe risk for injury. In accordance with the Law, staff recommends the "Keep out of Reach" text on the label be accompanied by the icon to quickly convey the safety message and direct the reader's attention to the label. The icon incorporated with the warning must be at least 8 mm in diameter.

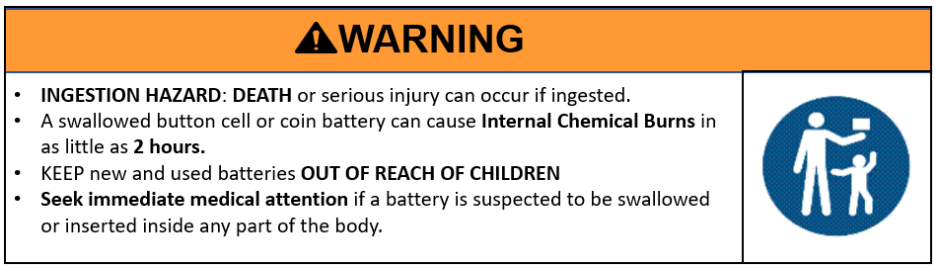


Figure 1. Proposed warning of ingestion hazard for battery packaging

Staff recommends including a warning regarding "insertion" in the last bullet on this warning, because insertions into the nose can lead to ingestion, including the hazards associated with oral ingestions.

2. If space prohibits the full warning, (See Table 1) the icon shown in Figure 2 must be placed on the principal display panel with the text shown in Figure 3 on the secondary display panel. The icon must be at least 20 mm in diameter for visibility.

3. Button cell or coin batteries included separately with the consumer product (but not yet installed in the product) must contain the warning label in Figure 1 on the principal display panel. If space prohibits the full warning, the icon shown in Figure 2 must be placed on the principal display panel with the text shown in Figure 3 on the secondary display panel, and the icon must be at least 20 mm in diameter for visibility. Once the product packaging is opened, spare batteries need to be stored out of reach of children. The goal is to ensure consumers have the opportunity to see the appropriate safety related warning information and take appropriate action to store spare batteries until needed.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Figure 2. Keep out of reach icon.

⚠WARNING **INGESTION HAZARD ● DEATH** or serious injury can occur ● A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours** ● KEEP new and used batteries **OUT OF REACH OF CHILDREN** ● **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 3. Example warning on the secondary display panel of battery packaging for limited space applications

C. Warning Label Requirements for Packaging of the Consumer Product containing Button Cell or Coin Batteries

1. The principal display panel must contain the warning in Figure 4. This is the same wording as shown in Figure 8 with the addition of "This produce contains a button cell or coin battery" after the word "INGESTION HAZARD." This is to highlight that the consumer product contains a button cell or coin battery. Staff assesses that this introduction is critical to the rest of the message by providing context for the message. The icon must be at least 8 mm in diameter.

⚠WARNING

- **INGESTION HAZARD**: This product contains a button cell or coin battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours.**
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 4. Proposed warning to indicate the presence of a button cell or coin battery and the ingestion hazard for consumer product packaging.

2. Consumer products that do not include packaging must have the warning in Figure 4 affixed to the product with a hang tag or sticker label.
3. Warning information must be on the principal display panel of the package. If space does not permit (see Table 1), the principal display panel of the packaging must include the warning in Figure 5 in a conspicuous[6] location. The icon must be at least 8 mm in diameter. The remaining statements, as shown in Figure 6, must be on the secondary display panel.

[6] Defined as legible, separately, and distinctively from other wording or designs. Clearly visible to the intended audience with a color contrasting to the background on which it appears (ASTM F963 section 5.3.6).

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

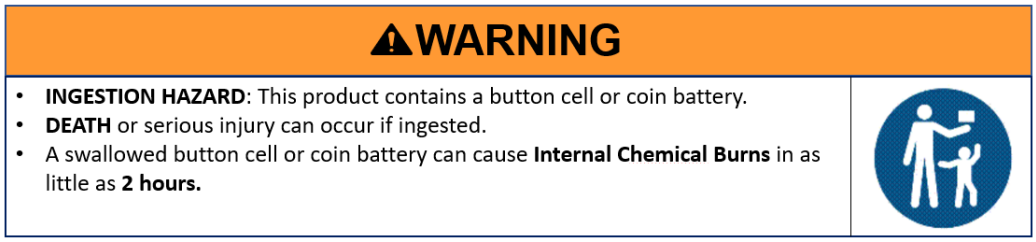


Figure 5. Proposed abbreviated warning for the principal display panel.

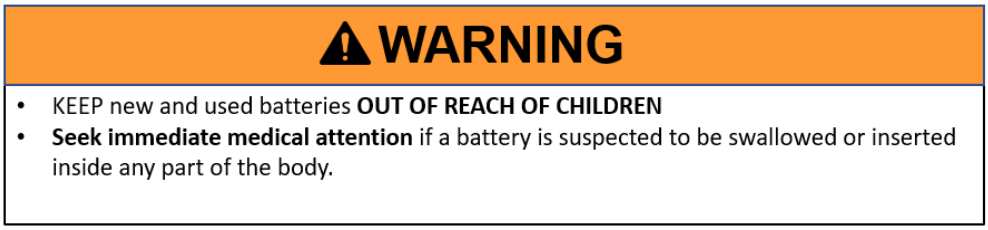


Figure 6. Proposed abbreviated warning for the secondary display panel.

D. Warning Label Requirements for Consumer Products containing Button Cell or Coin Batteries

1. Reese's Law requires the consumer product to include a warning label, "as practicable." Staff recommends the following approach to operationalize how manufacturers can meet this requirement in practical terms. A consumer product must be permanently marked with an ingestion warning on the product display panel as shown in Figure 7.

Figure 7. Proposed on-product warning label.

   - If space on the product is limited (See Table 1), use of the internationally recognized "Warning: Contains coin battery"[7] icon shown in Figure 8 is permitted without text. The icon must be at least 7 mm in width and 9 mm in height and must be on the product display panel and must be in yellow with black outlines as shown in Figure 8. The icon must be defined in accompanying printed materials such as instructions, manual, insert, or hangtag.

[7] Staff recognizes that this symbol specifies coin and not button batteries, however, based on incident data, consumers often use the term button and coin battery interchangeably.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Figure 8. Internationally recognized safety alert symbol to indicate “Warning: Contains coin battery”

Figure 9 demonstrates the scaled version of the above icon on a product containing a battery that has a 20 mm diameter as well as a product containing a 5 mm battery. Staff concludes that most consumer products can accommodate the icon.

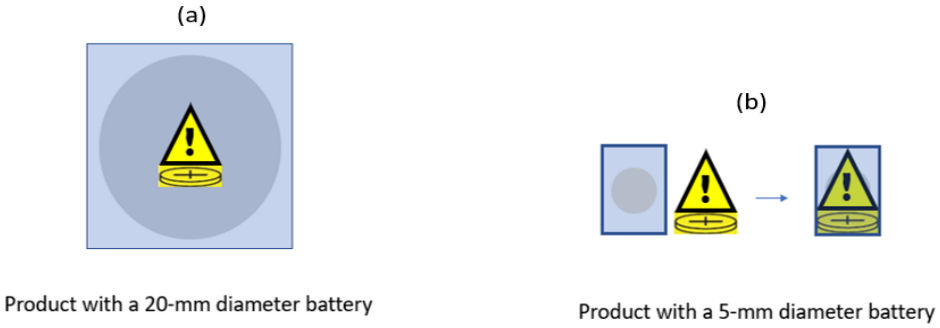


Figure 9 (a) consumer product with 20mm diameter battery and icon, (b) consumer product containing a 5mm battery and icon.

2. However, if the product itself is too small (See Table 1) to include the warning in Figure 7 or the icon (Figure 8) alone, it must,
   - Have packaging containing the warning (see requirements for packaging of consumer products), or
   - Contain a hangtag or sticker label with the full warnings (see requirements for packaging of consumer products).

E. Instructions/Manuals accompanying the Consumer Product containing Button Cell or Coin Batteries

1. Instructions and manuals, if provided, must include the warning label shown in Figure 4.

F. Point of Sale Requirements

To protect the public against the unreasonable risk of injury and death to children 6 years old and younger from button cell and coin battery ingestion, staff recommends the following performance and technical data be required at the point of sale pursuant to section 27(e) of the CPSA.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

1. Icon Requirements for the Button Cell and Coin Battery

Staff recommends requiring the "Keep out of Reach" icon be used on button cell or coin batteries that are visible within the packaging, where practicable, as an additional safety warning should the battery be removed from its packaging and not immediately installed in a consumer product. Consumers will see the "Keep out of Reach" icon at the point of sale. The icon will remain visible once the battery is removed from its package but not yet inserted into the consumer product. The goal is to inform the consumer of a hazard and to address incidents associated with batteries loose in the environment so that they can take the appropriate action of keeping the battery out of reach of children.

- Button cell and coin batteries must contain the "Keep out of Reach" icon (Figure 9) durably and indelibly marked where size permits.

    a. The icon must be, at a minimum 6 mm in diameter or 30% of the diameter of the battery.
    b. Durable indelibly marked include but are not limited to engraving, etching, embossing, and stamping. Figure 10 shows an example of durable and indelibly marked coin battery with the etched icon.

Figure 10. Example battery with an etched "Keep out of Reach" icon.

2. Websites or Apps that enable consumers to purchase products online

Given the increasing number of online sales, staff assesses that point of purchase includes online sales and consumers should be able to view safety information while purchasing products online. Consumer products containing button cell or coin batteries offered for sale online must include the applicable warnings[8] discussed above on the website or app that enables consumers to purchase a product. Otherwise, consumers are not exposed to the warnings until they receive the physical product and knowing the hazard associated with button cell or coin batteries may influence their purchasing decision or the actions they may take to avoid the hazard. Consistent with the limitations under section 27(e) of the CPSA, this recommended requirement would be limited to manufacturer (or importer) websites that allow for consumer purchase of the product.

Online sales and advertising must include the warning in Figure 4 clearly visible, prominent, and legible next to the product description or near the product image or near the product price so that consumers will notice it.

[8] For the sale of button cell or coin batteries, the applicable warnings are those for the battery packaging. For the sale of consumer products, the applicable warnings are those for the consumer product packaging.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

G. Other Battery Safety Information

In addition to the ingestion hazard warning, staff recommends requiring that the following information be placed on the battery packaging, consumer product packaging, and instructions. Consumers must be aware of safe handling and use of batteries to reduce the risk of battery ingestion, battery leakage, fire and/or explosion hazards that could lead to personal injury. Staff recommends the following additional safety information pursuant Reese's Law and to Section 27(e) of the CPSA:

1. Battery packaging:

The principal display panel or secondary display panel of the battery packaging must include the following:

- "Keep in original package until ready to use."

  This statement intends to instruct consumers to leave batteries in child resistant packaging.

- "Remove and immediately dispose of used batteries."

  This sentence reminds consumers how to prevent ingestion hazards from used batteries.

- "Call a local poison control center for treatment information."

  This sentence corresponds with the action to "immediately seek medical attention" and provides consumers with a resource.

- Battery type (*e.g.* LR44, CR2032)
- Battery chemistry (e.g. silver oxide button or lithium)
- Nominal voltage

  Having battery type, chemistry, and voltage on the packaging constitutes performance and technical data that may help identify the battery if an ingestion is suspected. For example, lithium button cell or coin batteries are associated with a higher likelihood of injury or death, in part because they have a greater voltage than other button cell or coin batteries. If a button cell or coin battery is ingested, knowing this information could assist medical providers to assess the severity of the risk of injury, and to treat the patient accordingly. The compatible battery type and voltage information on the product packaging will also help consumers avoid any hazards associated with using incompatible batteries, such as leakage, fire and/or explosion hazards, and reduce the risk of a loose batteries resulting from selection of the wrong battery. There have been incidents of children ingesting loose battery cells.

- Year and month or week of manufacture or expiration date
- Name or trademark of the manufacturer or supplier

  Identification of manufacture date and other manufacturer information is technical data that may facilitate recalls resulting from ingestion of button or coin batteries.

- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

This statement is intended to reduce the chance of consumers mixing batteries as described; mixing batteries can contribute to battery leakage, fire and/or explosion hazards that could lead to personal injury. The statement will better inform the consumer to use the correct type of battery cell that is called for the consumer product to minimize loose cells, such as the consumer taking a battery cell from the battery packaging and then realizing that it is the incorrect brand or type of battery. There have been incidents of children ingesting loose battery cells.

- "Ensure the batteries are installed correctly according to polarity (+ and -)."

The reminder statement is to inform the consumer that installing the battery cells with the correct polarity will properly operate the consumer product. Incorrect installation may result in the consumer removing the battery cells (loose cells) to install another set of battery cells. There have been incidents of children ingesting loose battery cells. Batteries installed with the wrong polarity can leak or explode.

- "Remove and immediately discard batteries from equipment not used for an extended period of time."

This statement is intended to ensure consumers immediately dispose of batteries in unused products, because if left for an extended amount of time these batteries can leak, discharge, or explode unexpectedly. Used battery cells still have sufficient energy to cause damage if ingested. There have been incidents of children ingesting loose battery cells.

- "Non-rechargeable batteries are not to be recharged."

This statement enhances safety because placing non-rechargeable batteries in a charger can cause battery leakage, fire and/or exploding hazards. This statement is intended to ensure consumers do not leave out or attempt to recharge non-rechargeable batteries. There have been incidents of children ingesting loose battery cells.

- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

This statement explains how the improper operation of a battery may result in injuries from chemical burns. Damaged battery cells may leak toxic chemicals that poses a risk when ingested.

2. Consumer product packaging:

The principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must include the following:

- Products with non-replaceable batteries must include a statement indicating the product contains non-replaceable batteries.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

If a consumer attempts to replace a non-replaceable battery, this action may damage the consumer product or the battery, and contribute to battery leakage, fire and/or explosion hazards. This may also cause the original or the replacement battery to become accessible, contributing to the ingestion hazard.

The following requirements were previously described for battery packaging, and are also required on either the principal display panel or secondary display panel of the consumer product packaging, or in the absence of consumer product packaging, the accompanying sticker or hangtag:

- Battery type (*e.g.* LR44, CR2032)
- Nominal voltage

3. Instructions and manuals:

Instructions and manuals, when provided with consumer products, must include the following additional battery safety-related information that is also required on the battery packaging:

- "Remove and immediately dispose of used batteries."
- "Even used batteries may cause severe injury or death."
- "Call a local poison control center for treatment information."
- Battery type (e.g. LR44, CR2032)
- Nominal voltage
- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."
- "Remove and immediately discard batteries from equipment not used for an extended period of time."
- "Non-rechargeable batteries are not to be recharged."
- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

If instructions or manuals are not provided with the consumer product, this information must be present on the principal display panel or the secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label. This ensures the consumer has the opportunity to see the appropriate safety-related information, whether the consumer product is supplied with a button cell or coin battery or not.

4. Battery Disposal Information

Battery packaging, product packaging and instructions (or any literature provided) must include guidance on battery disposal. Statements must advise consumers who to contact for disposal methods, for example, contact your local hazardous waste authority or find a local recycling center.[9] This statement should recommend disposal in a way that is inaccessible to children. Button cell or coin batteries which are not disposed of properly and promptly can be accessed by children and become an ingestion hazard. Staff are aware of incidents involving loose button cell

[9] U.S. Environmental Protection Agency recommends contacting local recycling centers and recommends two websites: Earth911 and Call2Recycle. Used Household Batteries | US EPA. https://www.epa.gov/recycle/used-household-batteries

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

or coin batteries which were improperly disposed of, including a loose button cell or coin battery that was involved in a death.

H. Zinc Air Batteries

The definition of button cell and coin batteries in Reese's Law appears to include zinc-air hearing aid batteries. Zinc-air batteries, based on chemistry, design, and functional use, present low risk for electrolyte leakage and becoming stuck in the esophagus if ingested (See Tab B, Scorpio, C. (2022). Staff's review of reported incident data (e.g., excluding NEISS) did not show any fatalities associated with zinc-air batteries (See Tab A, Topping, J. (2022). Because zinc-air batteries do not present a risk of ingestion (with chemical or hydroxide burns), staff recommends excluding zinc-air button cell or coin batteries from warning label requirements.

V. Conclusion

ESHF staff evaluated the applicable domestic and international standards for button cell and coin batteries and provided recommended warning labels and additional safety information to inform and educate consumers that are in line with the requirements specified in Reese's Law. The exact recommended language on warnings are included in Tab G. Staff requests comments on all staff recommendations, specifically on the following topics:

- Should all coin and button battery packaging include the warning label on the principal display panel?
- Staff seeks comments on the intention to allow the 20 mm "Keep out of Reach" icon alone on the principal display panel as a sufficient warning to address ingestion and other hazards associated with button cell or coin batteries.
- Is the content included in section "*C. Other Battery Safety Information"* sufficient to address ingestion and other hazards associated with button cell or coin batteries?
- Is the content and location adequate for the warning label on websites or apps that enable consumers to purchase a product online sufficient to address ingestion and other hazards associated with button cell or coin batteries?
- Should the safety symbol shown in Figure 8 be required on consumer products containing button cell or coin batteries and in the yellow color shown?
- Staff intends to require the "Keep out of Reach" icon on the button cell and coin battery where feasible and seeks comments related to this requirement.
- Should zinc-air battery packaging be exempt from all or part of the warning labels requirement.
- Whether there are any consumer products containing zinc-air batteries (*i.e.*, not medical devices such as hearing aids), and if so, whether these products can or should be exempt from all or part of the warning label requirement.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

References

A-Kader. (2010) Foreign body ingestion: children like to put objects in their mouth. World J Pediatrics, Vol 6 No 4 . November 15, 2010. www.wjpch.com.

Altman, A., Ozanne-Smith, J. (1997). Non-fatal asphyxiation and foreign body ingestion in children 0-14 years. *Injury Prevention.* 3:176-182.

American National Standards Institute. (2011). *ANSI Z535.4. American national standard: Product safety signs and labels*. Rosslyn, VA: National Electrical Manufacturers Association

ASTM International. *F963-19 Standard Consumer Safety Specification for Toy Safety*. ASTM International, West Conshohocken, PA, Published 2016, www.astm.org.

Conners GP,& Mohseni M. Pediatric Foreign Body Ingestion. [Updated 2021 Jul 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430915/ -.(accessed 4/12/22) Pediatric Foreign Body Ingestion - StatPearls - NCBI Bookshelf (nih.gov).

DeJoy, D. M. (1999a). Attitudes and Beliefs. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.), Warnings and risk communication (pp. 123–148). Philadelphia: Taylor & Francis.

DeJoy, D. M. (1999b). Motivation. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.), Warnings and risk communication (pp. 221–244). Philadelphia: Taylor & Francis.

Frantz, J. P.; Rhoades, T. P. (1993). A Task-Analytic Approach to the Temporal and Spatial Placement of Product Warnings. Human Factors: The Journal of the Human Factors and Ergonomics Society, 35(4), pp. 719-730.

Frankenburg, W.K., Dodds, J., Archer, P. (1990). The DENVER II Technical Manual 1990, Denver Developmental Materials, Denver, CO.

Gummin, D. G., Mowry, J. B., Beuhler, M. C., Spyker, D. A., Bronstein, A. C., Rivers, L. J., Pham, N. P. T., Weber, J. (2021). 2020 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 38th Annual Report, Clinical Toxicology, 59:12, 1282-1501, DOI: 10.1080/15563650.2021.1989785. https://doi.org/10.1080/15563650.2021.1989785.
Haddad, N., Wilson, J. D., Fard, D., & Levi, J. R. (2020). Pediatric button battery ingestion: Publication trends in the literature. *American Journal of Otolaryngol*. 41(3), https://doi.org/10.1016/j.amjoto.2020.102401.

Heim, S.W., & Maughan, K.L. (2007). Foreign Bodies in the ear, nose, and throat. *American Academy of Family Physicians, 76*, p.1186-1189.

Kasture, R. L., Gawade, S., Naik, S. P., & Patil, R. (date). Button Cell Battery Ingestion in Children and their Outcome. Retrieved 3.28.2022 https://www.themmj.in/wp-content/uploads/2021/12/MIMER_42_2020_8.pdf.

Kay, M., & Wyllie, R. (2005). Pediatric foreign bodies and their management. 7(3):212-8.

Laughery K. R., & Smith D. P. (2006). Explicit information in warnings. In Wogalter M.S. (Ed.), Handbook of warnings (pp. 419–428). Mahwah, NJ: Lawrence Erlbaum Associates.
Lee, J.H., (2018) Foreign Body Ingestion in Children. Clinical Endoscopy, 51:129-136.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Morbidity and Mortality Weekly Report (2012). *Injuries form Batteries Among Children ages <13 years-United States, 1995-2010*. Center for Disease control and Prevention, 61(34).

Morrongiello, B. (2005).Caregiver Supervision and Child-Injury Risk: I. Issues in defining and measuring supervision; II. Findings and directions for future research.

Morrongiello, B. A., Corbett, M., McCourt, M., & Johnston, N. (2006). Understanding unintentional injury-risk in young children I. The nature and scope of caregiver supervision of children at home. *Journal of Pediatric Psychology*, 31(6): 529–539.

