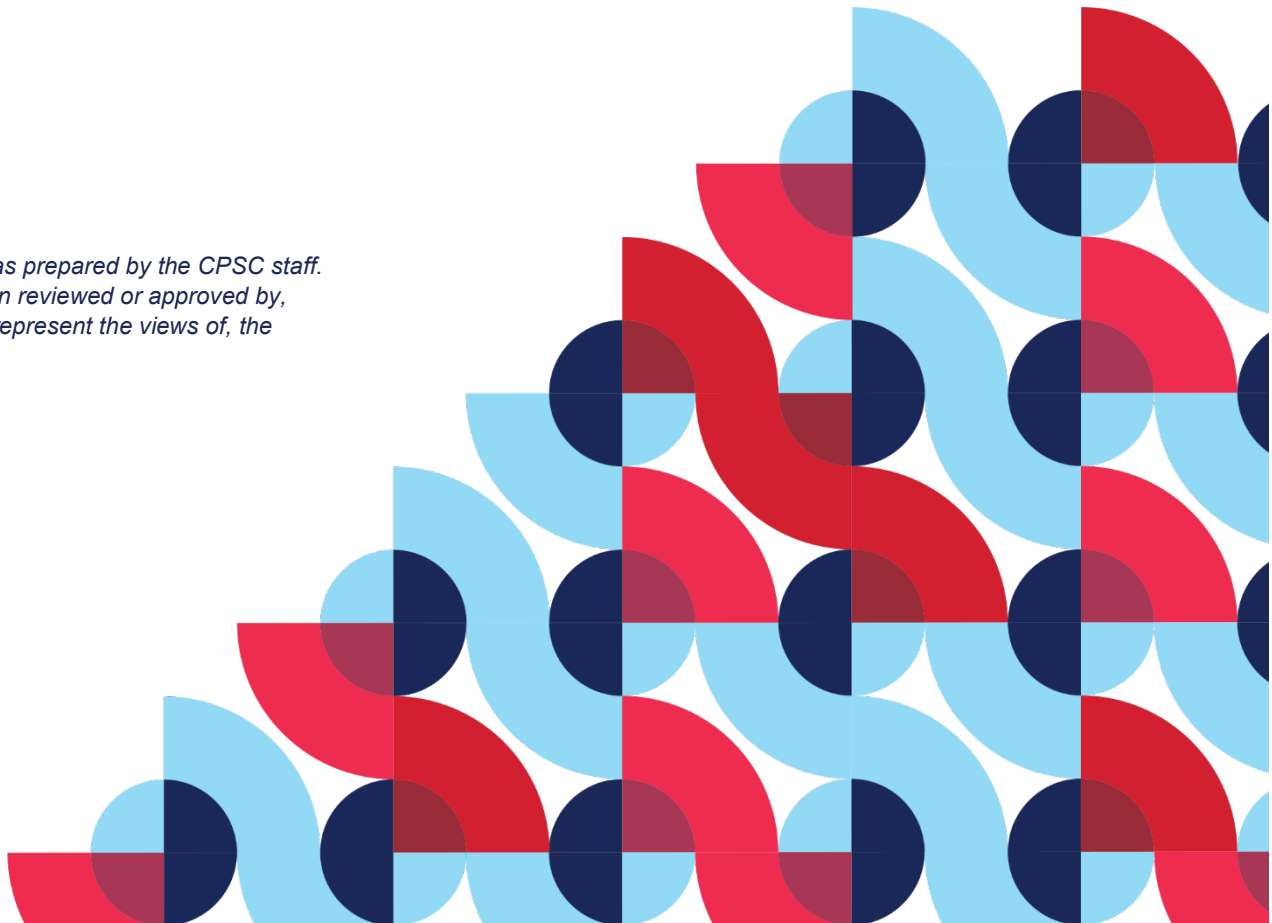
United States
Consumer Product Safety Commission

Organohalogen Flame Retardant Scope Document: Polyhalogenated Phenol Derivative Subclass

January 2024

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



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1. Executive Summary

This scope document addresses the polyhalogenated phenol derivative (PHPhD) subclass, one of 14 subclasses of organohalogen flame retardants (OFR). OFRs contain a carbon-halogen bond and are one of the main categories of flame retardants (FRs). FRs are substances that alter the normal degradation or combustion processes of materials. They are incorporated into materials or used on surfaces to reduce or eliminate the tendency to ignite when exposed to heat or flame for a short period of time.