Orsagh-Yentis D, McAdams RJ, Roberts KJ, et al. (2019). Foreign-Body Ingestions of Young Children Treated in US Emergency Departments: 1995–2015. *Pediatrics*. 143(5):e20181988.

Reilly, J. (1992, Fall). Airway Foreign Bodies: Update and Analysis. Int Anesthesiol Clin.30(4):49-55.

Richards, M.N., Putnick, D.L., Suwalsky, J.T.D., & Bornstein, M.H. (2020). Age Determination Guidelines: Relating Consumer Product Characteristics to the Skills, Play Behaviors, and Interests of Children (K.H. Phillips & J. Hurley, Eds.). Washington, DC: U.S. Consumer Product Safety Commission.

Sharp, S. J., Rochette, L. M., & Smith, G. A. (2012). Pediatric battery-related emergency department visits in the United States, 1990-2009. Pediatrics. 129(6), 1111–7.

Svider, P.F., Vong, A., Sheyn, A., Bojrab, D.I., Hong, R. S., Eloy, J.A., and Folbe, A.J. (2015). What are we putting in our ears? A consumer product analysis of aural foreign bodies. The Laryngoscope. 125, 709-714.

Tulve, N., Suggs, J., McCurdy, T., Cohen-Hubal, E., & Moya, J. (2002). Frequency of mouthing behavior in young children. *Journal of Exposure Analysis and Environmental Epidemiology*. 12, 259 – 264.

Wickens, C. D., & Hollands, J. G. (2000). Engineering Psychology and Human Performance (3rd Ed.). Upper Saddle River, NJ: Prentice Hall (pp. 714-715).

Wogalter, M. S., Brelsford, J. W., Desaulniers, D. R., & Laughery, K. R. (1991). Consumer product warnings: The role of hazard perception. Journal of Safety Research, 22(2), 71–82.

Wogalter, M. S., Forbes, R. M., Van't Slot, L. J. and Bariow, T. (1993). Facilitating communication of label information and warnings by increasing the surface area and print size on small product containers' in Proc Interface 93. Human Factors Society.

Wogalter, M.S., DeJoy, D.M., Laughery, K.R. (1999). Warnings and Risk Communication. Taylor and Francis, Philadelphia, PA.

Wogalter, M. S. and Leonard, S. D. (1999). Attention Capture and Maintenance. In M. S. Wogalter, D. M. DeJoy, & K. R. Laughery (Eds.), Warnings and Risk Communication (pp. 123–148). Philadelphia: Taylor & Francis.

Wogalter, M.S., Conzola, V. C., & Smith-Jackson, T. L. (2002). Research-based guidelines for warning design and evaluation. Applied Ergonomics, 33, 219-230.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Appendix - Analysis of Warning Labels in Mandatory and Voluntary Standards

A. U. S. Mandatory Standards

Staff evaluated existing standards that contain labeling requirements for button and coin batteries and how the safety information is communicated to consumers. (See ESMC memo for test requirements for battery accessibility). Currently, only one mandatory standard exists, *ASTM F963 Standard Consumer Safety Specification for Toy Safety S*tandard (Toy Standard), which is incorporated by reference in 16 CFR part 1250.[10] This standard sets forth uniform methods of addressing mechanical and chemical safety hazards and associated safety messaging in toys that are intended for children.

1. ASTM F963, Standard Consumer Safety Specification for Toy Safety

Battery

The standard does not include requirements associated with safety information on batteries.

Product

Safety labeling for toys that use batteries include, but are not limited to, the type, size, and number of batteries. Requirements on the physical toy relate to electrical concerns and must include the battery polarity, size, and voltage. Should the toy be powered by more than one battery per circuit, the product should say or be equivalent to:

- "Do not mix old and new batteries."
- "Do not mix alkaline, standard (carbon-zinc), or rechargeable batteries."
- "Battery is not replaceable" (if applicable).

The location of on-product safety labeling is dependent on the size of the product, as determined by the manufacturer. If the product is too small, the above information must be on the instructions.

Packaging

Toys powered by "button or coin cell batteries that are 1.5 volts or greater, regardless of chemistry, and are greater than 15mm in diameter and fit within the small parts cylinder" (§5.15.2.1) must have the following on its packaging;

- ⚠ WARNING: "Contains button or coin cell battery. Hazardous if swallowed – see instructions" (§5.15.2.1 (1)).

The standard requires that the "signal word (WARNING) be in all upper case sans serif letters not less than 1⁄8 in. (3.2 mm) in height and must be center or left aligned, the alert symbol to directly precede the signal word" and "the height of the triangle be at least the same height as the signal word, the height of the exclamation point be at least half the height of the triangle and

[10] Consumer Product Safety Improvement Act (CPSIA) of 2008. Pub. L. No. 110-314. Available at: https://cpsc.gov/s3fs-public/pdfs/blk_pdf_cpsia.pdf

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

be centered vertically in the triangle." The text that follows the signal word is required to be "in sans serif lettering, be either left aligned or center justified, and capital letters be no less than 1⁄16 in. (1.6 mm) (§5.3.1)."

Instructions

Toys powered by "button or coin cell batteries that are 1.5 volts or greater, regardless of chemistry, and are greater than 15mm in diameter and fit within the small parts cylinder" (§5.15.2.1) must have the following on the instructions:

- ⚠ WARNING: "This product contains a Button or Coin Cell Battery. A swallowed Button or Coin Cell Battery can cause internal chemical burns in as little as two hours and lead to death. Dispose of used batteries immediately. Keep new and used batteries away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention."

In case the toy does not come with instructions, the above warning must be on the packaging, or a paper insert packaged inside with the toy. Products with accessible (with the use of a coin, screwdriver or household tool) non-replaceable batteries must contain a statement that the batteries are not replaceable.

Staff Evaluation:

The Toy Standard is limited in that it only applies to children's toys, defined as "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." Other children's products containing button/coin batteries, such as clothing, accessories, and drinkware, are outside the scope of the standard. The toy standard does not address packaging concerns with spare batteries, or require warning on websites or apps that enable consumers to purchase a product. Spare batteries and warnings should be provided on websites or apps that enable consumers to purchase a product online. Reese's Law exempts toys within the scope of the toy standard from compliance with the performance and labeling requirements of the draft rule.

B. U. S. Voluntary Standards

ESHF staff reviewed relevant labeling requirements for voluntary consensus standards, including the American National Standards Institute (ANSI) standard for lithium and other battery chemistries, and standards published by Underwriters Laboratories (UL) for certain electronic and battery-operated consumer goods. Staff's assessment is below.

1. ANSI C18.1M Part 2-2019 American National Standard for Portable Primary Cells and Batteries with Aqueous Electrolyte - Safety Standard

This standard pertains to the design, testing and compliance, normal use and foreseeable misuse, and safety information of Portable Primary (non-rechargeable) batteries made of aqueous (alkaline) chemistries. This includes Carbon Zinc, Alkaline Manganese Dioxide, Silver Oxide, Zinc Air, and Nickel Oxy-Hydroxide. Size of batteries within scope are all those easily hand-carried (portable) cylindrical (round with an overall height is equal or greater than the diameter), prismatic (non-round geometry), and button (round with an overall height is less than the diameter) batteries.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Battery

Section 10 of the standard provides safety markings required for the battery. The list below must be on the battery:

a. Battery system-except carbon zinc
b. Designation (ANSI, IEC, or Common)
c. Polarity of terminal (when applicable)
d. Nominal voltage
e. Year and month or week of manufacture, which may be in code or the expiration date
f. Name or trademark of the manufacturer or supplier
g. Warnings or cautionary notes, where applicable
h. Caution for ingestion (small batteries only)

Product

The standard does not include requirements associated with safety information for products containing lithium cells.

Packaging

Should the battery be too small to print the above information, the battery safety markings a-h may be on the packaging. Small batteries[11] are required to be marked with the battery designation and polarity. Warnings and cautionary notes are suggested in Section 8, *Information for Safety;* however, this information is written for manufacturers. The two applicable cautionary statements are:

- "Keep batteries out of the reach of children, especially those batteries fitting within the limits of the ingestion gauge" (§8.12), and
- "Immediately seek medical attention if a cell or battery has been swallowed. Also, contact your local poison control center" (§8.13).

The standard does not indicate whether these statements should be included on the packaging or if these statements should be preceded by an alert symbol and signal word (*e.g.,* "WARNING" or "CAUTION").

Instructions

Instructions are recommended to include the following for safe battery use. These are:

- Always purchase the correct size and grade of battery most suitable for the intended use.
- Replace all batteries of a set at the same time.
- Clean the battery contacts and also those of the device prior to battery installation.
- Ensure the batteries are installed correctly with regard to polarity (+ and -).
- Remove batteries from equipment that is not to be used for an extended period of time.

[11] Defined as a "cell or battery fitting entirely with the limits of the ingestion gauge." The small parts cylinder is equivalent to the ingestion gauge.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- Remove used batteries promptly.

Annex A (§ A.6) provides Industry-recommended guidance for manufacturers, suggesting that instruction manuals for battery-operated products include the following:

> "In exceptional circumstance, batteries may leak fluids that can cause a chemical burn injury or damage to your device." To avoid battery leakage,
>
> a. Non-rechargeable batteries are not to be recharged.
> b. Do not mix different types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries.
> c. Do not mix old and new batteries.
> d. Batteries are to be with the correct polarity.
> e. Exhausted batteries are to be removed from the product.

Staff Evaluation:

The ANSI C18.1M Part 2 for Aqueous (alkaline) batteries standard does not address ingestion warnings in the requirements section of the standard; rather, the standard includes recommendations for safe design in Annex A (Informative[12]). The battery, if space permits and the manufacturer chooses, can have a cautionary statement for ingestion. Otherwise, this caution statement is recommended on the packaging, likely on the back side, along with safe-use guidance. Based on the battery chemistry, the signal word "caution" is used instead of "warning," which denotes less serious consequences. The standard does not mention use of the "Keep out of reach" warning text or use of the icon (Figure 1). Although child fatalities associated with aqueous batteries are rare, they have occurred (see Tab B, Scorpio, C. 2022). Based on the incident data, and the mandate in Reese's Law, CPSC staff concludes that consumers must also be alerted that a button battery can result in serious injury or death if ingested, and therefore, they should be kept out of reach of children. The standard includes multiple instructions to remove batteries from the product, if used, exhausted, or the product is not going to be used for an extended period. However, it does not include "immediately discard" in those instructions. Staff concludes that this should be added to such warnings and instructions.

The standard provides guidance for safety language in the instructional literature, not on the packaging. It is recommended that manufactures instruct consumers how to handle aqueous batteries safely to avoid leakage resulting in damage to your device. However, the effect (chemical burn) caused by unsafe handling is never mentioned. A warning indicating that unsafe handling can cause battery leakage resulting in chemical burns would be more implicit, and thus, having this warning on the packaging, rather than inside the packing in an instructional sheet, would be more noticeable when the consumer is purchasing. Not only does the chemical burn statement lack the standard warning format, the concern for chemical leakage associated with the product is not stated clearly indicating that ingestion may cause chemical burns, and what to do if ingested. Packaging of alkaline button batteries does not require design restrictions like lithium batteries, such as child-resistant packaging or separating cells so only one can be accessible at a time. Aqueous battery packaging presents a risk of releasing multiple batteries or allowing spare batteries to be packaged with products. Once the packaging is opened, loose batteries need to be stored out of reach of children. Consumers may not recognize that aqueous batteries present a hazard of ingestion if they are not packaged in child-resistant packaging and

[12] Informational.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

labeled with warnings. The subject standard does not address warnings on websites or apps that enable consumers to purchase a product online; nor do they indicate that the warning should be in a conspicuous location. The warning should reflect the ingestion hazard, and the same warnings should be included on products sold online.

2. ANSI C18.3M *Part* 2-2021 American National Standard for Portable Lithium Primary Cells and Batteries - Safety Standard

This standard pertains to the design, testing and compliance, normal use and foreseeable misuse, and safety information of lithium primary batteries. The scope of the standard includes lithium carbon monofluoride, lithium manganese dioxide and lithium iron disulfide chemistries. Size of batteries in scope are those easily hand-carried, coin (overall height is less than the diameter), cylindrical (round with an overall height is equal or greater than the diameter), and prismatic (non-round geometry).

Battery

Section 10 of the standard provides safety markings required on the battery or packaging. These include:

a. Battery system
b. Designation (ANSI, IEC, or Common)
c. Polarity of terminal (when applicable)
d. Nominal voltage
e. Year and month or week of manufacture, which may be in code or the expiration date
f. Name or trademark of the manufacturer or supplier
g. Warnings or cautionary notes, where applicable
h. Caution for ingestion (small batteries only)

Product

The standard does not include requirements associated with safety information for products containing lithium cells.

Packaging

Should the battery be too small to include all listed information above (a-h) may be printed on the packaging. Small batteries, at a minimum, are required to be marked with the battery designation (a) and polarity (c).

Section 8 *Information for Safety* provides manufacturers with information regarding safe use of primary lithium batteries. Two of the 13 statements relevant to the ingestion hazard are listed below:

- "Keep batteries out of the reach of children, especially those batteries fitting within the limits of the truncated cylinder, as defined in Figure 1" (§8.4), and
- "Immediately seek medical attention if a cell or battery has been swallowed. Also, contact your local poison control center" (§8.5).

The standard does not require these statements be included on the packaging, or that these statements be proceeded by an alert symbol and signal word (*e.g.*, "WARNING" or "CAUTION.")

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Instructions

Section 9, *Instructions for Use,* provides the manufactures with a list of standard instructions to print directly on the packaging; none pertains to ingestion. These are:

- Always select the correct size and type of battery most suitable for the intended use. Information provided with the appliance to assist correct battery selection should be retained for reference.
- Replace all batteries of a set at the same time.
- Clean the battery and appliance contacts prior to battery installation.
- Ensure that the batteries are installed correctly with regard[s] to polarity (+ and-).

The ANSI standard for lithium coin batteries sets forth additional safety provisions in Annex C (Normative). The normative language below, otherwise known as industry-accepted language to which most manufacturers comply, applies to lithium coin batteries *16 mm* diameter or larger and fit within the small parts cylinder. The following cautionary advice, or equivalent, must be printed on the ***back***[13] side of the battery packaging:

> ⚠ **WARNING**: "Death or serious injury can occur in as little as 2 hours if swallowed."

The standard requires that the signal word WARNING be in bolded, capitalized, sans serif font, 1.52 mm or larger, on a contrasting background. Additional cautionary advice manufacturers must provide on the ***back*** of the packaging includes the following or equivalent:

- Keep away from children text and the icon (shown in Figure 1A).
- Keep in original package until ready to use.
- Dispose of used batteries promptly.
- Seek immediate help if swallowed.
- Call a local poison control center for treatment information.
- Risk of fires and burns.
- Do not recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate.

Figure 1A. One of 3 icon choices

In addition to labeling requirements, Annex C Section C.2.1.1 of the standard denotes lithium coin batteries 16 mm in diameter and larger be contained in child-resistant packaging subject to PPPA requirements outlined in 16 CFR §§ 1700.15 (b) (1) and 1700.20 (a) (2).

13. Emphasis added.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Annex D (informative)[14] of the standard sets forth recommended best practices for manufacturers to use the safety icon shown in Figure 1A. Here, the icon is recommended for use with 20 mm diameter and larger coin batteries that are also small parts. The icon should be durably and indelibly marked (no color is required) and be a minimum of 6 mm in diameter.

Use of Icon on battery

- Indelibly marked on the battery.

Use of Icon on packaging

- Print the icon on the ***front***[15] of the package.

Staff Evaluation:

The use and location of the cautionary language (*i.e.*, ⚠ WARNING: "Death or serious injury can occur in as little as 2 hours if swallowed") and the icon shown in Figure 1, are dependent upon the diameter of the lithium coin battery (20mm and larger). Due to the hazard severity, staff recommends for consistency, all coin battery packaging, regardless of diameter, include the icon on the front and in a conspicuous location.

3. UL4200A Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies

UL marking is a widely recognized symbol on most industrial equipment, home appliances, and electrical products. UL has more than 1,500 industry standards for electrical components and products, such as personal grooming appliances, household appliances, and fans, some of which are portable.

Battery

The standard does not include requirements for safety markings on batteries.

Product

UL4200A requires products incorporating replaceable button/coin cell batteries to include the following statement:

> ⚠ WARNING: "Chemical Burn Hazard. Keep batteries away from children. See Manual"

Markings must be permanent and specifications for font size is provided, although this depends on the size of the product. The symbol (⚠) alone can be marked close to the battery compartment in lieu of the wording.

[14] For informational purposes.
[15] Emphasis added.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Product Packaging

The standard does not include requirements associated with safety information on product packaging.

Instructions

In addition to the chemical burn hazard listed above, instructions for products with replaceable button/coin cell batteries must identify that the product contains said battery and the following:

- "This product contains a lithium button/coin cell battery. If a new or used lithium button/coin cell battery is swallowed or enters the body, it can cause severe internal burns and can lead to death in as little as 2 hours. Always completely secure the battery compartment. If the battery compartment does not close securely, stop using the product, remove the batteries, and keep it away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention" or equivalent.
- The cells must be disposed of properly, including keeping them away from children,
- Even used cells may cause injury.

If the product's lithium button/coin cell battery cannot be replaced, the instructions must indicate the presence of button/coin cell, that it cannot be replaced, and the cells must be disposed of properly.

Staff Evaluation:

This standard only pertains to certain household products containing button/lithium coin cell batteries. Many portable products involved in the incident data fall outside the scope of this standard or other UL standards that incorporate compliance to UL 4200A.

The UL standard requires one on-product warning to advise parents to keep button/coin cell batteries away from children due to a chemical burn hazard. The warning does not distinguish if this burn hazard is dermal or internal, or mention ingestion. Consumers may not readily associate chemical burns with an ingestion hazard. In addition, the warning statement is not formatted to ANSI Z535.4, *American National Standard for Product Safety Signs and Labels* with an alert symbol and signal word. The ANSI Z535.4 American National Standard Product Safety Signs and Labels is the primary voluntary consensus standard providing guidelines for the design of safety signs and labels for application to products. The standard includes recommendations for the design, application, use, and placement of warning labels. The subject warning does not rise to the same level of concern as ⚠ WARNING: "Death or serious injury can occur in as little as 2 hours if swallowed." If the product is too small to mark with the text, only the safety alert symbol will be on the product without text. This assumes consumers understand what the symbol means. The "Keep Out of Reach" icon and text may be more effective to inform the consumer.

UL 4200A does not require or suggest that packaging of consumer products indicate the presence of a button/coin battery or what specific part of the product contains the battery. This standard also does not address spare batteries that may be shipped with the product. Spare

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

batteries should require child-resistant packaging, and warnings should be consistent on consumer products and packaging.

4. UL 1642 Standard for Lithium Batteries

UL 1642 pertains to primary non-rechargeable and secondary rechargeable lithium batteries, including coin cells, as power sources. It covers metallic lithium or lithium alloy or lithium ion batteries and is intended to reduce the risk of fire or explosion.

Battery
Primary batteries (non-rechargeable) must have the following or equivalent:

> "WARNING: Risk of fire and burns. Do not recharge, open, crush, heat above x (to be filled in by manufacturer), or incinerate."

This warning must be on the packaging if the battery does not have space. Primary batteries intended to be user-replaceable may use the word "CAUTION" in place of "WARNING."

Product

The standard does not include requirements associated with safety information for products containing lithium cells.

Packaging

User-replaceable batteries: must contain the following or equivalent:

> "CAUTION: "Risk of fire and burns. Do not recharge, disassemble, heat above x (to be filled in by manufacturer), or incinerate. Keep battery out of reach of children and in original packaging until ready to use. Dispose of used batteries promptly."

In addition, user-replaceable lithium primary coin cells (3.0V) must include on the packaging the following or equivalent:

> "WARNING – Never put batteries in mouth. Swallowing may lead to serious injury or death. If ingested, immediately seek medical attention and have the doctor phone the National Capital Poison Control Center."

Both statements may be combined on the packaging if the signal word is "WARNING."

Instructions

The standard does not include requirements associated with safety information in instructions.

Staff Evaluation:

The subject standard addresses a fire hazard as a CAUTION and has the "Keep Out of Reach" text included with other language that may reduce noticeability, leading to the information being overlooked. "Caution" does not have the same significance as "Warning." The standard does not include the use of the alert symbol before either safety statement. The subject standard does not suggest child-resistant packaging or warnings be conspicuously placed on websites or apps that enable consumers to purchase a product online. Staff concludes the potential for

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

death or serious injury requires the use of the signal word "WARNING," and consistent warning label format will improve consumer awareness of the ingestion hazard.

5. ASTM F2999 -19 Standard Consumer Safety Specification for Adult Jewelry

The Adult Jewelry Standard applies to jewelry designed or intended for consumers over age 12 and designed and intended to be worn as an ornament and includes anklets, arm cuffs, bracelets, brooches, chains, tiaras, cufflinks, hair accessories with significant decorative elements, earrings, ear cuffs, necklaces, pins, rings, body piercing jewelry, jewelry placed in the mouth for display or ornament, shoe or clothing charms, beads, chains links, pendants designed to be removed and worn independently or attached to an item worn by a person, watches, and jewelry components in craft kits.

Adult jewelry containing batteries that are swallowable or small parts must not be accessible without the use of a coin, screwdriver, or other household tool.

Battery

The standard does not include requirements for safety markings on batteries.

Product

The standard does not require warning labels pertaining to button or coin batteries on the product.

Packaging

The standard does not require warning labels pertaining to button or coin batteries on the packaging.

Instructions

Jewelry generally does not come with instructions.

Staff Evaluation:

Although this standard does address the safety of "swallowable[16] batteries" stating that they shall not be accessible, it does not require a statement on the packaging or any literature indicating the presence of a battery or type or warnings associated with ingestion hazard. Staff concludes that the potential for death or serious injury and immediately seeking attention if a battery is ingested should be added to such warnings and instructions. Products like accessories (handbag or belt, or footwear, or functional like keys, keychains and other items not intended to be worn as decoration), fall outside the scope of the standard; some of these products have been reportedly involved in incidents.

6. ASTM F2923-20 Standard Specification for Consumer Product Safety for Children's Jewelry

The Children's Jewelry Standard applies to jewelry designed or intended for consumers under the age of 12 and designed and intended to be worn as an ornament. Products excluded from

[16] Defined in the standard as small enough to fit entirely, without compression, within the small parts cylinder.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

this standard are toy jewelry, accessories such as handbags, apparel, and footwear. Included are anklets, arm cuffs, bracelets, brooches, chains, tiaras, cufflinks, hair accessories with significant decorative elements, earrings, ear cuffs, necklaces, pins, rings, body piercing jewelry, jewelry placed in the mouth for display or ornament, shoe or clothing charms, beads, chains links, pendants designed to be removed and worn independently or attached to an item worn by a person, watches, and jewelry components in craft kits.

Children's jewelry containing batteries that are small parts shall not be accessible without the use of a coin, screwdriver, or other household tool.

Battery

The standard does not include requirements for safety markings on batteries.

Product

The standard requires small batteries not be accessible without the use of a coin, screwdriver of other household tool. Children's jewelry that uses more than one replaceable battery in one circuit must state the following;

- "Do not to mix old and new batteries."
- "Do not to mix alkaline, standard (carbon-zinc), or rechargeable (nickel-cadmium) batteries."

This information shall be on the instructions if there is insufficient space on the jewelry.

Warnings are recommended on jewelry that contains non-replaceable batteries. Should the battery be small and accessible (with the use of a with use of coin, screw, common household tool), the packaging shall state that the battery is not replaceable.

This information shall be on the instructions if there is insufficient space on the jewelry.

Packaging

The only requirement on the packaging is a statement that the battery not replaceable should it be accessible (with the use of a with use of coin, screw, common household tool).

Instructions

Should the manufacturer deem jewelry cannot be labeled, instructions for those containing replaceable batteries must state;

- "Do not to mix old and new batteries."
- "Do not to mix alkaline, standard (carbon-zinc), or rechargeable (nickel-cadmium) batteries."

Staff Evaluation:

Similar to the Adult Jewelry standard, the Children's Jewelry standard exempts accessories (handbag or belt) and some apparel (*e.g.*, hair accessory with significant elements are included), some footwear, and functional jewelry like keys, keychains & other items not intended to be worn

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

as decoration). Based on incident data reviewed for this memo, staff is aware of a child accessing a battery from a tutu skirt. The standard does not require an alert notifying consumers that the product has a coin or button battery or that it presents an ingestion hazard. Staff concludes that this information should be included in the warnings and instructions.

C. International Voluntary Standards

1. IEC 60086-4 (2019) 5th Edition - International Standard for Safety of Lithium Batteries -Primary Batteries

This standard specifies tests and requirements for the safe use of Lithium Primary batteries under intended use and reasonably foreseeable misuse. Safe use includes safety information and cautions on both the battery and its packaging.

Battery

Section 9 of the standard refers to markings on the battery and packaging of batteries. These include,

a. Designation (IEC or Common)
b. Year and month or week of manufacture, which may be in code or the expiration date
c. Polarity of the positive terminal (when applicable)
d. Nominal voltage
e. Name or trademark of the manufacturer or supplier
f. Cautionary advice

To address 9(f), the standard provides a written example of cautionary text: "Keep batteries out of the reach of children," as listed in section 7.2. Batteries that fit within the small parts ingestion gauge, and do not have adequate space shall be marked at a minimum with (a) Designation (IEC, or Common) and (c) Polarity of the positive terminal.

Batteries 20 mm or greater must be engraved with the icon denoting "KEEP OUT OF REACH OF CHILDREN" shown in Figure 1.

Packaging

Packaging of swallowable batteries, identified as those that fit within the small parts ingestion gauge,[17] and intended for direct sale to consumers (in replaceable applications) shall include (b), (d), (e), and (f) of the list above. In addition, the packaging must have a written caution about ingestion, such as the statement: "KEEP OUT OF REACH OF CHILDREN" or its representative icon (Figure 1), on the immediate packaging. Best practices for marking the packaging include that the safety sign should be on contrasting background. The background should cover at least 50 percent of the area of the pictogram, and the size of the safety sign should be 6 mm in diameter or larger. If the text, KEEP OUT OF REACH OF CHILDREN is used, it should contrast with the background color on which it is printed.

[17] Equivalent to the small parts cylinder.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Instructions

Battery instructions shall direct consumers to select the correct size and battery type for the intended equipment, replace all batteries at the same time, clean the battery contacts, ensure correct installation based on polarity, and to remove batteries promptly when exhausted.

Child Resistant Packaging

Swallowable batteries intended for direct sale in consumer-replaceable applications and are 16 mm diameter or larger must be packaged in child-resistant packaging. Compliance with one of the following is required; IEC 60086-4 Annex E, PPPA 16 CFR §1700.15(b)(1), EN 862, or AS 5808-2009.

Staff Evaluation:

The warnings in this standard are similar to ANSI C18.3M Part 2 requirements for lithium batteries, as are the requirements for child-resistant packaging for batteries with a diameter of 16 mm or greater. IEC 60086-4 allows for a mechanical test option instead of three[18] methods using child testing. Staff's Report on PPPA Protocol Testing of Button Battery Packaging,[19] dated June 2019, indicates additional research is needed with additional packaging types and a larger child panel size to verify comparability. Staff contacted the Battery Association of Japan for additional information on the methodology, procedures, and packaging types tested to this requirement, and we received limited feedback.

Similar to ANSI C18.3M Part 2, the IEC standard recommends adding the language, "Keep batteries out of the reach of children," on the battery (packaging if limited space), but it does not go further to warn about the potential for death or serious injury if ingested or to recommend seeking medical attention immediately. The location of the warning text or icon is left to the discretion of the manufacturer, and there is no mention of requirements associated with websites or apps that enable consumers to purchase a product online. Staff concludes that the potential for death or serious injury and the warning language to seek medical attention immediately if a battery is ingested should be added to such warnings and instructions, and the location of the labels should be specified.

2. IEC 60086-5 2021 Primary batteries – Part 5: Safety of batteries with Aqueous electrolyte

This standard pertains to the design, testing and compliance, normal use and foreseeable misuse, and safety information of Portable Primary batteries made of aqueous chemistries.

Battery

Section 9 of the standard states the following must be marked on the battery:

a. Designation (IEC or Common)
b. Year and month or week of manufacture, which may be in code or the expiration date

[18] 16 CFR § 1700.15(b)(1), EN 862, or AS 5808-2009.

[19] https://www.cpsc.gov/content/Report-on-PPPA-Protocol-Testing-of-Button-Battery-Packaging-June-2019

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

c. Polarity of the positive terminal (when applicable)
d. Nominal voltage
e. Name or trademark of the manufacturer or supplier
f. Cautionary advice

Cautionary advice that complies with section 9(f) is provided in section 7 *Information for safety*; much of this relates to the safe handling, use, transportation, storage, and disposal of aqueous batteries. Cautionary advice for ingestion is satisfied by marking the battery with the text "KEEP OUT OF REACH OF CHILDREN" or providing its equivalent icon (Figure 1A). Swallowable batteries (those that fit within the small parts ingestion gauge[20]) must be marked with (a) Designation (IEC or Common), and (c) Polarity of the positive terminal. Swallowable button batteries made of Zinc (Manganese dioxide and Silver dioxide) and are equal or greater than 20 mm must be engraved with the icon equivalent of: "KEEP OUT OF REACH OF CHILDREN," shown in Figure 1A.

Packaging

Packaging of swallowable batteries is recommended to include the "KEEP OUT OF REACH OF CHILDREN" icon, whereas packaging of swallowable button batteries made of Zinc Oxygen air, Manganese dioxide, and Silver oxide having diameters < 16 mm, 16 mm ≤ d < 20 mm, and ≥ 20 mm is required to have the safety icon on its packaging. The location of the icon is not specified.

Swallowable button batteries made of Zinc Manganese dioxide and Silver dioxide having a diameter ≥ 20 mm must be packaged in child-resistant packaging.

Instructions

Battery instructions shall include direction that the consumer must select the correct size and battery type for intended equipment, replacing all batteries at the same time, cleaning the battery contacts, ensuring correct installation based on polarity, removing batteries from equipment not used for an extended period of time, and removing batteries promptly when exhausted. There is no requirement that the "KEEP OUT OF REACH" text or icon be printed in the instructions.

Staff Evaluation:

Required labeling for Aqueous batteries in the IEC 60086-5 standard is similar to the IEC 60086-4 in that both require the "KEEP OUT OF REACH" icon to be engraved on button batteries having a diameter greater than 20 mm and require child-resistant packaging. This is more adequate to reduce the risk of injury than the ANSI C18.1M Part 2 **(**Aqueous) standard, which does not have any battery marking requirements or child-resistant packaging for this type of battery.

Unlike the ANSI standards, the "KEEP OUT OF REACH" icon and text are used synonymously to a warning for ingestion hazard. The IEC standard does not specifically alert consumers to an ingestion hazard, nor indicate that serious injury, and perhaps death from internal chemical burns can occur or that consumers should seek immediate medical attention. The IEC does not address cautionary advice or warnings for online sales. Staff concludes that the potential for

[20] Small parts cylinder.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

death or serious injury and the need to seek medical attention immediately if a battery is ingested should be added to such warnings and instructions.

3. IEC 62115 International Standard for Electric Toys

This consensus standard is used in conjunction with the ISO Toy Safety standard and applies to electronic toys "for use in play by children under the ages of 14 years" and have at least one function dependent on electricity. This standard pertains to the design, testing and compliance, normal use and foreseeable misuse, and safety information for electronic toys. This standard also provides requirements for the markings, safety labeling, and instructions for electronic toys.

Battery

The standard does not include requirements for safety markings on batteries.

Product

Electronic toys must be marked legibly and durably on the main part of the toy with the name, trademark, manufacturer, or responsible vendor and model or type reference. Should the size of the product have limited space, the information must be on the packaging or instructions accompanying the product. Use of any internationally recognized symbols listed in Annex D of the standard may be used in place of text, for example, the icon for "Keep out of reach of children," and the symbol's meaning must be explained in the instructions.

Replaceable batteries

Safety labeling for electric toys with replaceable batteries shall be marked with the battery voltage, shape, and polarity (see example in Figure 2A). This should be on the battery compartment, cover, or other suitable place close to the batteries. The standard also addresses specific safety labeling requirements for electric toys with a battery box, transformer, or a power supply that are not provided in this report.

Figure 2A. Example of battery compartment (partial image from IEC 62115 Figure 1 section 7 *Marking and instructions*.)

Packaging

When instructions are not provided, information shall be on the packaging along with a statement indicating packaging must be retained as it contains important information.

Electronic toys powered by replaceable coin batteries must have the following or equivalent:

WARNING: "Contains coin battery. Hazardous if swallowed – see instructions."

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Alternatively, symbols shown in Figure 3A can be used instead of the warning text, provided the instructions define the symbol's meaning.

Figure 3A. Internationally recognized symbols
"Warning: Contains coin battery," and "Read operator's manual," respectively.

Instructions

Cleaning and product maintenance shall be provided when necessary for the safe operation of the toy. This can be provided on a leaflet, packaging, or on the product itself. Instructions are required for electronic toys that are intended to be assembled by a child and/or are necessary for the safe use of the toy. If the assembly must be performed by an adult, the instructions must indicate this. When information is provided on the instructions only, there shall be a statement indicating instructions must be retained as they contain important information. If the information is only on the packaging, consumers must be instructed to keep the packaging.

Electronic toys with replaceable batteries shall indicate, as applicable, the following information for safe use:

- How to remove and insert the batteries.
- That non-rechargeable batteries are not to be recharged.
- For electric toys using rechargeable batteries, the batteries should be charged under adult supervision. For batteries charged using a battery charger for use by children, this instruction may be replaced by the text: "Batteries are only to be charged by persons of at least 8 years old."
- Different types of batteries, or new and used batteries, are not to be mixed.
- Batteries are to be inserted with the correct polarity (+ and -).
- Exhausted batteries are to be removed from the toy.
- The supply terminals are not to be short-circuited.

Electric toys containing non-replaceable batteries shall state the substance of the following:

> This toy contains batteries that are non-replaceable.

Electric toys containing replaceable coin cell batteries:

> **WARNING:** This product contains a coin battery. A coin battery can cause serious internal chemical burns if swallowed.
>
> **WARNING:** Dispose of used batteries immediately. Keep new and used batteries away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.

Electric toys containing replaceable button batteries:

> **WARNING:** Dispose of used batteries immediately. Keep new and used batteries away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.

Staff Evaluation:

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Packaging and/or instructions do not have to indicate a presence of a button or coin battery unless it is replaceable. Some products with non-replaceable batteries may become accessible if the product is damaged, or have accessible battery compartments for recycling purposes. Consumers should be aware of the presence of and the hazards associated with button and coin batteries. Although this standard allows for a "Contains coin battery" symbol, it does not instruct to "Keep out of reach of children" on the packaging, instructions, or product. The IEC standard does not address warning requirements for websites or apps that enable consumers to purchase a product online. The instruction to keep the batteries out of reach of children should be added to such warnings and instructions, and the websites or apps that enable consumers to purchase a product online should include the same warnings.

D. International Mandatory Standards

1. Australian F2022C00445 Mechanical requirements for products that contain button/coin batteries

Staff Evaluation:

Labeling requirements are not addressed in this standard. See Tab D for the review of the standard.

2. Australian F2020L01657 *Warning requirements on products that contain button/coin batteries*

General Requirements

Below warnings are subject to size, legibility, and durability requirements of product safety labels outlined in Annex D of ISO 3864-2 *Graphical symbols – Safety colors and safety signs – part 2: Design principles for product safety labels.*

Warning content

The following are applicable to product, product packaging, and instructions as outlined in the standard.

- "Alert" word (DANGER, WARNING OR CAUTION)
- Internationally recognized safety alert symbol regarding the presence of coin battery (see Figure 4A). The symbol combines the safety alert symbol (exclamation mark in a triangle) with the coin cell or coin battery image identified in IEC 60417-6367.
- Statement that the battery is hazardous and to keep both new and used batteries away from children.
- Lithium chemistries must include a statement that the battery can cause severe or fatal injuries in less than 2 hours if swallowed or placed inside any part of the body.
- Non-lithium chemistries must include a statement that the battery can cause serious injury if swallowed or placed inside any part of the body.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

- Seek medical attention immediately if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 4A. Internationally recognized safety alert symbol meaning “Warning: Contains coin battery”

Recommended best practice

- Include the following or equivalent language; Contact the Australian Poisons Information Center immediately for 24/7 fast, expert advice, and include the phone number.
- Safe disposal advice as some old or used batteries may still cause serious harm.

Battery

The standard does not include requirements associated with safety information on batteries.

Product

There are no requirements for on-product warnings. Recommended best practices are for consumer goods to have a clearly visible, durable, and legible warning located close to where the battery is accessible. The warning should include the safety alert symbol regarding the presence of coin battery (Figure 4A), and if space on the product permits, include the following,

- Consumer goods with lithium button/coin battery should have statement to the effect that the battery can cause severe or fatal injuries in less than 2 hours if swallowed or placed inside any part of the body,
- Consumer goods with non-lithium button/coin battery should have a statement to the effect that the battery can cause serious injury if swallowed or placed inside any part of the body.

Packaging

If the product is packaged, the *warning content*, stated in the general requirements section above, is required. If the size of the packaging is too small, the front panel must be marked with the safety alert symbol (Figure 4A) that is clearly visible, prominent, and legible.

Recommended best practice is for the packaging of consumer goods to have a clearly visible, durable, and legible warning that is prominent. The alert word (DANGER, WARNING, OR CAUTION) and statement indicating the battery is hazardous and to keep both new and used batteries away from children should be on the front of the packaging. Additionally, the statement for ingestion or insertion in any part of the body for lithium or non-lithium batteries (respectively), as well as advice to seek medical attention should also be present on the front. If space on front packaging does not permit, the last three items may be printed elsewhere on the packaging.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Consumer goods that do not include packaging must have the *warning content* affixed to the product, such as with a sticker label or "swing tag."[21]

Instructions

If instructions are provided, they must include the *warning content* clearly visible, prominent, and legible. If instructions are not provided with packaged consumer goods, the warnings must be attached using a sticker or "swing tag" or included with the consumer goods.

Lower-risk consumer goods

"Lower-risk consumer goods" are defined as consumer goods that include instructions and one or more of the following is applicable: (1) are hearing aids, (2) have fully enclosed batteries, (3) batteries not intended to be removed or replaced by a consumer, and (4) require a specialist to install or remove. Low-risk consumer goods must include the same messaging *warning content*. If instructions are not provided with these low-risk consumer goods, the warnings must be attached to or included with the consumer good.

Websites or apps that enable consumers to purchase a product online

Recommended best practices for consumer goods sold online should contain the bulleted *warning content* in the products description, and this must be clearly visible, prominent, and legible.

Staff Evaluation:

Unlike U.S. voluntary standards (ANSI), Australia has labeling requirements for both lithium, non-lithium, and lower-risk products. Products containing lithium batteries require a warning that includes the phrase "severe or fatal injuries if swallowed" and products with non-lithium batteries require a warning with the phrase "serious injuries if swallowed." Australia has provisions for packaging, instructions, and on the product if instructions are not included. This standard provides recommended best practices for instructions for websites or apps that enable consumers to purchase a product online while other U.S. voluntary standards do not offer such recommended best practices. The warnings should be on the product as practicable, and websites or apps must contain such warnings.

3. Australia F2020L01659 Warning requirements for button/coin batteries and packaging

Battery

Lithium button/coin batteries with a diameter of 20 mm or larger must be marked with the internationally recognized "keep out of reach" symbol (Figure 5A). This symbol is defined in ISO 7010 - Graphical symbols — Safety colours and safety signs — Registered safety signs to signify that the item must be kept out of reach of children. This symbol should be at least 6 mm in diameter, clearly visible, prominent, and indelible.

[21] Wording used in the standard is equivalent to a hangtag.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Figure 5A. Internationally recognized "Keep out of reach" icon

Recommended best practices are to include the symbol in Figure 5A on lithium button/coin batteries if there is significant space and the symbol is at least 6 mm in diameter.

Product

The standard does not address safety information for products containing batteries.

Packaging

All warnings are subject to size, legibility, and durability requirements of product safety labels outlined in Annex D in ISO 3864-2 *Graphical symbols – Safety colors and safety signs – part 2: Design principles for product safety labels.*

Warning contents

- Alert word (DANGER, WARNING OR CAUTION).
- A combination of an internationally recognized safety alert symbol and an internationally recognized “Keep out of reach” symbol (see Figure 6A and Figure 5A, respectively).
- Statement that the battery is hazardous and to keep both new and used batteries away from children.
- Lithium chemistries must include a statement that the battery can cause severe or fatal injuries in less than 2 hours if swallowed or placed inside any part of the body.
- Non-lithium chemistries must include a statement that the battery can cause serious injury if swallowed or placed inside any part of the body.
- Seek medical attention immediately if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 6A. Internationally recognized safety alert symbol

The warning label requirement is met provided the packaging is marked with the below image (Figure 7A) specified in IEC 60086-4 Primary Batteries clause 7.2, Figure 9.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

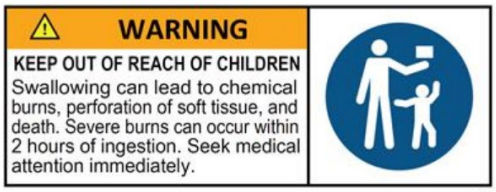


Figure 7A. IEC 60086-4 clause 7.2, Figure 9

Additional warnings as recommended best practice are as follows:

- Include the following or equivalent language, if it is suspected that a battery has been swallowed or inserted in any part of the body, instruct the person to contact the Australian Poisons Information Center immediately for 24/7 fast, expert advice, and include the phone number.
- Safe disposal advice as some old or used batteries may still cause serious harm.