Informed by initial review of the market and use research, evidence maps, and availability of physicochemical data for the PHPhD subclass and its analogs, as well as the Criteria for Scoping Determination described in this document, Consumer Product Safety Commission (CPSC or Commission) staff concludes, at the time of writing, that the PHPhD subclass has sufficient data to proceed with risk assessment. Next steps, as resources are available, involve completing the hazard, dose-response, and exposure assessments before drafting the class-based risk assessment.

2. Introduction

This document contains the results of scoping efforts by CPSC staff to characterize readily available information on the chemistry, uses, human toxicity, exposure, and human health risk of members of the PHPhD subclass of OFRs. This document is one of the scope documents that CPSC staff is producing to address each of 14 OFR chemical subclasses.

The primary question answered by the scope documents is:

> *Can a risk assessment for this subclass be completed based on a combination of existing data and estimation (modeling) approaches?*

To answer this question, the scope document developed for each subclass outlines the criteria for determining sufficiency for hazard assessments and exposure assessments, describes the data available, and provides the scoping determination for sufficiency to proceed. If the answer to the question above is yes for that subclass, the scope document describes (i) CPSC staff's interpretation of available data through evidence maps and estimation approaches and (ii) the analysis plan and conceptual model that CPSC staff plans to follow to complete this assessment. These subclasses will then be prioritized for risk assessments.

If the answer is no, then the scope document for that particular subclass describes (i) CPSC staff's interpretation of available data through evidence maps and estimation approaches and (ii) key data gaps. These subclasses will be temporarily deprioritized for risk assessments.

For additional details on how the information contained in all scope documents was compiled, refer to the following CPSC companion documents: [1]

- Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory
- Market and Use Report: Characterizing OFR Chemistries, Sources, and Uses in the U.S. and International Markets, Volumes 1 and 2 (Appendices)
- Literature Survey Guide: Approaches Taken to Develop Evidence Maps from Readily Available Databases, Completed Assessments, and Literature Reviews

3. Background

In 2015, several organizations and individuals petitioned CPSC (Petition HP 15-1) to ban the use of additive OFRs, as a class, in durable infant or toddler products, children's toys, childcare articles, or other children's products (other than car seats), residential upholstered furniture, mattresses and mattress pads, and the plastic casings of electronic devices. In 2017, the Commission voted to grant the petition to direct staff to convene a Chronic Hazard Advisory Panel,[2] and to complete a scoping and feasibility study in cooperation with the National Academy of Sciences, Engineering, and Medicine (NASEM).

NASEM established a committee of experts to address the charge and published the Committee's report, "A Class Approach to Hazard Assessment of Organohalogen Flame Retardants," in May 2019 (NASEM, 2019). The Committee first decided to determine whether the chemicals of interest can be defined as a single class or as subclasses, based on structure, physicochemical properties, biology, or a combination of characteristics. The Committee stated that if a class approach is viable, then the hazard assessment approach would be to survey the literature to determine availability of all types of toxicity data (human, animal, in vitro, other relevant studies) for all relevant toxicity end points. Then, if relevant data are available on any chemical of interest for a given end point, the plan would be to extract, evaluate, and integrate the data to reach a decision about potential hazards that can be applied to the entire class or subclass. A key conclusion of the Committee is that OFRs cannot be treated as a single class. Rather, the Committee identified 14 subclasses of OFRs, based on chemical structure, physicochemical properties of the chemicals, and predicted biological activity.