All warnings are subject to size, legibility, and durability requirements of product safety labels outlined in Annex D in ISO 3864-2 *Graphical symbols – Safety colors and safety signs – part 2: Design principles for product safety labels.* Warning information should be on the front of the package if there is sufficient space. If space does not permit, the front packaging must have the alert word (DANGER, WARNING OR CAUTION), a combination of the symbols shown in Figure 5 and Figure 6 and statement indicating the battery is hazardous and to keep both new and used batteries away from children. The remaining safety information may be present elsewhere on the packaging.

Best Practice for Websites or Apps that enable consumers to purchase a product online

Recommended best practices for consumer goods sold online should contain the bulleted *warning content* located in the Packaging section above, and this must be clearly visible, prominent, and legible.

Staff Evaluation:

Although not applicable in the United States, warning requirements for button/coin batteries and packaging of such batteries identified in Australia F2020L01659 align with Reese's law and staff's proposed rule.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

TAB D

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

MEMORANDUM

TO: Daniel Taxier, Project Manager
Division of Mechanical and Combustion Engineering

DATE: January 11, 2022

THROUGH: Caroleene Paul, Director
Division of Mechanical and Combustion Engineering

FROM: Frederick deGrano
Division of Mechanical and Combustion Engineering

SUBJECT: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Voluntary Standards Assessment and Proposed Requirements

---

I. Introduction

Staff of the U.S. Consumer Product Safety Commission (CPSC) recommends rulemaking pursuant to Reese's Law, Public Law 117-171, to prevent injuries and deaths resulting from ingestion of button cell or coin batteries by children 6 years old and younger obtained from consumer products. The proposed requirements apply to all consumer products within CPSC's jurisdiction, and include remote controls, portable lights, wearable accessories, location trackers, and kitchen products. However, the proposed rule excludes toys that are within the scope of 16 CFR 1250, which incorporates by reference American Society for Testing and Materials (ASTM) F963-17, *Standard Consumer Safety Specification for Toy Safety* (ASTM F963), as well as other products that are not within the Commission's jurisdiction under section 3 of the Consumer Product Safety Act (CPSA), such as medical devices like hearing aids and thermometers.

In this memorandum, staff will provide the following information:

- Description of products
- Description of hazards
- Assessment of current voluntary standards
- Summary of tests
- Recommendation for draft proposed rule

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

II. Button Cell and Coin Batteries

A battery (also called a cell when referring to a button cell or coin battery) stores chemical energy, which is converted to electrical energy when the battery is connected to a circuit. A battery consists of an anode (negative terminal), a cathode (positive terminal), a separator and electrolyte between the anode and cathode, as shown in Figure 1. When the battery terminals are connected with a conductive material such as moist human tissue, an electric circuit is formed and electric current flows through the conductive material and between the terminals. Batteries come in many shapes and sizes and are composed of different materials and chemicals. Power (voltage and capacity) and size requirements are the main driver of battery shape, chemical composition, and the number of required batteries or cells.

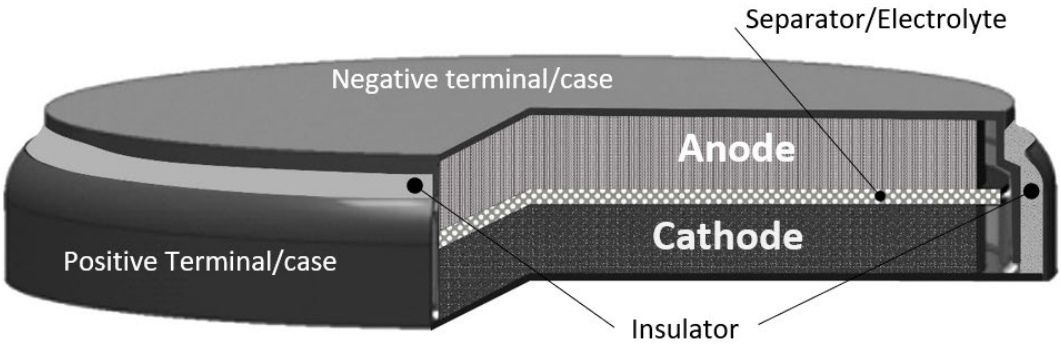


Figure 1. Battery Construction

Batteries come in many shapes and sizes and are composed of different materials and chemicals. Reese's Law defines button cell and coin batteries as single cell batteries with a diameter greater than the height of the battery. Power (voltage and capacity) and size requirements are the main driver of battery shape and composition. A button cell battery is a small single-cell battery that ranges from 5 to 25 mm in diameter and 1 to 6 mm in thickness, resembling a button. Wider diameter (and thinner thickness) batteries are usually called coin batteries because they resemble flatter coins.

Reese's Law also specifies the definition as any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard. Although cylindrical batteries such as AAA batteries may be ingested, staff concluded that these battery types often pass through the esophagus and impaction is rare. Therefore, cases involving cylindrical batteries rarely resulted in death and were often successfully treated. The memorandum from Directorate for Health Sciences, Tab B, discusses this topic in more detail.

A. Button Cell Batteries

Button cells are used to power small portable electronics products such as wrist watches, and pocket calculators. A button cell is a single cell that is usually a primary battery or non-

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

rechargeable and can be replaced. Button cells chemistries tend to be manganese dioxide (alkaline), silver oxide, carbon monofluoride, cupric oxide or oxygen from the air. Figure 2 below shows some common button cell battery sizes.

		
LR44 button cell, 11.6mm (0.45 inch) diameter x 5.4mm (0.21 inch) thick	LR754 button cell, 7.9 mm (0.31 inch) diameter, 5.4mm (0.21 inch) thick	LR626 button cell, 6.8 mm (0.26 inch) diameter, 2.6mm (0.10 inch) thick

Figure 2. Example button cell batteries: LR44 (left), LR754 (middle), LR626 (right)

B. Coin Batteries

Lithium coin cell batteries were originally developed in the 1970's as a 3-volt miniature power source for low drain and battery backup applications, but because of their high energy density and long shelf life, manufacturers found them useful for their applications. As electronics have evolved over the decades, product designers have found lithium coin cell batteries to be a useful power source because of their small size in comparison to their high energy capacity. Lithium coin cell batteries tend to be much thinner than button cell batteries and commonly at least 20 mm in diameter. Figure 3 below shows some common coin battery sizes.

		
CR2032, 20mm (0.787 inch) diameter	CR2025, 20mm (0.787 inch) diameter	CR2450, 24mm (0.945 inch) diameter

Figure 3. Example coin batteries

C. Products

A wide variety of consumer products use button cell or coin batteries for their source of power because of their small size and efficient energy capacity. Many of these consumer products are common household portable electronic products, wearable accessories, or decorative electronic products. Some examples of household objects that may use button cell or coin batteries appear in the list below and Figure 4.

- Remote controls
- Flashlights
- Games and toys

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- Calculators
- Bathroom scales
- Key fobs [1]
- Watches and electronic jewelry
- Flashing shoes & clothing
- Cameras
- Holiday ornaments
- Flameless candles
- Musical greeting cards

Figure 4. Example products that use button cell or coin batteries: LED candle (left), watch (middle), keychain flashlight (right)

III. Hazard

CPSC staff estimates that between 2011-2021, there were approximately 54,300 emergency room visits associated with ingestion, impaction, or insertion of button cell or coin batteries (Tab A). The data shows these incidents occur most often with children aged 4 years or younger. Through this same time period, 25 incidents resulted in death.

Based on staff's analysis of incident data, the hazard pattern for battery ingestion involved a child's access to button cell or coin batteries in three ways:

1. Victim removed battery from product's battery compartment directly before ingestion.
    a. 79 out of 112 fatal and nonfatal CPSRMS incident narratives identified in Tab A refer to products with button cell and coin battery compartments that are potentially easily accessed by children.
2. The battery compartment broke or failed to contain the battery as intended.
    a. 43 of the 79 fatal and nonfatal CPSRMS incidents involving products describe the batteries coming out of the battery compartment or the product or the battery compartment opening or breaking, often while a child was interacting with the product. 18 of these incidents specifically describe products with screws that were ineffective, including comments about stripped threads, continuous

[1] Key fobs that are used for car remote controls are not consumer products.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

spinning, screws that were "too short," and compartments that popped open even though there was a screw.

3. Victim removed battery from battery packaging, or battery was out of the packaging or product and accessed by victim.
    a. 6 out of 112 fatal and nonfatal CPSRMS incident narratives refer to loose batteries or battery packaging hazards, and staff estimate that at least 7% of NEISS incidents involve loose batteries or batteries liberated from the packaging.

Staff concludes that reducing the likelihood that children can access button cell or coin batteries from consumer products that have been associated with battery ingestion incidents can address hazard 1 and 2. Child resistant packaging as required by §3(a) of Reese's Law addresses the packaging hazard 3.

IV. Voluntary Standards

Staff reviewed the following voluntary standards that address hazards associated with button cell and coin battery accessibility:

- UL 4200A, *Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies* (UL 4200A)
- ASTM F963 *Standard Consumer Safety Specification for Toy Safety*
- Voluntary standards referenced by Australian F2020L01656, including:
    - IEC 62368-1 *Audio/video, information and communication technology equipment-Part 1: Safety requirements*
    - IEC 62115 *International Standard for Electric Toys – Safety*
    - AS/NZS 60065:2018 *Audio, video and similar electronic apparatus-Safety requirements*
    - AS/NZS 60598.1:2017 *Luminaires Part 1: General requirements and tests*

This section describes the standards and staff's assessment of the adequacy of the standards in addressing the ingestion hazard associated with child access to button cell and coin batteries in consumer products.

A. UL 4200A

The scope of Underwriters Laboratories (UL) 4200A requirements cover household-type products that incorporate or may use button cell or coin batteries of lithium technologies. This standard intends to minimize the risk of children removing and ingesting or aspirating button cell or coin batteries. UL 4200A uses the term "button/coin cell battery," defined as "[a] single cell battery having a diameter of 32 mm (1.25 in) maximum, and diameter greater than its height." UL 4200A specifies requirements for construction and durability of the battery compartment.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

1. Requirements

Section 5.5 of UL 4200A specifies that products with removeable or replaceable button/coin cell batteries inside a battery compartment must be designed with one of two methods to access removable/replaceable battery compartments:

1) To open the battery compartment, consumers must use a tool, such as a screwdriver or coin. For a battery compartment secured by a screw or a twist-on access cover, a minimum torque of 0.5 Nm and a minimum angle of 90 degrees of rotation shall be required to open the compartment or the fastener shall engage a minimum of two full threads. Section 5.6 specifies that fasteners used to secure the battery door/cover must be "captive to the door, cover or device," meaning the fastener is permanently attached and can be fastened and unfastened but will not detach when unfastened. This requirement excludes large panel doors on large devices which are not likely to be discarded or left off the equipment.
2) The battery compartment door or cover must require the application of a minimum of two or more independent and simultaneous movements to open by hand.

Section 6 of UL 4200A specifies that the battery compartment door/cover shall not open (when tested with a finger probe) and shall remain functional after the product is pre-conditioned and subjected to a series of mechanical abuse testing. Pre-conditioning consists of a thermal stress-relief test of plastic components and a battery replacement test to simulate mechanical wear of the battery compartment parts. After pre-conditioning, the abuse testing consists of drop tests, followed by an impact test and crush test.

For products with button cell or coin batteries that are not intended to be removed or replaced, and that are accessible using a probe, section 5.7 of UL 4200A specifies that the product must either meet the same pre-conditioning, abuse, and finger probe tests as products with removeable batteries, or the product must secure the battery in such a way that the battery does not separate from the product when tested with a hook probe.

2. Pre-conditioning

Section 6.2 of UL 4200A specifies that products with battery compartments (including door/cover) made of thermoplastic materials shall be heated to at least 158 degrees Fahrenheit for 7 hours. Section 6.2 also specifies that the battery compartment door/cover be opened and closed, and the battery removed and replaced for ten cycles. This includes removing and replacing screws that secure the battery enclosure with a torque value based on the size of the screws. This step simulates the mechanical wear to the battery compartment through repeated battery replacements. The pre-conditioning tests ensure that the battery compartments of the products are in a realistic state after expected use of the product may have loosened or settled the components.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

3. Abuse testing

UL 4200A specifies a series of mechanical abuse tests to stress the battery compartments. These tests are conducted in sequential order after the products have been pre-conditioned. The first test is a drop test in which products are dropped from a height of 1.0 m (39.4 in) onto a horizontal hardwood surface. The standard states that the products shall be dropped in a position such that the impact would produce the maximum possible force on the battery compartment or enclosure. The number of drops depends on the size of the product: 3 drops for portable devices and 10 drops for hand-held products. UL 4200A defines portable products as products specifically designed to be carried easily, with mass not exceeding 18 kg (39.7 lb). UL 4200A does not specifically define what constitutes a hand-held product.

The second test is an impact test subjecting the battery compartment enclosure to three, 2-J (1.5-ft·lbf) impacts. For this test, a steel sphere 50.8 mm (2 inches) in diameter, weighing approximately 0.5 kg (1.1 lb) drops onto the battery compartment. The sphere can be dropped or tethered and swung like a pendulum from a height, H, that produces the required 2-J of energy on impact with the battery compartment.

The third test is a crush test. This test applies a compressive load of 330 ±5 N (74.2 ± 1.1 lbf) on a product that is supported by a rigid surface. The standard specifies that the product shall be positioned in such a way that produces the most adverse results as long as the position can be self-supported. A flat, rigid surface measuring approximately 100 by 250 mm (3.9 by 9.8 in) applies the crushing force on the product.

4. Compliance to Requirements

A finger probe test determines compliance of the battery compartment (or product with non-removeable battery whose battery is enclosed in a battery compartment) after the product has been subjected to the abuse tests. Section 6.3.5 of UL 4200A specifies the application of Test Probe 11 of IEC 61032 *The Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification* with 45 ±1 N (10.1 ±0.2 lbf) of force to the battery compartment door/cover for 10 seconds. The probe applies a force on the battery enclosure at the most unfavorable position and in the most unfavorable direction to cause the compartment door/cover to open or gain access to the battery. The probe shall apply a force one direction at a time. Section 6.3.5 specifies that the battery compartment door/cover shall not open, shall remain functional, and the battery shall not be accessible after the probe test.

For consumer products with accessible non-removeable batteries that are permanently secured, a hook test determines the adequacy of the battery securement. Figure 5 below shows the test hook for this compliance test. Section 6.4.1 specifies using a test hook to apply 20 ±2 N (4.5 ±0.4 lbf) of outward force for 10 seconds at all points where the hook can be applied. Section

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

6.4.1 specifies that the button cell or coin battery shall not separate from the product after the hook test.

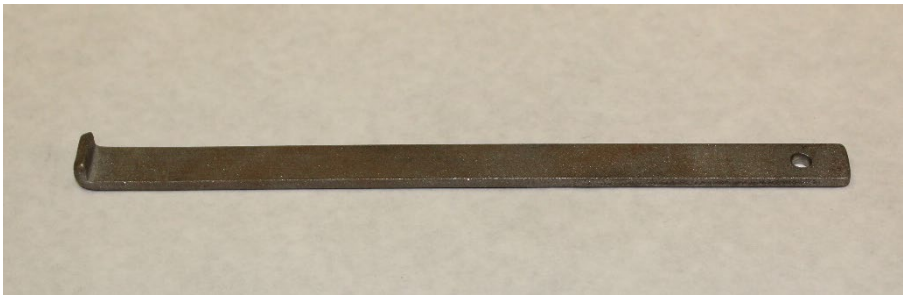


Figure 5. UL 4200A Test Hook

B. ASTM F963

16 CFR part 1250 mandates ASTM F963-17 as the mandatory standard for toys within the scope of the standard beginning on February 28, 2018. ASTM F963 defines a button cell battery as a "small round non-lithium battery, in which the overall height is less than the diameter" and states the definition for button cell batteries is "from ANSI C18.1 M Part 1; these batteries are typically identified by a SR or LR designation; for example: SR44, LR44, SR45, LR45, SR54, LR 54."

1. Requirements

Section 4.25.5 requires that all battery-operated toys (with batteries that fit within the small parts cylinder) require the use of a coin, screwdriver, or other common household tool to access the batteries. Accessibility of the battery is tested before and after normal abuse testing in section 8.5 and relevant abuse testing described in sections 8.6 through 8.10. The normal abuse testing described in section 8.5 states toys "shall be subject to appropriate tests to simulate the expected mode of use of the particular toy" and is intentionally vague in recognition of the wide range of toy designs. Because no specific requirements are defined, staff concludes only the abuse testing specified in sections 8.6 through 8.10 are relevant to staff's assessment of the voluntary standard requirements that address battery ingestion.

2. Abuse Testing

Although ASTM F963-17 specifies many abuse tests for toys in general, ESMC staff concludes that the abuse tests that are relevant to button cell and coin battery products subject to the proposed rule are the following:

- Section 8.7.1 Drop Test

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

- Section 8.8 Torque Tests for Removal of Components
- Section 8.9 Tension Test for Removal of Components
- Section 8.9.1 Tension Test for Seams in Stuffed Toys and Beanbag-Type Toys
- Section 8.10 Compression Test.

The drop, compression, torque, and tension tests can be specifically applied to test for the durability of battery compartments, and the tension tests for seams can be applied to test the accessibility of battery compartments in non-rigid type products.

Section 8.8 specifies a torque test for removal of components, including "a projection, part, or assembly that a child can grasp with at least the thumb and forefinger or the teeth," which can include all or part of a battery compartment enclosure. This test applies a torque evenly for a period of 10 seconds until either a rotation of 180° is achieved or the required torque is exceeded. This test repeats in both the clockwise and counterclockwise direction.

Similar to the torque test above, Section 8.9 specifies a tension test for the same components. This test applies a tension load on the components using a clamp over a period of 10 seconds along the major axis of the test component. This test repeats along the perpendicular axis and maintained over 10 seconds.

Section 8.9.1 specifies an alternative tension test that can be applied to battery compartments covered by pliable material such as textiles and have seams for example that are stitched or glued. This tension test uses special clamps with jaws consisting of ¾ inch diameter flat washers. The clamps apply a tension adjacent to the seam (but no closer than ½ inch) in way of the battery compartment in any direction and maintained over 10 seconds.

Section 8.10 specifies a compression test that for any area on the surface of a toy that is accessible to a child and inaccessible to flat surface contact during the drop test shall be subjected to a compression test. The magnitude of the compressive force exerted onto the test subject depends on the intended age range of the toy ranging between 20 to 30 lbs. A disk measuring 1.125 ± 0.015 in. (0.380 mm) in diameter and 0.375 in. (9.52 mm) in thickness applies the compressive force on the surface of the toy. The test procedure specifies that the load shall be applied for 10 seconds while the toy rests flat on a hard surface in a position where the disk parallel to the bottom surface applies the compressive force on the target area.

3. Compliance to Requirements

ASTM F963 tests for compliance of the battery compartment before and after the product has been subjected to abuse testing. Section 4.25.5 of ASTM F963 states that the batteries shall not be accessible (defined as any area that can be contacted by an accessibility probe) without the use of a coin, screwdriver, or other common household tool.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

C. Australian F2020L01656

In 2020, the Australian Competition and Consumer Commission published regulatory standard F2020L01656 for consumer goods containing button cell or coin batteries. The purpose of this safety standard is to reduce the risk of death or serious injury to children as a result of accessing button cell or coin batteries from products. This standard applies to any consumer product that contains a button cell or coin battery whether or not the battery is intended to be replaceable. This standard does not apply to hearing aids, professional equipment not intended for sale to the general public, and audio, video, information and communication technology with button cell or coin batteries soldered in place. F2020L01656 specifies test requirements depending on the product category from the following international standards, and the following sections summarize how these standards address battery accessibility and ingestion hazards.

- IEC 62368-1:2018 Audio/video, information and communication technology equipment-Part 1: Safety requirements
- IEC 62115:2017 Electric toys—Safety
- AS/NZS 60065:2018 Audio, video and similar electronic apparatus-Safety requirements
- AS/NZS 60598.1:2017 Luminaires Part 1: General requirements and tests
- UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies

1. IEC 62368-1 Audio/video, information and communication technology equipment-Part 1: Safety requirements

The scope of IEC 62368-1 applies to the safety of electrical and electronic equipment within the field of audio, video, information and communication technology, and business and office machines with a rated voltage not exceeding 600 V. This standard replaces and supersedes IEC/AS/NZS/EN/UL 60065. IEC 62368-1 has equivalent standards published in individual countries including Australia/New Zealand (AS/NZS 62368-1), Europe (EN 62368-1), and the United States (UL 62368-1). IEC 62368-1 and the equivalent standards above specify requirements for button/coin cell battery access that are identical to those defined in UL 4200A.

2. IEC 62115 International Standard for Electric Toys – Safety

The scope of IEC 62115 covers electric toys that have at least one function dependent on electricity for use in play by children under 14 years of age. IEC defines button cell and coin batteries as having overall height is less than the diameter. The standard differentiates between button cell and coin batteries by their electrochemical system: lithium-based batteries are referred to as “coin cells” and non-lithium-based batteries are referred to as “button cells.”

IEC 62115 defines accessibility for batteries that fit wholly within the ISO standard[2] small parts cylinder as requiring a tool before the battery can be made removeable. If a toy has a part that

[2] Section 5.2 of ISO 8124-1:2014.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

fits within the ISO standard small parts cylinder and has a battery, the part shall require a tool to be removed from the toy. The standard specifies a compliance test for these small parts by applying a 50 N (11.2 lbf) push force and either a 30 N (6.7 lbf) or 50 N (11.2 lbf) pull force depending on the size of the small part containing the battery. If the part is likely to be twisted, the compliance test adds a torque of 2-4 Nm (17.7-35.4 in.-lbf) to both the push and pull tests depending on the size of the part. The part shall not become detached to pass compliance.

IEC 62115 specifies tests for screws such as those that would secure a battery enclosure. The test is similar to the preconditioning steps in UL 4200A for repeated removal and replacement of the battery, requiring ten total cycles and applying a torque to the screw based on its diameter.

IEC 62115 specifies multiple mechanical abuse tests to check for compliance for battery accessibility. The first test subjects a toy to a drop from a height of 93 cm ± 5 cm (36.6 in.) onto an impact surface made out of vinyl composition tile of approximately 3 mm nominal thickness and 0.3 m^2 area laid over concrete of at least 64 mm thickness. The test procedure specifies a required Shore 'A' hardness for the tile of 80 ± 10. The drop test repeats 10 times for toys intended for children younger than 18 months old and 4 times for toys intended for 19-96 months old. The test procedure specifies that the toys shall be dropped in a random orientation. IEC 62115 also specifies an impact test in which enclosures are subjected to three blows having an impact energy of 0.5 J. Lastly, toys are subjected to a tension test for all electric toys and for electric toys having textile or other flexible materials covering batteries. The test procedures are identical to those specified in ASTM F963 above except a force of 70 N ± 2 N (15.7 lbf ± 0.45 lbf) is applied.

3. AS/NZS 60065:2018 Audio, video and similar electronic apparatus-Safety requirements

First published in 1952, IEC 60065 and its equivalent adaptations in Australia/New Zealand (AS/NZS 60065), Europe (EN 60065), and United States (UL 60065) were superseded by IEC 62368-1 in 2010. Therefore, the requirements in this standard no longer apply to the battery ingestion hazard.

4. AS/NZS 60598.1:2017 Luminaires Part 1: General requirements and tests

IEC first published international standard IEC 60598-1 *Luminaires – Part 1: General requirements and tests* in 1979 and has been updated numerous times since. In 1998, Australia published their equivalent standard AS/NZS 60598-1 for which their regulation references. Similarly, Europe published the equivalent standard EN 60598-1 in 1993. This standard specifies general requirements for luminaires or electric light sources with supply voltages up to 1,000 V. Australian regulation F2020L01656 (see section C) references tests detailed in section 4.101.1 of the AS/NZS 60598-1 standard, but staff was unable to find the referenced tests in the latest versions of IEC and AS/NZS. Staff is unsure whether the section number referenced in F2020L01656 is incorrect or the standard referenced is incorrect. IEC 60598-1 primarily specifies requirements for light sources that receive power from alternating currents and do not address battery operated products. Therefore, staff concludes this standard is not relevant to the subject hazard.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

D. Comparison of voluntary standards

Table 1 compares how the above standards address the battery ingestion hazard with requirements that are intended to minimize the risk of children removing batteries from the consumer product.

Table 1. Summary of Voluntary Standards

Standard	Scope	Action to Open Battery Compartment	Abuse Testing
UL 4200A	Household type products that incorporate or may use button cell or coin batteries of lithium technologies	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test –74 lbf. over 38 square inches for 10s in positions likely to produce the most adverse results
ASTM F963	Toys intended for use by children under 14 years of age	Coin, screwdriver, or other common household tool required to open battery compartment	(1) Drop test – maximum 10 times at 4.5 ft in random orientation; minimum of 4 times at 3 ft in random orientation (2) Torque test – 2-4 in-lbs. of torque over 10 seconds (3) Tension test – 10-15 lbs. of tension over 10 seconds (4) Tension test for pliable materials – 10-15 lbs. of tension over 10 seconds (5) Compression test –20-30 lbf over 1 square inch for 10 seconds
IEC 62368-1	Electrical and electronic equipment within the field of audio, video, information and communication technology, and business and office machines with a rated voltage not exceeding 600 V	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test – apply 74 lbf. for 10s in positions likely to produce the most adverse results
IEC 62115	Electric toys being any product designed or intended for use in play by children under 14 years of age	Batteries that fit wholly within the small parts cylinder shall not be removable without the aid of a tool, screw fasteners must be captive.	(1) Screw test – Remove/replace screws 10 times with torque applied (2) Drop test – maximum 10 times at 93 cm ± 5 cm (36.6 in.) in random orientation; minimum 4 times at 93 cm ± 5 cm (36.6 in.) in random orientation (3) Impact test – 3 impacts by hammer imparting 0.5-J of energy (4) Tension test – 70 N ± 2 N (15.7 lbs.) of tension over 10 seconds (5) Tension test – 70 N ± 2 N (15.7 lbs.) tension force on a textile seam over 10 seconds

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

All the above standards specify similar requirements for locking mechanisms to secure the battery compartment. All the standards specify requirements for using a tool to open the battery compartment of the product to reduce the possibility of children removing the battery. UL 4200A and IEC 62368-1 also specify an option for the battery compartment door to require a double action mechanism to open by hand. UL 4200A is the only standard that specifies either a minimum torque of 0.5 Nm (4.4 in-lbf) and a minimum angle of rotation of 90 degrees for the battery compartment fastener mechanism or a minimum of two full threads engaged. UL 4200A also specifies an additional option for battery compartment enclosures that requires at least two independent and simultaneous movements to open the compartment by hand.

All the above standards, except ASTM F963-17, include a requirement for captive screws, which are screws that remain in the compartment or cover when unscrewed. Holding the screws captive is intended to ensure that when a consumer changes the battery, the screw is not lost or discarded when the consumer seeks to reclose and secure the compartment. Ensuring that consumers do not lose screws and use them to resecure the battery compartment every time the battery compartment is opened is paramount to the success of this locking mechanism to prevent child access to batteries. If the screw is not captive to the compartment door, consumers can more easily lose the screw or defeat the locking mechanism by removing the screw, perhaps not understanding that one purpose of a screw is to prevent child access to the battery and the associated ingestion hazard. Accordingly, the requirement for a captive screw helps to ensure that the screw is maintained and used by consumers each time the battery compartment is opened and reclosed.

The above standards all specify similar abuse tests designed to test products' durability against reasonable, foreseeable use or misuse. UL 4200A specifies:

- Heat pre-conditioning of plastic components of the product, compared to no such requirements in ASTM F963 and IEC 62115. Staff's testing demonstrated that heat pre-conditioning of the product will stress plastic components and more realistically simulate the expected condition of the product during normal use.
- Mechanical pre-condition of the product by opening and closing the battery compartment and by removing and installing the battery, compared to no such requirements in ASTM F963. IEC 62115 specifies screw tests identical to these preconditioning steps. Staff's testing confirmed that mechanical pre-conditioning breaks-in the components associated with securing the battery compartment and will address some quality issues such as stripping of threads.
- 10 drop tests from a height of 3.3 feet in positions likely to produce the maximum force, compared to requirements in ASTM F963 and IEC 62115 which allow for as few as 4 drops from a height of 3 feet in random orientation. The greater drop height and increased number of repetitions specified in UL 4200A will impart more energy upon impact on the sample battery enclosures and therefore will lead to more robust product construction to meet this requirement. In addition, because UL 4200A specifies an orientation that can specifically target battery enclosures on impact, this will ensure that each time the maximum amount of energy is imparted on the battery enclosure.
- Three impact tests that impart 2-J of energy directly on the battery compartment with a steel ball, compared to no such requirements in ASTM F963. IEC 62115 specifies an

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

impact test but only 0.5-J of energy are imparted on the battery enclosure. The greater energy requirement of UL 4200A will lead to stronger battery enclosure construction.

Both UL 4200A and ASTM F963 specify a compression test. ASTM F963's compression test subjects a compressive load on areas of the product that are "accessible to a child and inaccessible to flat surface contact during the [drop tests]." This test applies an effective pressure (force over area) of 30 psi to the product on areas over one square inch. UL 4200A's compression test would apply a larger 74 lb. compressive load on the entire product.

Staff concludes that the tension test requirements based on ASTM F963-17 and IEC 62115 should be required. Both standards require a tensile force on a battery enclosure or on a textile seam covering a battery enclosure. Staff testing included many soft goods constructed from textile, gel, paper, etc. that have an electronic component drawing power from button/coin cell batteries. The batteries and electronics may be stored in a compartment within the accessory that may become accessible through tearing or pulling on the fabric or paper. Therefore, staff recommends a 15.7 lb (70 N) tensile test for textile seams based on ASTM F963-17 and IEC 62115 to be included for soft products to account for the different soft bodied materials used in these consumer products. Additionally, ASTM F963-17 and IEC 62115 specify a torque and tension tests for removable hard components that UL 4200A does not. Adding this requirement will ensure that mechanisms securing battery enclosures are able to withstand reasonable applied forces without the double action being manipulated or screws being unfastened. The torque and tension tests should be conducted after completing the drop, impact, and crush tests because it will test the products in a more weakened state. This test order assumes that a product has already been used and abused prior to a child having access to the product and manipulating it.

Each of these four standards relies on a test probe based on a child's finger to verify whether certain components are accessible, but only IEC 62368-1, IEC 62115, and UL 4200A require a force to be applied with their respective probes to verify compliance. The IEC 62368-1 test probe head has a 3.5 mm (0.14 in.) radius, and compliance is verified with a force of 30 N ± 1 N (6.7 lbf ± 0.2 lbf). IEC 62115 and UL 4200A each use Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032. This test probe head has a 4 mm (0.16 in.) radius. Compliance is verified with a force of 50 N in IEC 62115, and a force of 45 N ± 1 N (10.1 lbf ± 0.2 lbf) in UL 4200A. Using Test Probe 11 from IEC 61032 with a force of 50 N (11.2 lbf), per IEC 62115, would better address a child's ability to get into the compartment, even though the probe is slightly larger than the IEC 62368-1 probe, because the greater force accounts for more children's abilities to push with a finger.

UL 4200A and IEC 62368-1 have requirements that may exclude products containing non-removable button cell or coin batteries from abuse testing. UL 4200A specifies that if a product has a battery that is not intended to be removed or replaced by the user that is held fully captive by soldering, fasteners, or any equivalent means, that product is not subject to abuse testing and only subject to applicable pre-conditioning tests and secureness testing using a test hook and a force of 4.5 lb. (20 N). Similarly, IEC 62368-1 excludes any products with non-removable batteries from all abuse testing, but it does not require any secureness test. Staff are aware of incidents involving children gaining access to non-removable batteries in products such as

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

computers. Although non-removable batteries may be secured to the product through various mechanical means, it is foreseeable that these products could be used or abused in a way that could potentially dislodge the batteries from the product, and it remains unclear whether the secureness test in UL 4200A will adequately address the secureness of non-removable batteries. Staff requests comment on whether the secureness test in UL 4200A is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries.

V. Staff Testing of Products to UL 4200A

Staff tested 83 products to the performance requirements specified in UL 4200A to explore and study the test methods to determine whether the standard is adequate to address the risk of children accessing a button cell or coin battery from a consumer product. Figure 6 below shows an example of the wide variety of consumer products tested. The testing included pre-conditioning and the sequential abuse tests as described in the Voluntary Standards section above. Only one item had a UL listing (clip light), which means the product was tested to UL and has been certified to the UL standard for the product category.

Figure 6. Tested product samples

Staff tested a variety of consumer products powered by replaceable button cell and coin batteries. Examples of the types of products included: calculators, greeting cards, lights (*e.g.*, bicycle lights, candle lights, clip lights, string lights), remotes and switches (for cameras, doorbells, garage doors, heaters, lights, multimedia devices), kitchen gadgets (measuring scales and timers), trackers, wearables (*e.g.*, hat, gloves, ring, shoelace, suspenders), and children's products (*e.g.*, board game, writing tablet). Staff also tested 33 remotes and

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

receivers, 18 lights, 11 wearables, eight trackers, six calculators, four kitchen gadgets, one board game, one card, and one writing tablet. Table 1A in Appendix A contains a summary of the test results.

The types of batteries found in the products during testing included CR1220, CR1632, CR2016, CR2025, CR2032, CR927, L1131F, LR1130, LR44, LR521, and LR54. The battery nomenclature has letters to classify the battery chemistry and shape and two sets of numbers to signify the diameter and thickness. For example, CR means lithium and round and 2025 signifies a 20mm diameter and 2.5mm thickness. Some common batteries have abbreviated names such as LR44, which is the same as LR1144. The L stands for alkaline while the R means round. The 1144 signifies an approximate 11mm diameter and 4.4mm height. The most common battery types utilized in the consumer products tested were CR2025 and CR2032 batteries. Approximately 51% of the samples used CR2032 batteries, 20% of samples used CR2025 batteries, 7% of samples used CR2016 batteries, and the remaining samples used one of the remaining listed batteries. Most of the batteries included were pre-installed in the product as-received and did not require installation of batteries before testing. Some products came with spare batteries included in the packaging, either loose in the packaging or in dedicated battery packaging.

Staff tested seventeen products with screws. Two products included captive screws. Nine out of the 17 products with screws passed the abuse testing, but these nine failed the captive screw requirement. Staff randomly selected five products from different product categories with screws (a kitchen gadget, writing tablet, light, calculator, and remote) to gather data on the screw sizes. Staff measured the screw diameters to be 0.056, 0.065, 0.073, 0.076, and 0.084 inches. One of the products passed UL 4200A and the other five failed the standard. Staff observed stripped screw heads and screw hole threads when attempting to follow the torque requirements specified in section 6.2 especially for products made of plastic without metal screw inserts. Staff deviated from the torque requirements and hand tightened the screws with a screwdriver until the covers were flush with the product or seated into the countersink to have intact samples for evaluation to the drop, impact, crush and secureness tests.

Staff also evaluated different battery compartment closing mechanisms used for the products tested. The different types of locking mechanisms to secure the battery compartment included single action tabs, doors, and covers, multiple action tabs, doors, and covers, screws for the battery compartment or to enclose the entire product, twist-on access covers, and permanent enclosures. Single action tabs, doors, and covers failed the requirements of section 5.3 if the battery was accessible with the finger probe per the instructions of section 5.4, which state “part of the enclosure that may be opened or removed by the user, either without using a tool or with less effort than two independent and simultaneous movements by hand, is to be opened or removed.” An example of a single action locking mechanism is shown in Figure 7 below. The battery compartment in the example requires a pull force in a single direction to slide the battery compartment out of the product.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

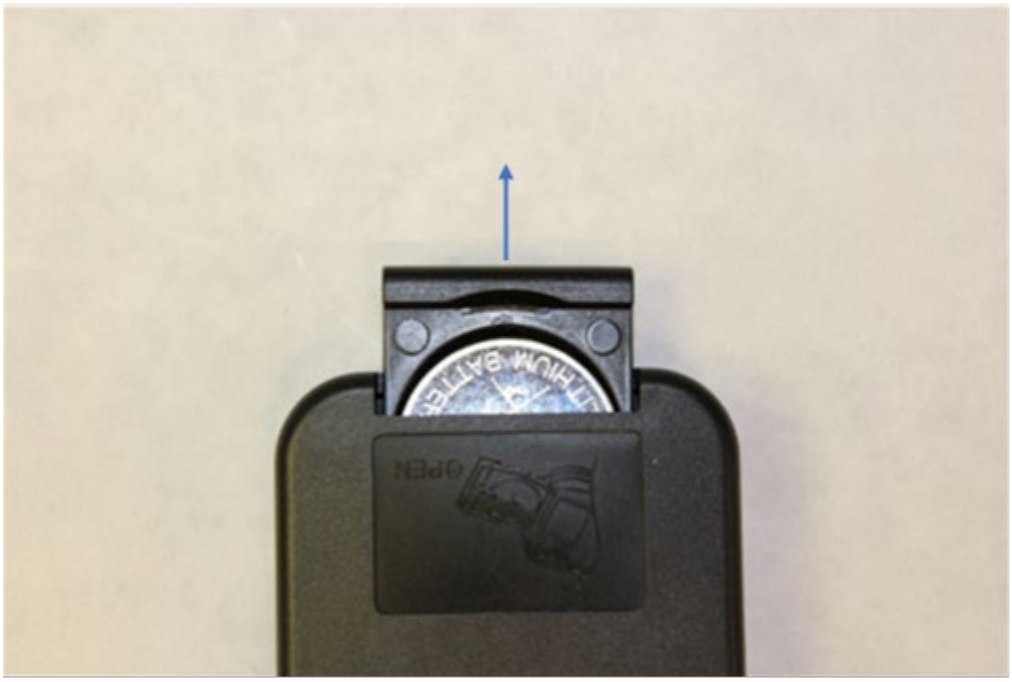


Figure 7. Single action example

Comparatively, a “double action” locking mechanism requires two independent and simultaneous movements. Figure 8 below shows a double action locking mechanism. The user applies a horizontal force on battery compartment tab and simultaneously pulls the battery compartment out of the product. Staff found this particular double action lock would require very fine motor skills to manipulate the small latch components. Staff concluded that this double action lock could be effective in preventing a child from opening the battery compartment because it required two hands and manipulation of the locking latch with the fingertip or fingernail.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

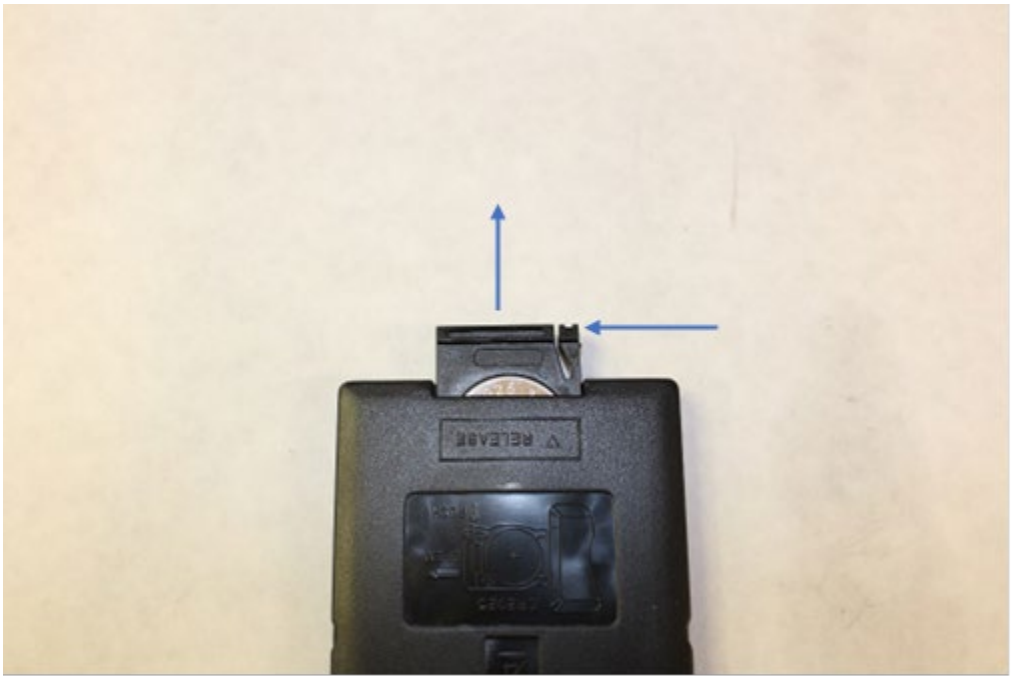


Figure 8. Double action example

Staff noticed some products that were designed as double action, but can be opened with a single action. For example, the product shown in Figure 9 required the consumer to first lift the tab by the grooves and then twist the cover. However, staff was able to push from underneath the tab in a diagonal direction to open the compartment as shown in Figure 10. Staff's draft proposed rule (TAB G) contains requirements to prevent this type of double action latch.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