In fiscal year 2020 (FY 2020), CPSC staff developed a process for assessing the risks of OFRs in consumer products. A staff report to the Commission (Staff Plan) (CPSC, 2020) builds on the recommendations from the NASEM committee and outlines options and recommendations for proceeding with the project in FY 2021 and beyond (subject to availability of resources). In brief,

[1] Project documents, including CPSC staff reports, contractor reports, and key references may be found on the CPSC Organohalogen Flame Retardant Chemicals Assessment website (https://www.cpsc.gov/Business--Manufacturing/Organohalogen-Flame-Retardant-Chemicals-Assessment) or Docket No. CPSC-2015-0022 (https://www.regulations.gov/docket/CPSC-2015-0022).
[2] CHAP review would occur prior to finalizing any subclass risk assessment if carcinogenicity, mutagenicity, or reproductive/developmental toxicity were chosen as relevant endpoints.

the Staff Plan outlined work that initially would establish procedures for class-based risk assessment of each OFR subclass, refine the chemicals and analogs for multiple OFR subclasses, identify data sources, and determine available toxicity, chemical use, and exposure information. Staff subsequently initiated several activities, largely through contractors and interagency collaborations, to begin work on the project.

4. Approach

4.1. Criteria for Scoping Determination

CPSC staff will determine whether a subclass has sufficient data to proceed, at this time, with risk assessment based on data availability. In this context, data availability among subclass members and among identified analog chemicals is characterized as "no data," "some data," or "data rich" for both hazard information and exposure information, with definitions of each category provided below.

4.1.1. Hazard

The criteria for sufficiency for hazard assessment for the subclass are:

- At least one data-rich chemical among the subclass chemicals or analog chemicals, and
- Multiple chemicals with some data among subclass chemicals or analog chemicals with empirical short-term toxicity and other data (availability of modeled physicochemical and toxicity data can contribute to the determination).
- Only a minority of the substances in the subclass are "no data" substances.

The data availability categories are defined using the literature survey results as follows:

- Chemicals with no data:
    - No empirical data for physicochemical characteristics, and
    - No empirical data for toxicity, and
    - No or limited predicted/modeled physicochemical or toxicity data.
- Chemicals with some data (i.e., chemicals that are neither data rich nor have no data):
    - Some physicochemical data (may include empirical or modeled), and
    - No to limited traditional chronic/subchronic animal toxicity studies, and
    - Some short-term toxicity, in vitro, high-throughput, or other nonanimal data.

- Chemicals that are data rich:
    - Near complete empirical physicochemical data, and
    - Multiple traditional animal toxicity studies (i.e., acute, systemic repeated dose toxicity, or reproductive/developmental), and
    - Multiple short-term in vivo toxicity studies, and in vitro, high-throughput, or other nonanimal data, and
    - Available empirical data likely support derivation of a quantitative toxicity reference value(s).
    - Modeled toxicity data, if such data demonstrate close agreement with available empirical data, are acceptable to support this category, but such data are not required.
    - Available human data support this category but are not required.

In addition to evaluating the amount and breadth of available data for each chemical in a subclass, CPSC staff plans to consider the availability of similar types of data for multiple subclass members (e.g., similar subchronic/chronic studies, similar endpoints evaluated, and similar short-term toxicity studies, in vitro assays, or mechanistic data). That is, CPSC staff plans to consider consistency in data availability across members of a subclass.

4.1.2. Exposure

The criteria for sufficiency for exposure assessment for the subclass are:

- At least one data-rich chemical among the subclass chemicals for which average daily doses for human populations have been reported or can be estimated, and
- Multiple subclass chemicals with some data from environmental monitoring, biomonitoring, product testing, or any toxicokinetic studies (availability of modeled physicochemical, emissions, migration, occurrence, or disposition data can contribute to the determination).
- Note that subclass members classified as “no data” chemicals do not have sufficient information for exposure assessment.

The data availability categories are defined using the literature survey and market and use research results as follows:

- Chemicals with no data:
    - No market and use information indicating use as a flame retardant.

- Chemicals with some data (i.e., chemicals that are neither data rich nor have no data):
    - Some evidence (per market and use information) that it has been, currently is, or could be used as a flame retardant, and
    - Some physicochemical data (may include empirical or modeled), or
    - At least one experimental environmental monitoring, biomonitoring, product testing, or toxicokinetic study, or comparable modeling studies that provide information on estimated occurrence, emissions, or disposition, or
    - Existing or de novo modeled estimates of physicochemical properties, emissions, migration, occurrence, or disposition.
- Chemicals that are data rich:
    - Evidence (per market and use information) that it has been, currently is, or could be used as a flame retardant, and
    - Near complete empirical physicochemical data, and
    - Multiple environmental monitoring, biomonitoring, product testing, or toxicokinetic studies, and
    - Available empirical data likely support estimates of quantitative average daily dose(s) for human exposure, and
    - Modeled exposure data (emissions, occurrence, disposition), if such data demonstrate close agreement with empirical data, are acceptable to support this category, but such data are not required.