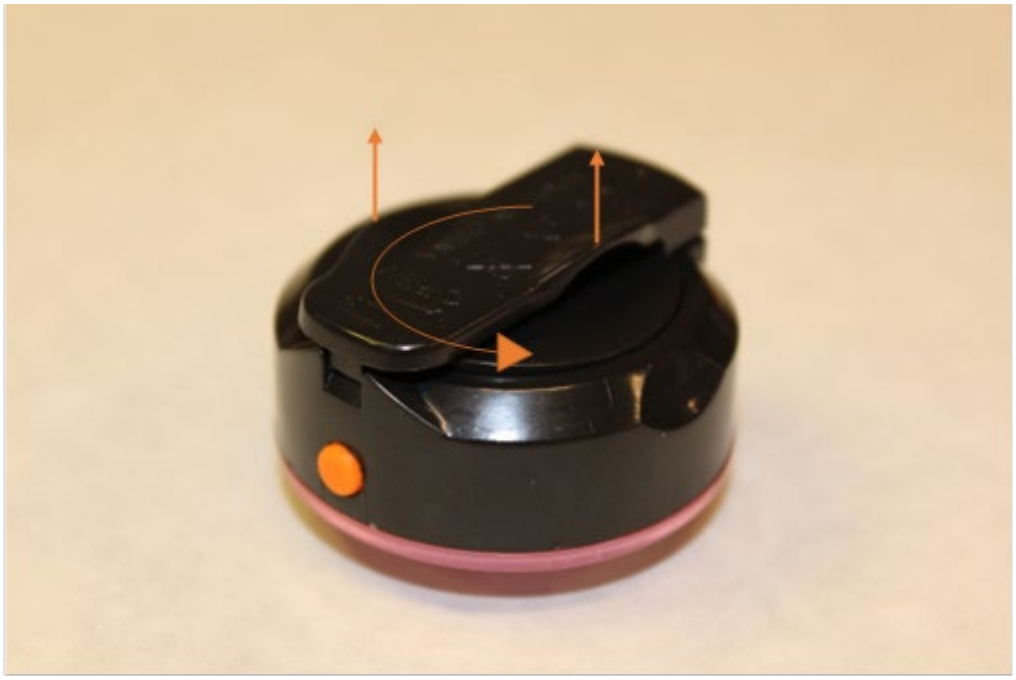


Figure 9. Sample product with intended double action locking mechanism

Figure 10. Single diagonal force to open battery compartment cover

Four products had twist-on covers which opened with an angle of rotation less than 90 degrees. Therefore, these products failed the requirements in section 5.5 of UL 4200A to have a minimum of 90 degrees of rotation to open the compartment. Figure 11 contains an example of a product with this issue.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

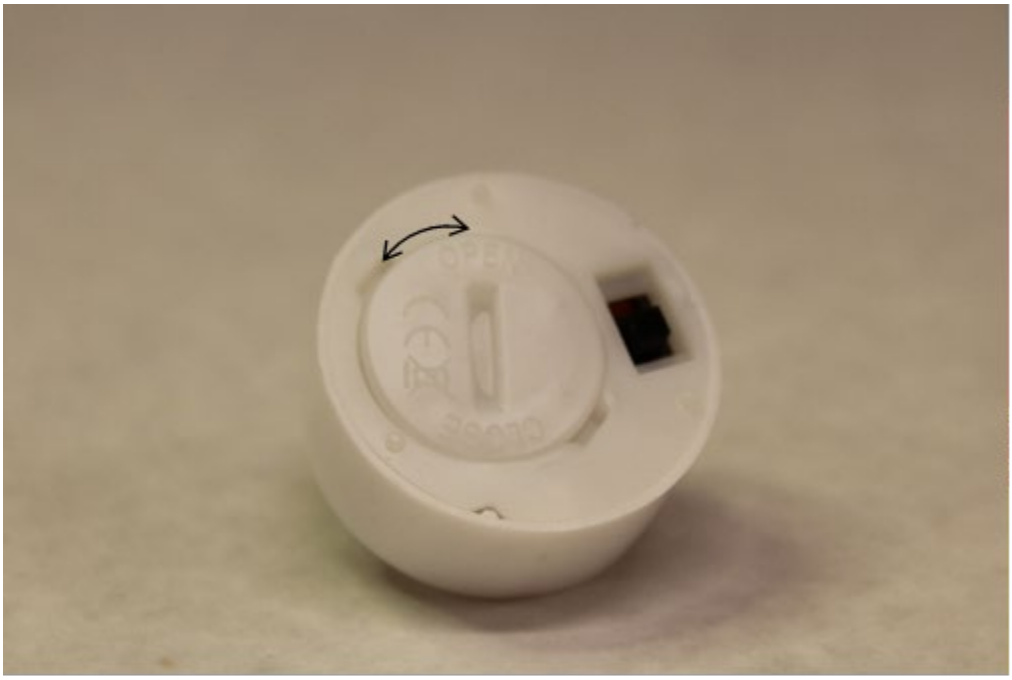


Figure 11. Twist-on cover with less than 90-degree rotation

VI. Recommended Requirements

Staff's review of voluntary standards showed that no one standard contained performance requirements sufficient to address a child accessing the battery enclosures in consumer products. Staff concluded that a general requirements and abuse testing based on UL 4200A and additional test requirements based on ASTM F963-17 would provide adequate requirements to meet Reese's law to promulgate:[3]

(1) a performance standard requiring the button cell or coin battery compartments of a consumer product containing button cell or coin batteries to be secured in a manner that would eliminate or adequately reduce the risk of injury from button or coin cell battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions.

Staff recommends the requirements based on UL 4200A with the following clarification to the captive screw requirements, double action lock requirements, the following additions based on the ASTM F963-17 standard, and greater force requirements from IEC 62115:

[3] 15 U.S.C.§ 2056e(a)(1).

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

A. Scope

Each of the standards reviewed by staff have limited scopes that do not adequately address the button/coin battery ingestion hazard or the scope of Reese's Law. In particular, UL 4200A only addresses products with button/coin batteries of lithium chemistry; however, Health Sciences staff in Tab B describe injuries and deaths involving button cell or coin batteries of alkaline chemistry. Therefore, staff recommends including all consumer products (as defined in the CPSA) which use a button cell or coin battery, excluding toys for children 14 years of age or younger which meet 16 CFR part 1250 (*i.e.,* ASTM F963), to align with the scope of Reese's Law.

B. Performance Requirements

1. Captive Screw Requirements

UL 4200A and IEC 62368-1 exclude from the requirement for captive screws any large panel doors leading to button cell or coin battery compartments which are not likely to be discarded or left off the equipment; however, staff are unsure to what products with button cell or coin batteries this exception would apply. Any door to a button cell or coin battery compartment left unsecure because of missing screws could allow a child to access the button cell or coin battery and pose a risk of ingestion. Therefore, staff recommends not including this exception to the captive screw requirements.

2. Double Action Locks

UL 4200A describes as acceptable certain locks that require two independent and simultaneous movements by hand, or double action locks. Staff's testing showed that clarification of a double action is needed to reduce the likelihood of poorly designed double-action mechanisms. Staff found that some products with double action locking mechanisms were easily opened by combining the two actions into one single action and therefore those actions are not truly independent (e.g., the diagonally-applied force described previously). This may lead to products with battery enclosure locking mechanisms that may be inadvertently opened by a child or outside force. Staff recommends using this test in the proposed rule, but clarifying what makes for an acceptable double action lock by specifying that the two actions to be performed must be independent and cannot be combined into one single action.

3. Drop Test

The drop test in UL 4200A specifies that portable products, defined as products designed to be carried easily with mass not exceeding 18 kg (39.7 lbs.), be dropped three times, expanding this to ten times for hand-held products. The term "hand-held" is undefined and subjective, which may lead to a product being subjected to a different number of drops by different testers. To avoid this confusion, staff recommends subjecting all products in scope to the greater number of 10 drops.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

4. Compression Test

For some products with recessed compartments or complex polygonal surfaces, impacts from a drop test or impact test on a flat surface may not directly access the battery enclosures due to their shape such as a feature formed around the battery compartment. ASTM F963-17 specifies a compression test that applies a maximum 30.5 lbf (135.7 N) load on a surface approximately 1.125 in. (0.380 mm) in diameter specifically for any areas that are inaccessible to flat surface contact. Staff considers the 30.5 lbf (135.7 N) compression test applied to a small area and the 74.2 lbf (330 N) crush test specified in UL 4200A are reasonable loads that a child could apply to a product while squeezing, pressing or stepping on the product. Staff recommends utilizing this test in the proposed rule to account for potential child access to these surfaces of the product.

5. Torque and Tensile Tests

Many of the non-rigid products passed staff's abuse tests from UL 4200A because they can absorb the energy from the tests, but the batteries can be easily accessed through other methods not considered in UL 4200A, such as torque or tension loads which simulate a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth. ASTM F963-17, IEC 62115, and other standards do include torque and tension tests addressing these hazards. Therefore, staff recommends the torque and tension tests based on ASTM F963-17 and IEC 62115 to the performance requirements.

6. Greater Forces

The maximum force requirements in IEC 62115 for the tensile test and the accessibility probe are greater than those in ASTM F963-17 and UL 4200A, respectively. The use of these greater forces will better address children unintentionally accessing the battery compartment. Therefore, staff recommends basing the minimum force requirements for the tensile test and the accessibility probe on the maximum force requirements in IEC 62115.

Staff concludes that a rule based on UL 4200A with modification and additional requirements would result in products with more robust battery enclosures and would reduce the likelihood of a young child gaining access to the battery within the enclosure.

VII. Conclusion

Based on the review of standards and testing products to UL 4200A, staff concluded that the performance requirements in UL 4200A and sections of ASTM F963-17, with modifications, would result in consumer products with more child-resistant battery enclosures and would adequately reduce the risk of injury from button or coin cell battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions. Staff tested 83 products to UL 4200A. The test samples represented a convenience sample of consumer products containing button cell or coin batteries. The testing showed that pre-conditioning and abuse tests specified in UL 4200A, failed products with poorly designed battery compartment enclosures. Staff's testing showed that clarification of a double action is needed to reduce the

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

likelihood of poorly designed double-action mechanisms. Staff testing also showed that an additional torque and tensile abuse test similar to ASTM F963-17 and IEC 62115 for certain types of soft goods are needed. Many of the non-rigid products passed staff's abuse tests from UL 4200A because they can absorb the energy from the tests, but the batteries can be easily accessed through other methods not accounted for in UL 4200A such as torque or tension loads. Staff concludes that a rule based on UL 4200A with modification to clarify requirements for double action and additional torque, tension and compression requirements would result in products with more robust battery enclosures and would reduce the likelihood of a young child gaining access to the battery within the enclosure.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Appendix A

Table 1A below is a summary of staff's testing. The results of the testing showed that 29 of the 83 products passed and 54 of the 83 products failed the requirements of UL 4200A. Twenty-two of the 83 products failed because the battery was accessible without the use of a tool or double action mechanism. In 14 tested products, the batteries became accessible with the finger probe after the drop test, and in seven products the batteries became accessible with the finger probe after the impact test. No products tested failed the crush test.

Table 1A. Summary of Staff's Testing to UL4200A Requirements

Sample	Pass/Fail	Performance Requirement Failed	Product Category	Locking Mechanism	Battery Type	Comment
1	P		Remote	Double action	CR2025	
2	F	6.3.2 Drop test for portable devices	Remote	Double action	CR2025	
3	P		Remote	Double action	CR2025	
4	P		Remote	Double action	CR2025	
5	F	6.3.2 Drop test for portable devices	Remote	Double action	CR2025	
6	P		Remote	Double action	CR2032	
7	P		Remote	Double action	CR2025	
8	F	6.3.3 Impact test	Remote	Double action	CR2025	
9	F	5.4 Enclosure opening	Remote	Single action	CR2025	
10	F	6.3.3 Impact test	Remote	Tool required	CR2032	
11	F	6.3.2 Drop test for portable devices	Remote	Tool required	CR2032	
12	F	6.3.2 Drop test for portable devices	Remote	Single action	CR2016	
13	F	6.3.2 Drop test for portable devices	Remote	Tool required	CR2032	
14	P		Remote	Double action	CR2032	
15	P		Remote	Tool required	CR2032	
16	P		Remote	Tool required	CR2032	

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Sample	Pass/Fail	Performance Requirement Failed	Product Category	Locking Mechanism	Battery Type	Comment
17	F	6.3.2 Drop test for portable devices	Remote	Double action	CR2032	
18	F	6.3.2 Drop test for portable devices	Calculator	Screw	LR44	Non-captive screw
19	P		Lights	Permanent	CR2032	
20	F	6.3.2 Drop test for portable devices	Lights	Single action	CR2032	
21	F	5.6 Captive Screw	Lights	Screw	CR2032	Non-captive screw
22	F	5.4 Enclosure opening	Lights	Single action	CR2016	
23	F	5.6 Captive Screw	Calculator	Screw	L1131F	Non-captive screw
24	F	5.6 Captive Screw	Calculator	Screw	LR1130	Non-captive screw
25	P		Lights	Double action	CR2032	
26	F	5.4 Enclosure opening	Lights	Single action	CR2032	
27	F	5.6 Captive Screw	Calculator	Screw	L1131F	Non-captive screw
28	P		Wearable	Permanent	***	Battery type unknown without permanently opening product
29	F	5.4 Enclosure opening	Battery switch	Single action	CR2032	
30	F	5.4 Enclosure opening	Tracker	Single action	CR2032	
31	F	6.3.2 Drop test for portable devices	Wearable	Tool required	LR1130	
32	F	6.3.3 Impact test	Calculator	Screw	LR1130	Non-captive screw
33	F	6.3.2 Drop test for portable devices	Writing tablet	Screw	CR2032	Non-captive screw
34	F	5.4 Enclosure opening	Lights	Screw	CR2032	
35	P		Tracker	Tool required	CR2025	
36	F	5.4 Enclosure opening	Kitchen Appliance	Single action	CR2032	
37	P		Kitchen Appliance	Screw	CR2032	Captive screw
38	P		Tracker	Tool required	CR2032	
39	F	5.4 Enclosure opening	Tracker	Single action	CR1632	

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Sample	Pass/Fail	Performance Requirement Failed	Product Category	Locking Mechanism	Battery Type	Comment
40	F	6.3.2 Drop test for portable devices	Lights	Single action	CR2032	
41	F	5.4 Enclosure opening	Lights	Single action	CR2032	
42	F	5.4 Enclosure opening	Tracker	Single action	CR2032	
43	F	5.4 Enclosure opening	Wearable	Single action	CR2016	
44	P		Remote	Double action	CR2025	Double action and screw
45	F	5.3 Accessibility	Wearable	Screw cover	LR521	
46	F	6.3.3 Impact test	Lights	Screw	CR2016	Non-captive screw
47	F	5.5 90-degree rotation	Tracker	Screw cover	CR2032	Less than 90-degree rotation required
48	F	5.4 Enclosure opening	Tracker	Single action	CR2032	No specific battery compartment door, but entire product can be opened by hand.
49	F	5.6 Captive Screw	Wearable	Screw	CR2032	Non-captive screw
50	F	6.3.3 Impact test	Board game	Screw	LR44	Non-captive screw
51	F	6.3.3 Impact test	Lights	Single action	LR44	
52	F	5.5 90-degree rotation	Kitchen Appliance	Screw cover	CR2032	Less than 90-degree rotation required
53	F	5.4 Enclosure opening	Wearable	Single action	CR2032	Pull tab
54	F	5.6 Captive Screw	Wearable	Screw	CR2032	Non-captive screw
55	F	5.4 Enclosure opening	Wearable	Single action	CR2032	Pull tab
56	F	6.3.2 Drop test for portable devices	Wearable	Single action	CR2016	
57	F	5.5 90-degree rotation	Remote	Screw cover	CR2032	Less than 90-degree rotation required
58	F	6.3.3 Impact test	Receiver	Tool required	CR2032	
59	P		Card	Permanent	***	Battery type unknown without permanently opening product
60	F	5.6 Captive Screw	Lights	Screw	CR2032	Non-captive screw
61	F	5.5 a) Twist on access cover	Lights	Screw cover	CR927	Less than 0.5 Nm

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Sample	Pass/Fail	Performance Requirement Failed	Product Category	Locking Mechanism	Battery Type	Comment
62	F	5.5 a) Twist on access cover	Lights	Screw cover	CR2032	Less than 0.5 Nm
63	F	6.3.2 Drop test for portable devices	Kitchen Appliance	Single action	LR1130	
64	F	5.6 Captive Screw	Calculator	Screw	LR54	Non-captive screw
65	P		Tracker	Permanent	***	Battery type unknown without permanently opening product
66	F	5.5 90-degree rotation	Lights	Screw cover	CR2032	Less than 90-degree rotation required
67	P		Wearable	Permanent	***	Battery type unknown without permanently opening product
68	P		Lights	Permanent	CR2032	
69	F	5.6 Captive Screw	Lights	Screw	CR2016	Non-captive screw
70	F	5.4 Enclosure opening	Wearable	Single action	CR2032	
71	P		Remote	Double action	CR2025	
72	P		Remote	Screw	CR2032	Captive screw
73	F	5.4 Enclosure opening	Remote	Single action	CR2032	
74	P		Remote	Double action	CR2032	
75	P		Remote	Double action	CR2025	
76	P		Remote	Double action	CR1220	
77	F	6.3.2 Drop test for portable devices	Remote	Double action	CR2025	
78	F	6.2.1. Replacement	Lights	Single action	CR2032	Cover broke when opening
79	P		Remote	Double action	CR2032	
80	P		Remote	Double action	CR2025	
81	P		Remote	Double action	CR2025	
82	P		Remote	Double action	CR2025	
83	P		Remote	Double action	CR2025	

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

TAB E

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission

Initial Regulatory Flexibility Analysis

Draft Proposed Rule: Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

January 11, 2022

For additional information, contact:

Mark Bailey
Economist
Directorate for Economic Analysis
Office of Hazard Identification and Reduction
Email: mbailey@cpsc.gov

U.S. Consumer Product Safety Commission
4330 East West Highway

Bethesda MD. 20814

This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

I. Introduction

Pursuant to the passage of Reese's Law, Public Law 117-171, staff of the Consumer Product Safety Commission (CPSC) is submitting a draft proposed rule for Commission consideration that would establish a mandatory safety standard and notification requirements for button cell or coin batteries and consumer products containing such batteries. These products include (but are not limited to) remote controls, portable lights, and other consumer products (referred to throughout this report as *button battery powered products*). These *button battery powered products* do not include toys under 16 CFR 1250, and hearing aids.

Whenever an agency publishes a proposed rule, the Regulatory Flexibility Act (5 USC 601 – 612) requires that the agency prepare an initial regulatory flexibility analysis (IRFA) that describes the impact that the rule would have on small businesses and other entities, unless the rule would not have a significant economic impact on a substantial number of small entities. The IRFA must contain –

(1) a description of why action by the agency is being considered;
(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
(5) an identification to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

An IRFA must also contain a description of any significant alternatives that would accomplish the stated objectives of the applicable statutes and which would minimize any significant economic impact of the proposed rule on small entities. Alternatives could include (1) the establishment of differing compliance or reporting requirements that account for the resources available to small businesses; (2) the clarification, consolidation, or simplification of compliance and reporting requirements for small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part of the rule thereof, for small entities. This report provides an IRFA examining the potential impact of the draft proposed rule on small businesses and other small entities.

II. Reason for Agency Action

The draft proposed rule is intended to address the ingestion hazard involving button cell or coin batteries, as stated and required by Reese's Law. The Directorate for Epidemiology, Division of Hazard Analysis (EPHA), reports that there are an average of 2.5 button/coin battery fatal injuries annually (Tab A Topping). Additionally, EPHA reports that from 2011 to 2021 there was an annual average of 4,900 non-fatal injuries involving button or coin batteries treated in

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

hospital emergency departments across the U.S. Among these injuries, 82 percent were treated and released from the emergency department.

The proposed rule would adopt performance requirements for *button battery powered products* as detailed in Tab D and the labeling/packaging requirements in Tab C. Staff assesses these requirements as effective at preventing access to button/coin batteries by children and by extension effective at reducing injuries associated with button or coin battery ingestion. The draft proposed rule would only address the injuries associated with *button battery powered products*. The number of injuries involving *button battery powered products* where staff could identify and confirm the source product equates to an annual average of about 0.5 fatal injuries and 1,100 non-fatal injuries.[1]

III. Objectives of and Legal Basis for the Rule

The objective of the rule is to adequately reduce or eliminate the risk of serious injury or death related to ingestion of button cell or coin batteries in children six years old and younger. The proposed rule would be issued under the authority of Reese's Law, Public Law 117-171, which authorizes the Commission to conduct notice and comment rulemaking under 5 U.S.C. section 553 to establish a safety standard for child-resistant battery compartments on consumer products and warnings on such products and on button cell and coin battery packaging.

IV. Small Entities to Which the Rule Will Apply

The North American Industry Classification System (NAICS) defines product codes for U.S. firms. Firms that manufacture *button battery powered products* may list their business under a large variety of NAICS product codes as these products include a wide variety of consumer products. A majority of these firms likely fall under NAICS codes 334118 Computer Terminal and Other Computer Peripheral Equipment Manufacturing, 334310 Audio and Video Equipment Manufacturing, 335999 All Other Miscellaneous Electrical Equipment and Component Manufacturing, and 339920 Sporting and Athletic Goods Manufacturing. Importers of *button battery powered products* are also as varied as the manufacturers and staff expects a majority of the firms to fall under the following NAICS codes as wholesalers; 423620 Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers, 423430 Computer and Computer Peripheral Equipment and Software Merchant Wholesalers, and 423690 Other Electronic Parts and Equipment Merchant Wholesalers. Retailers of *button battery powered products* consist of a large variety of retailer types from large, "big box" retailers to smaller specialized product firms. Nearly every NAICS code listed under retail trade (44, 45) may sell a product within scope of the proposed rule. Staff estimates that a majority of these products are sold by firms listed in NAICS codes 443140 Electronics and Appliance Retailers, 455219 All Other General Merchandise Retailers, 459420, Gift, Novelty, and Souvenir Retailers, 452000 General Merchandise Stores, and 459110 Sporting Goods Retailers. Staff note that these NAICS codes for retailers, importers, and manufacturers are not meant to be all inclusive as the scope of the rule is wide and includes products ranging from, but not limited to, lighting,

[1] Staff could not identify the source product for a majority of the incidents reviewed as the documentation lacked sufficient detail.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

safety, audio, entertainment, health, cooking, and sport devices. The wide scope of the proposed rule could affect a much greater number of firms than estimated.

Under Small Business Administration guidelines, a manufacturer, importer, and retailer of *button battery powered products* is categorized as small based on the associated NAICS code. Manufacturers are categorized as small by the number of employees and importers/retailers by annual revenues. Based on 2017 data from U.S. Census Bureau, and a sample of retailers' estimated revenues, staff estimated the number of firms classified as small for each NAICS code listed above (Census Bureau, 2020).[2] The tables below provide the estimates of number of small firms by each code.

[2] Staff reviewed a small convenience sample of retailers within NAICS codes 443140, 455219, 459420, 452000, and 459110. Annual revenue estimates were obtained for the sample from Dun and Bradstreet commercial data.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 1. Estimate of Number of Small Manufacturers and Importers

NAICS Code	Description	SBA Size Standard for Manufacturers/Importers (# of Employees)	Number of firms that meet size standard
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000	509
334290	Other Communications Equipment Manufacturing	750	305
334310	Audio and Video Equipment Manufacturing	750	453
335210	Small Electrical Appliance Manufacturing	1,500	119
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	500	734
339920	Sporting and Athletic Goods Manufacturing	750	1,564
339940	Office Supplies (except Paper) Manufacturing	750	412
339999	All Other Miscellaneous Manufacturing	500	5,714
423420	Office Equipment Merchant Wholesalers	200	2,197
423430	Computer and Computer Peripheral Equipment and Software Merchant Wholesalers	250	5,743
423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers	225	1,956
423690	Other Electronic Parts and Equipment Merchant Wholesalers	250	8,826
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	100	4,521
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100	8,350

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 2. Estimate of Number of Small Retailers

NAICS Code	Description	SBA Size Standard for Retailers (Annual Revenue) $millions	Number of firms that meet size standard
444110	Home Centers	$41.50	1,526
444130	Hardware Retailers	$14.50	9,623
444240	Nursery, Garden Center, and Farm Supply Retailers	$19.00	13,228
443140	Electronics and Appliance Retailers	$35.00	18,906
455110	Department Stores	$35.00	11
455211	Warehouse Clubs and Supercenters	$41.50	3
455219	All Other General Merchandise Retailers	$35.00	7,812
456110	Pharmacies and Drug Retailers	$33.00	18,912
459110	Sporting Goods Retailers	$23.50	16,123
459410	Office Supplies and Stationery Retailers	$35.00	2,646
459420	Gift, Novelty, and Souvenir Retailers	$12.00	15,264
459999	All Other Miscellaneous Retailers	$10.00	36,225
452000	General Merchandise Stores	$35.00	7,832

V. Compliance Requirements of the Draft Proposed Rule, Including Reporting and Recordkeeping Requirements

The draft proposed rule would establish a performance standard for *button battery powered products* as stated in Tab D and labeling/packaging requirements as stated in Tab C of this package.

Under section 14 of the CPSA, manufacturers or importers of general use products will be required to certify, based on a test of each product or upon a reasonable testing program, that their *button battery powered products* comply with the requirements of the draft proposed rule. Each certificate of compliance must identify the manufacturer or importer issuing the certificate and any manufacturer, firm, or third party conformity assessment body on whose

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

testing the certificate depends. Children's products must be certified based on testing performed by a third party conformity assessment body as determined by CPSC. The certificate must be legible and in English and also include the date and place of manufacture, the date and place where the product was tested, including the full mailing address and telephone number for each party, and the contact information for the person responsible for maintaining records of the test results. The certificates may be in electronic format and must be provided to each distributor or retailer of the product. Upon request, the certificates must also be provided to the CPSC.

VI. Costs of Draft Proposed Rule That Would Be Incurred By Small Manufacturers

Button battery powered products may require redesign to accommodate the screw lock or a double-action lock required by the draft proposed rule. *Button battery powered products* manufacturers would most likely adopt a screw lock for affected products that currently do not conform to the proposed rule performance requirements. The potential costs of this rule are therefore the incremental cost to incorporate a screw lock, and the one-time research/development and retooling costs associated with the changes to battery compartments. For products that incorporate a double-action lock to secure the compartment, staff expects the only cost incurred would be the redesign of compartment to accommodate the change.[3]

Estimates of the incremental costs to modify a battery compartment for a screw lock range from $0.02 to $0.04 per product based on an ESMC staff estimate.[4] Staff also estimated a range of 1 to 2 months of labor by an electrical engineer is required for research, design, validation, and retooling. Data from the Bureau of Labor Statistics (BLS) reports the median hourly wage of an electrical engineer in the U.S. is $48.93. (BLS 2022) Staff expects firms will be able to incorporate updated battery compartment designs across all products lines the manufacturer offers without additional effort required for each product line. This equates to a range of possible research/development and retooling costs of $7,700 to $15,400 per firm.[5] Firms that choose to meet the requirement through the use of a double-action lock are only expected to incur research and development costs based on staff's analysis.

Some additional costs might be incurred related to updating and/or adding labels to the product or the packaging. Generally, the costs associated with modifying/adding warning labels are low on a per unit basis because nearly all manufacturers already provide warning labels with their product. Therefore, staff estimates the cost related to the labeling/packaging provisions to be incremental and negligible to the overall cost of compliance with the draft proposed rule.

[3] Double-action locks may require an additional plastic tray or stronger locks, but the cost of the additional plastic required is expected to be near $0.00.
[4] Cost estimate based on a review of prices for a #2 and #6 machine screw along with required lock washers for each.
[5] This estimate is a high estimate as it is based on US labor rates. Lower costs would be expected for firms utilizing engineering labor in countries such as China and India.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Manufacturers would likely incur additional costs to certify that their *button battery powered products* meet the requirements of the draft proposed rule as required by Section 14 of the CPSA. For general use products, the certification must be based on a test of each product or a reasonable testing program. Manufacturers may complete the testing themselves or use a testing laboratory. Certification of children's products, however, must be completed by a CPSC-accepted third party conformity assessment body (third party laboratory). Based on quotes from testing laboratory services for consumer products, the cost of the certification testing will range from $150 to $350 per product sample.[6] These third-party testing costs are likely an overestimate and should be treated as a possible maximum testing cost of the draft proposed rule. Note that the requirement to certify compliance with all product safety rules is a requirement of the CPSA and not of the draft proposed rule. Certificate content requirements are set forth in 16 C.F.R. part 1110. A reasonable testing program performed by the manufacturer would meet the requirements for general use (non-children's) products, but children's products are required to be tested and certified based on the third party testing requirements in 16 C.F.R. part 1107.

VII. Impact on Small Manufacturers

To comply with the draft proposed rule, small manufacturers are expected to incur one-time redesign and continuous incremental component costs described above for some product lines which currently do not meet the requirements. Staff does not expect most small manufacturers to suffer a disproportionate cost effect from the draft proposed rule but firms that heavily rely on the production of small unique/novel electronic products or high volume-low price products could be adversely affected. Retail prices for *button battery powered products* vary widely with the least expensive on a per unit basis being mini flashlights of $1.00.[7] A small manufacturer could incur costs that exceed 1 percent of annual revenue if the firm only produced these high volume-low price or novel electronic products. Also, smaller manufacturers with under $1,540,000 in annual revenue could incur one-time costs that exceed 1 percent of annual revenue based on CPSC staff's estimate of the potential research and development costs which ranged from $7,700 to $15,400 per firm.

Generally, staff considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. CPSC staff expects a potentially significant impact on some small firms which manufacture *button battery powered products.*[8] Most small firms are not expected to incur costs that exceed 1 percent of annual revenues and therefore not significantly impacted by the proposed rule. CPSC staff requests comment on the number of small firms impacted and expected cost impact on small firms (as a percentage of annual revenue) of the draft proposed rule.

[6] Based on quotes from firms to conduct product certification tests to the current UL4200A standard.
[7] Based on staff's review of product offerings on retailer websites and in-store locations. Some lighting products can be purchased in bulk quantities at lower prices per unit.
[8] One small business interviewed by CPSC staff indicated that a proposed rule concerning battery compartments would result in significant costs and potential reductions to product offerings.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

VIII. Federal Rules which may Duplicate, Overlap, or Conflict with the Proposed Rule

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the draft proposed rule.

IX. Alternatives for Reducing the Adverse Impact on Small Entities

Under section 603(c) of the Regulatory Flexibility Act, an initial regulatory flexibility analysis should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." CPSC staff assessed that the broad scope of Reese's Law does not allow for a significant alternative that would reduce impacts to small businesses, as methods for reducing impacts to small firms such as limiting scope, providing exemptions, and consumer education in lieu of regulatory action would not meet the applicable statutes. To reduce impact of the rule on small firms, CPSC could remove the additional labeling requirements under section 27(e) of the CPSA as recommended by staff, but not required by Reese's Law.[9] Removing 27(e) performance and technical data is expected to reduce burden by an inconsequential amount as firms would still have to conform to the other labeling provisions. Simply stated the *incremental* increase in burden from staff's additional labeling requirements is insignificant.

[9] These additional requirements can be found in Tab C section V subsections D, E, and section VI.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

References

Bureau of Labor Statistics, U.S. Department of Labor, 2022. Occupational Outlook Handbook, Electrical and Electronics Engineers, at https://www.bls.gov/ooh/architecture-and-engineering/electrical-and-electronics-engineers.htm (visited October 05, 2022)

Census Bureau, 2020. Statistics of US Businesses (SUSB) 2017. Suitland, MD. Census Bureau.

Degrano, Fredrick, 2022. “Memorandum to Daniel Taxier; Draft Proposed Rule to Establish a Safety Standard for Child-Resistant Button or Coin Cell Battery Compartments on Consumer Products: Voluntary Standards Assessment and Proposed Requirements.” Bethesda, MD: U.S. Consumer Product Safety Commission.

Topping, John, 2022. “Memorandum to Daniel Taxier; NEISS estimates and analysis of reported incidents related to button and coin cell battery ingestion, insertion, or impaction through the mouth, nose, or ears.” Bethesda, MD: U.S. Consumer Product Safety Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Tab F

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

DATE: January 11, 2022

TO: Daniel Taxier, Project Manager,
Button and Coin Cell Battery Regulation
Office of Hazard Identification and Reduction

THROUGH: Robert S. Kaye, Assistant Executive Director
Office of Compliance and Field Operations

FROM: Salman Sarwar, Compliance Officer,
Children's Product Team (CRE)
Office of Compliance and Field Operations

SUBJECT: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Summary of Recalls Involving Button/Coin batteries – January 1, 2011, through July 31, 2022

I. Introduction

The Office of Compliance provides this summary in support of the notice of proposed rulemaking to establish a safety standard and notification requirements for button cell or coin batteries and consumer products containing such batteries.

The Office of Compliance conducted six recalls of products containing button cell and coin batteries and related to a battery ingestion hazard between January 1, 2011, and July 31, 2022. Table 1 below summarizes the recalls, and notes the recall dates, the firms involved, hazard(s), the approximate number of units affected, number of reported incidents/injuries and the press release numbers. The recalls were processed by Office of Compliance and Field Operations, Fast Track Team.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 1. Summary of Recalls Involving Products with Button and Coin Cell Batteries.

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
10/10/2016	Target	The gel clings can separate and expose the inner decal and LED/button battery compartment, posing choking and button battery ingestion hazards to children.	About 172,000 units Halloween LED Gel Clings	No Injuries Reported	17-020[1]
12/16/2016	Figi's Companies Inc.	The tin's music sound chip mechanism can separate and expose button batteries, posing choking and button battery ingestion hazards to children.	About 5,000 units "Christmas Wishes" Tins	No Injuries Reported	17-120[2]
5/23/2017	Hobby Lobby	The battery cover can detach and expose the small coin cell batteries, posing choking and ingestion hazards to young children.	About 43,400 units Easter and July 4th-themed Light-Up Spinner Toys	Received one report of a 14-month-old child who ingested the battery.	17-166[3]
12/19/2019	Toysmith	The battery cover can detach and expose the button-cell batteries, posing choking and ingestion hazards to young children.	About 58,000 units Light-Up Magic Wands	One report of a child swallowing one of the batteries removed from the toy. Medical attention was required to remove the battery.	20-045[4]

[1] Target Recalls Halloween LED Gel Clings Due to Choking and Button Battery Ingestion Hazards | CPSC.gov. https://www.cpsc.gov/Recalls/2017/Target-Recalls-Halloween-LED-Gel-Clings

[2] Figi's Companies Recalls "Christmas Wishes" Tins Due to Choking and Button Battery Ingestion Hazard (Recall Alert) | CPSC.gov. https://www.cpsc.gov/Recalls/2017/Figis-Companies-Recalls-Christmas-Wishes-Tins

[3] Hobby Lobby Recalls Easter and July 4th Light-Up Spinner Toys Due to Choking and Ingestion Hazards | CPSC.gov. https://www.cpsc.gov/Recalls/2017/hobby-lobby-recalls-easter-and-july-4th-light-up-spinner-toys

[4] Toysmith Recalls Light-Up Magic Wands Due to Choking and Ingestion Hazards | CPSC.gov. https://www.cpsc.gov/Recalls/2020/Toysmith-Recalls-LightUp-Magic-Wands-Due-to-Choking-and-Ingestion-Hazards

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
5/12/2021	K & M International	The coin cell battery inside the slap watches can fall out, posing battery ingestion and choking hazards to young children.	About 463,000 units Wild Republic Slap Watches	No incidents or injuries have been reported.	21-134[5]
12/1/2021	Halo Brand Solutions	A child can disassemble the projector flashlight and access the button cell batteries, posing ingestion and choking hazards.	About 82,500 units Projector Flashlights.	Received two reports of children accessing the button cell batteries from the flashlight, and in one case, a child required surgery to remove a swallowed battery.	22-024[6]

[5] K & M International Recalls Slap Watches Due to Coin Cell Battery Ingestion and Choking Hazards | CPSC.gov. https://www.cpsc.gov/Recalls/2021/K-M-International-Recalls-Slap-Watches-Due-to-Coin-Cell-Battery-Ingestion-and-Choking-Hazards

[6] Halo Recalls Promotional Children's Projector Flashlights Due to Button Battery Ingestion and Choking Hazards | CPSC.gov. https://www.cpsc.gov/Recalls/2022/Halo-Recalls-Promotional-Childrens-Projector-Flashlights-Due-to-Button-Battery-Ingestion-and-Choking-Hazards

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

TAB G

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: The File **DATE:** January 11, 2022

THROUGH: Duane Boniface, Assistant Executive Director,
Office of Hazard Analysis and Reduction (EXHR)

FROM: Reese's Law Rulemaking Team

SUBJECT: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Recommended Regulatory Text

I. Introduction

This memorandum provides staff's recommended regulatory text for the draft proposed rule to establish a safety standard and notification requirements for button cell or coin batteries and consumer products containing such batteries. This regulatory text includes general provisions, such as scope and definitions, as well as the recommended performance requirements for products containing button and coin cell batteries, and warning label requirements for packaging containing button cell or coin batteries and consumer products containing such batteries. Finally, staff recommends requiring point of sale performance and technical data authorized under section 27(e) of the Consumer Product Safety Act (CPSA), to assist in educating caregivers about the unreasonable risk of injury to young children who obtain button batteries and swallow them.

II. Recommended Regulatory Text

16 C.F.R part 1263: Safety Standard for Child-Resistant Button Cell or Coin Battery Compartments on Consumer Products

§ 1263.1 Scope, Purpose, Effective Date, Units, and Exemption

(a) Scope and purpose. As required by Reese's Law (15 U.S.C § 2056e, Public Law 117-171), this part establishes performance requirements for child-resistant button cell or coin battery compartments on consumer products during reasonably foreseeable use and misuse of the consumer product, to address the risk of injury and death to children 6 years old and younger from ingesting these batteries. This part also establishes warning label requirements for packaging containing button cell or coin batteries, and packaging of consumer products containing such batteries, as well as point of sale performance and technical data pursuant to section 27(e) of the Consumer Product Safety Act (15 U.S.C. 2076(e).

(b) Effective Date. Except as provided in paragraph (d) of this section, all consumer products and packaging containing button cell or coin batteries that are manufactured or imported after [INSERT 180 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] are subject to the requirements of this part.

(c) Units. In this part, values stated without parentheses are the requirement. Values in parentheses are approximate information.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(d) *Exemption*. Any object designed, manufactured, or marketed as a plaything for children under 14 years of age that is in compliance with the battery accessibility and labeling requirements of 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys, is exempt from the requirements of this part.

(e) *Batteries that Do Not Present an Ingestion Risk*. Button cell or coin batteries that the Commission has determined do not present an ingestion risk are not subject to this rule. These are: zinc-air button cell or coin batteries.

§ 1263.2 Definitions

In addition to the definitions given in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052), the following definitions apply for purposes of this part:

(a) *Accessibility probe* means Test Probe 11 in IEC 61032 Protection of Persons and Equipment by Enclosures - Probes for Verification.

(b) *Accessible* means able to be contacted by the *accessibility probe*.

(c) *Button cell or coin battery* means (1) a single cell battery with a diameter greater than the height of the battery; or (2) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard.

(d) *Ingestion hazard* means a hazard caused by swallowing a button cell or coin battery whereby (1) the button cell or coin battery can become lodged in the digestive tract or airways, and (2) can potentially cause death or serious injury through choking, generation of hazardous chemicals, leaking of hazardous chemicals, electrical burns, pressure necrosis, or other means.

(e) *Principal display panel* means the display panel for a retail package of button cell or coin batteries or retail package of consumer product containing such batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.

(f) *Product display panel* means the surface area on, near, or in the battery compartment of a consumer product containing button cell or coin batteries. For consumer products with replaceable button cell or coin batteries, the product display panel must be visible while a consumer installs or replaces any button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel must be visible upon access to the battery compartment.

(g) *Secondary display panel* means a display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

§ 1263.3 Requirements for Consumer Products Containing Button Cell or Coin Batteries

(a) *General*. Consumer products that contain button cell or coin batteries must meet the performance and labeling requirements in this part to minimize the risk of children accessing and ingesting button cell or coin batteries. Consumer products that allow consumers to remove or replace a button cell or coin battery must comply with the performance requirements of § 1263.3(b). Consumer products that do not allow for the removal or replacement of button cell or coin batteries must comply with the performance requirements in § 1263.3(c).

(b) *Performance requirements for removable button cell or coin batteries*. (1) A removable or replaceable button cell or coin battery in a consumer product must not be made accessible when tested pursuant to § 1263.3(d).

(2) Battery compartments for removable or replaceable button cell or coin batteries must meet the requirements in § 1263.3(e) and be secured using at least one of the following methods:

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(i) Secure the battery compartment enclosure so that it requires a tool, such as a screwdriver or coin, to open the battery compartment. Opening a battery compartment secured by one or more screws, or a twist-on access cover, must require a minimum torque of 0.5 Nm (4.4 in-lb) and a minimum angle of 90 degrees of rotation, or the fastener(s) must engage a minimum of two full threads. Screws or fasteners used to secure the battery compartment enclosure must be captive to the compartment door, cover, or closure.

(ii) Secure the battery compartment enclosure so that it requires a minimum of two independent and simultaneous hand movements to open. The movements to open cannot be combinable to a single movement with a single finger or digit.

(c) *Performance requirements for consumer products containing non-removable button cell or coin batteries*. Consumer products that contain button cell or coin batteries not intended for removal or replacement must be made inaccessible by (1) using a battery compartment enclosure that complies with the performance requirements of § 1263.3(b), or (2) securing the button cell or coin battery using soldering, fasteners such as rivets, or equivalent means, that passes the Secureness Test in § 1263.3(f).

(d) *Accessibility test method*. This test assesses whether a child can access a button cell or coin battery installed in a consumer product by determining whether the accessibility probe can contact a button cell or coin battery.

(1) To determine whether a button cell or coin battery is accessible, first open and remove any part of the battery compartment enclosure that can be opened or removed without a tool or that can be opened or removed with anything less than two independent and simultaneous movements (for example, a zipper or hook and loop).

(2) If a part of the battery compartment enclosure is protected by pliable material such as fabric, paper, foam, or vinyl, or a pliable material with a seam, apply the *Tension Test for Seams in Stuffed Toys and Beanbag-Type Toys* test in 16 CFR 1250 to determine whether the battery compartment enclosure can become exposed or accessible, using a force of at least 70.0 N (15.7 lbf). If a new part of the battery compartment enclosure becomes exposed or accessible, repeat the preceding step (1) and this step (2) until no new part of the battery compartment becomes exposed or accessible, and then conduct the test in § 1263.3(d)(3).

(3) Insert or apply the accessibility probe to any depth that a battery compartment opening will permit, and rotate or angle the accessibility probe before, during, and after insertion or application through the battery compartment opening to any position that is necessary to determine whether the probe can contact the button cell or coin battery. This test is not intended to judge the strength of the material comprising the battery compartment. Use the minimum force necessary in determining whether the probe can contact a button cell or coin battery.

(e) *Performance tests for consumer products containing button cell or coin batteries.* After pre-conditioning in § 1263.3(e)(1), consumer products containing a button cell or coin battery must pass the performance requirements in § 1263.3(e)(2) or § 1263.3(f) in the order presented, as applicable.

(1) *Pre-conditioning*. Subject each test sample consumer product to applicable pre-conditioning:

(i) *Stress relief*. Subject each sample consumer product with a battery compartment enclosure, door/cover, or door/cover opening mechanism that is made from molded or formed thermoplastic materials to a stress relief test. Place each test sample consumer product in a circulating air oven for at least 7 hours, using an oven temperature of the higher of at least 70°C (158°F) or at least 10°C (18°F) higher than the maximum temperature of thermoplastic battery compartment enclosures, doors/covers, or door/cover opening mechanisms during the most stringent normal operation of the consumer product. Allow the sample consumer product to cool to room temperature after removal from the oven.

(ii) *Battery replacement*. This step only applies to consumer products with button cell or coin batteries intended to be removable or replaceable. Open the battery compartment enclosure, remove and replace the button cell or coin battery, and close the battery compartment enclosure for a total of ten

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

cycles. This test is intended to simulate replacing the button cell or coin battery 10 times per the manufacturer's instructions. For battery compartment enclosures that are secured with a screw(s), the screw(s) must be loosened and then tightened using a suitable screwdriver, applying a continuous linear torque according to the Torque to be Applied to Screws table, Table 20, of the Standard for Audio, Video and Similar Electronic Apparatus – Safety Requirements, UL 60065. If the screw(s) do not meet the specified torque requirements during this step, remove the screw(s) and repeat the test in § 1263.3(d).

(2) *Abuse tests*. Subject each test sample consumer product to the following abuse tests, performed sequentially, as applicable. Check compliance of the sample using § 1263(e)(3). If the consumer product contains button cell or coin batteries that are not intended for removal or replacement, and that are accessible based on § 1263.3(c), then the consumer product must be tested under § 1263.3(f) and this § 1263.3(e)(2) does not apply.

(i) *Drop test*. Drop each sample consumer product ten times from a height of 1.0 m (39.4 in) onto a horizontal hardwood surface in positions likely to produce the maximum force on the battery compartment enclosure. The hardwood surface must be at least 13 mm (0.5 in) thick, mounted on two layers of nominal 19 mm (0.75 in) thick plywood, and placed on a concrete or equivalent non-resilient surface.

(ii) *Impact test*. Subject the battery compartment enclosure door or cover on each sample consumer product to three, at least 2-J (1.5-ft·lbf) impacts. Produce the impact by dropping a steel sphere, 50.8 mm (2 in) in diameter, and weighing approximately 0.5 kg (1.1 lb) from the height required to produce the specified impact, as shown in Figure 1, or suspend the steel sphere by a cord and swing as a pendulum, dropping through the vertical distance required to cause the steel sphere to strike the battery compartment enclosure door or cover with the specified impact, as shown in Figure 2. The steel sphere must strike the battery compartment enclosure door or cover perpendicular to the surface of the battery compartment enclosure.

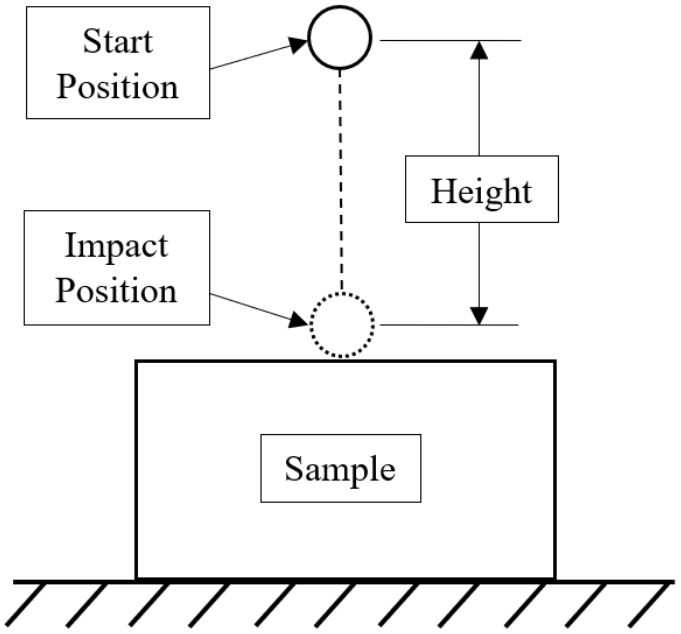


Figure 1. Example impact test with a dropped steel sphere.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

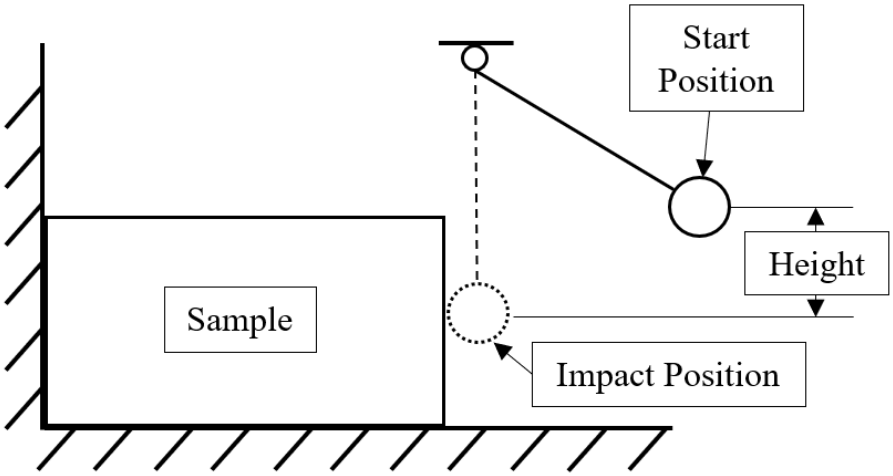


Figure 2. Impact Test with a swinging steel sphere.

(iii) *Crush test*. Support each sample consumer product by a fixed rigid supporting surface, in positions likely to produce the most adverse results as long as the position of the consumer product is self-supported. Apply a crushing force of at least 335 N (75.3 lbf) to the exposed surface for a period of 10 seconds. Apply the force using a flat surface measuring approximately 100 by 250 mm (3.9 by 9.8 in).

(iv) *Compression test*. If any surface of the battery compartment enclosure is accessible to a child and inaccessible to flat surface contact during the drop test, apply the *Compression Test* from 16 CFR part 1250 to that surface, using a force of at least 136 N (30.6 lbf).

(v) *Torque test*. If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, apply the *Torque Test for Removal of Components* from 16 CFR part 1250 to the battery compartment enclosure, using a torque of at least 0.50 Nm (4.4 in.-lbf).

(vi) *Tension test*. If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, apply the *Tension Test for Removal of Components* from 16 CFR part 1250 to the battery compartment enclosure, using a force of at least 72.0 N (16.2 lbf).

(3) *Compliance*. If a button cell or coin battery becomes accessible or liberates from a consumer product as a result of any of the abuse tests in §1263.3(e)(2), the consumer product is non-compliant and fails testing. Additionally, after completing all abuse testing, apply a force of at least 50 N (11.2 lbf) for 10 seconds to the battery compartment enclosure door or cover using the accessibility probe. Apply the accessibility probe at the most unfavorable position on the battery compartment enclosure, and in the most unfavorable direction. Apply a force in only one direction at a time. If the battery compartment enclosure door or cover opens or does not remain functional, or the button cell or coin battery becomes accessible, the consumer product is non-compliant and fails testing.

(f) *Secureness test*. Button cell or coin batteries installed in a consumer product that are not intended for removal or replacement, and that are accessible based on § 1263.3(d), must be tested by applying a test hook, as shown in Figure 3, using a force of at least 22 N (4.9 lbf), directed outwards, applied for 10 seconds at all points where application of a force is possible. To pass the test, the button cell or coin battery cannot liberate from the consumer product during testing.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

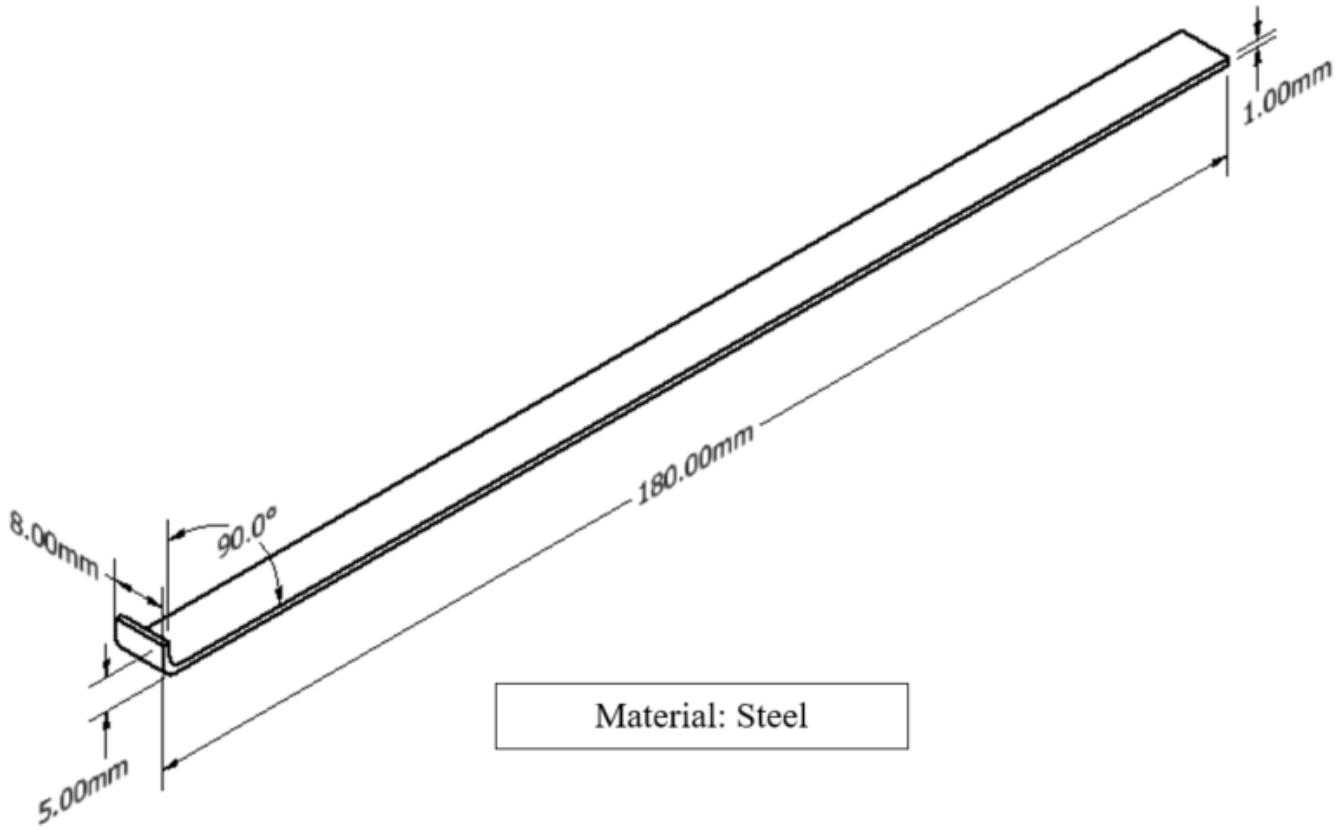


Figure 3. Secureness test hook for consumer products with accessible button cell or coin batteries not intended for removal or replacement.

§ 1263.4 Requirements for Marking and Labeling

(a) *General Requirements*. (1) All warning statements must be clearly visible, prominent, legible, and permanently marked.

(2) Warning statements must be in contrasting color to the background onto which the warning statement is printed.

(3) Warning statements must be in English.

(4) The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.

(5) The signal word “WARNING” must be in black letters on an orange background. The signal word must appear in sans serif letters in upper case only.

(6) Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels to get the attention of the reader.

(7) For labels that are provided on a sticker, hang tag, instructions or manual, the safety alert symbol and the signal word “WARNING” must be at least 0.2 in. (5 mm) high. The remainder of the text must be in characters whose upper case must be at least 0.1in. (2.5 mm), except where otherwise specified.

(8) For labels that are required to be on the packaging of button cell and coin batteries, the packaging of consumer products containing such batteries, and directly on consumer products, text size must be dependent on the area of the principal display panel. Text size must be determined based on Table 1.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Table 1. Letter size for recommended warning labels.
Information based on 16 CFR part 1500.19(d)(7).

Letter size measurements in inches								
Display Area: Inches²	*0–2*	*+2–5*	*+5–10*	*+10–15*	*+15–30*	*+30–100*	*+100–400*	*+400*
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display Area: cm²	*0-13*	*+13-32*	*+32-65*	*+65-97*	*+97-194*	*+194-645*	*+645-2,581*	*+2,581*
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397

(b) *Warning label requirements for button cell or coin battery packaging*. (1) The principal display panel of the packaging must include the warning label in Figure 4. The icon must be at least 8 mm (0.3 inches) in diameter. The text must state the following:

WARNING
- **INGESTION HAZARD: DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

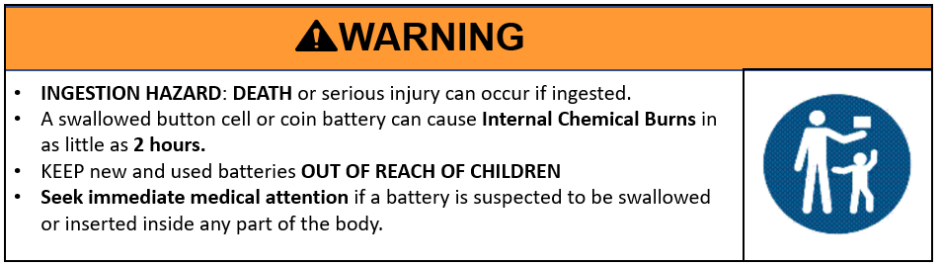


Figure 4

(2) If space prohibits (see Table 1) the full warning label shown in Figure 4, place the icon shown in Figure 5 on the principal display panel with the text shown in Figure 6 on the secondary display panel. The icon must be at least 20 mm in diameter. The text must state the following:

WARNING
- **INGESTION HAZARD: DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

Figure 5

WARNING **INGESTION HAZARD** ● **DEATH** or serious injury can occur ● A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours** ● KEEP new and used batteries **OUT OF REACH OF CHILDREN** ● **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

Figure 6

(3) The following safety-related statements must be included on the principal display panel or secondary display panel:

- "Keep in original package until ready to use."
- "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash."
- "Call a local poison control center for treatment information."
- Battery type (*e.g.* LR44, CR2032)
- Battery chemistry (e.g. silver oxide or lithium)
- Nominal voltage
- Year and month or week of manufacture or expiration date
- Name or trademark of the manufacturer or supplier
- "Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries."
- "Ensure the batteries are installed correctly according to polarity (+ and -)."
- "Remove and immediately discard batteries from equipment not used for an extended period of time."
- "Non-rechargeable batteries are not to be recharged."
- "Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns."

(4) For button cell or coin battery packaging included separately with a consumer product, only (b)(1) and (b)(2) of this subsection (b) apply.

(c) *Warning label requirements for packaging of consumer products containing button cell or coin batteries*. (1) The principal display panel must contain the warning label in Figure 7. The icon must be at least 8 mm in diameter. The text must state the following:

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

WARNING
- **INGESTION HAZARD:** This product contains a button or coin cell battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**.
- **Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body.

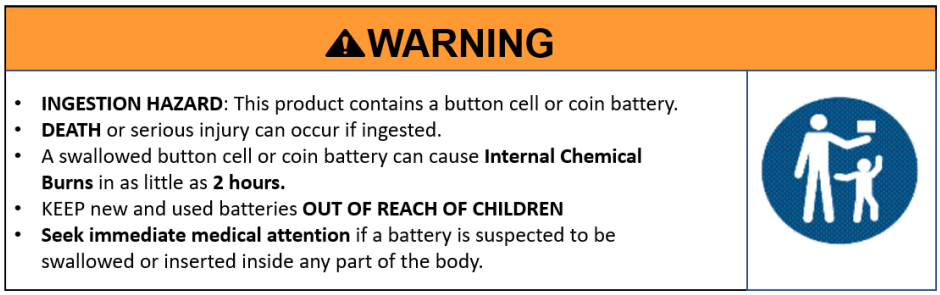


Figure 7

(2) Consumer products that are not contained in packaging must have the warning label in Figure 7 affixed to the consumer product with a hang tag or a sticker label.

(3) If space on the principal display panel of the consumer product packaging does not permit the warning label in Figure 7 (see Table 1), the principal display panel must include the warning in Figure 8 in a conspicuous location. The icon must be at least 8 mm in diameter. The remaining warning statements must be on a secondary display panel, as shown in Figure 9. The text must state the following on the principal display panel:

WARNING
- **INGESTION HAZARD:** This product contains a button or coin cell battery.
- **DEATH** or serious injury can occur if ingested.
- A swallowed button or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.

The text must state the following on the secondary display panel:

WARNING
- KEEP new and used batteries **OUT OF REACH OF CHILDREN**
- **Seek immediate medical attention** if battery is suspected to be swallowed or inserted inside any part of the body.

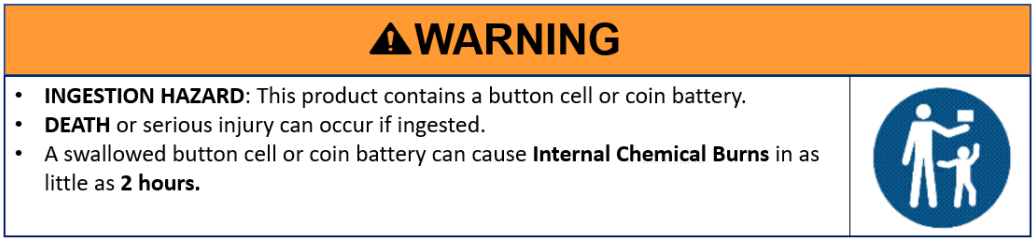


Figure 8

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

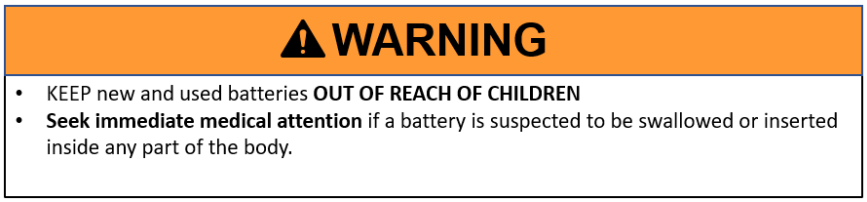


Figure 9

(4) The principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must include the following:

- For products with non-replaceable batteries, include a statement indicating the product contains non-replaceable batteries.
- Battery type (*e.g.* LR44, CR2032)
- Nominal voltage

(d) *Warning label requirements for consumer products that contain button cell or coin batteries*. (1) Consumer products must be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or coin battery. The warning text must include the safety alert symbol and signal word. See Figure 10. The text must state the following:

"WARNING: INGESTION HAZARD This product contains a button or coin battery."

Figure 10

(2) If space on the product is limited (see Table 1), use the internationally recognized "Warning: contains coin battery" icon shown in Figure 11 without text. The icon must be at least 7 mm in width and 9 mm in height and must be on the product display panel and must be in yellow with black outlines as shown in Figure 11. The icon, must be defined in accompanying printed materials such as instructions, manual, insert, or hangtag.

Figure 11

(3) If the product itself is too small (see Table 1) to include the warning with text in Figure 10 or the icon (Figure 11), it must:

(i) Have packaging containing the warning label following the requirements in § 1263.4(c), or

(ii) Contain a hangtag or sticker label with the full warning label using requirements for the packaging of consumer products containing batteries in § 1263.4(c).

(e) *Instructions/Manuals accompanying consumer products containing button cell and coin batteries*. (1) Instructions and manuals, if provided, must include the warning label shown in Figure 7.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)

(2) Instructions and manuals must include the following warning statements:

- “Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash.”
- “Even used batteries may cause severe injury or death.”
- "Call a local poison control center for treatment information.”
- Compatible battery type (e.g. LR44, CR2032)
- Nominal voltage
- For products with non-replaceable batteries, include a statement indicating the product contains non-replaceable batteries.
- “Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries.”
- “Ensure the batteries are installed correctly according to polarity (+ and -).”
- “Remove and immediately discard batteries from equipment not used for an extended period of time.”
- “Non-rechargeable batteries are not to be recharged.”
- “Do not force discharge, recharge, disassemble, heat above (manufacturer’s specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns.”

(3) If instructions and manuals are not provided, the warning statements in § 1263.4(e)(2) must be present on the principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label.

(f) *Online information*. Manufacturers shall include, in a manner that is clearly visible, prominent, and legible (either next to the product description, the product image, or the product price):

(1) in their online materials that enable consumers to purchase button cell or coin batteries, the warning in Figure 4; and

(2) in their online materials that enable consumers to purchase products containing button cell or coin batteries, the warning in Figure 7.

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

CLEARED FOR PUBLIC RELEASE
UNDER CPSA 6(b)(1)