4.2. Inventory

The NASEM committee, as part of its consideration of class approaches to hazard assessment, created an inventory of 161 OFRs and identified more than 1,000 analog chemicals (i.e., chemicals with similar functional, structural, and predicted biological activity) across 14 chemical subclasses. Subsequently, CPSC staff, in collaboration with the U.S. Environmental Protection Agency (EPA), refined a Quantitative-Structure-Use-Relationship (QSUR) model to predict the probability of whether a chemical is a flame retardant or an OFR. These efforts, in combination with market and use research, led to a manuscript, "Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory," published in *Nature Scientific Data* (Bevington et al., 2022). This work identified additional OFR chemicals, resulting in an expanded inventory of 488 OFRs in 14 subclasses.

The OFR inventory completed by CPSC staff should not be considered a fixed and final list of all possible OFR chemicals. This project, including the market and use research and literature survey work, has used established identifiers for each chemical, such as CAS RN®,[3] DTXSID,[4]

[3] CAS RN®, or CAS Registry Number®, is a unique identification number for individual chemical substances assigned by CAS, a division of the American Chemical Society.
[4] DTXSID, or DSSTox substance identifier, is an alphanumeric identifier for individual chemical substances used in the U.S. Environmental Protection Agency's CompTox Chemicals Dashboard.

INCHIKEY,[5] PUBCHEM ID,[6] and SMILES,[7] as well as chemical names and common synonyms. However, even with identifiers that should uniquely describe chemicals, there are a few cases in the inventory of the same chemical identified in different ways. CPSC staff also acknowledges that some identifiers correspond to mixtures.[8] To the extent that information on chemicals would be located using different identifiers, CPSC staff will maintain separate listings; however, once staff confirms that multiple records apply to a single chemical (or mixture), analyses of the chemical will consider the combined data for that chemical regardless of the identifiers.

CPSC staff also notes that the inventory may be modified through the course of the project as staff continues analyses of chemicals in each subclass and considers additional information. The result of additional analyses could be the removal or addition of chemicals to the inventory.

4.3. Market and Use Research

The OFR market and use research was intended to collect relevant information and data to (1) characterize each OFR subclass, (2) identify uses of chemicals in each OFR subclass, and (3) identify trends associated with each OFR subclass. CPSC staff sought information about production or consumption of OFR chemicals and identified uses in consumer products and other market information. CPSC staff also sought information on regulatory actions, including current and proposed laws, policies, and regulations related to OFR chemicals at international, federal, state, and local levels of government. Detailed descriptions of the approach and process are found in Volume 1 of the Market and Use Profile (see Appendix: Supporting Files) completed under a CPSC-sponsored contract. Briefly, the market and use research captured information from targeted scientific literature and gray literature, and from readily available data sources in other formats. Data sources included national chemical inventories, other government data, such as from required reporting of production and waste information for specified chemicals or other types of curated databases, and certain commercial sources.

4.3.1. Targeted Literature Search

Section 3.2.6 of the Market and Use Report explains the methodology used for the targeted literature search completed for the OFR market and use research. The targeted searches for literature related to the flame-retardant market identified sources of relevant material from databases, websites, or other online information repositories, and broader searches of internet-based sources using standard search tools such as Google Scholar and selected searches of

[5] INCHIKEY, stands for International Chemical Identifier and is a unique 27-character identifier.
[6] PUBCHEM ID is a unique identifier specific to the National Library of Medicine's PUBCHEM database.
[7] Simplified molecular-input line-entry system (SMILES) describes the structure of a chemical in a way that can be used by a computer.
[8] See, for example, CAS RN 85535-84-8, which refers to a group of halogenated aliphatic chain chemicals with chain length from 10 to 13 carbons. Chemical names associated with this CAS RN include short chain chlorinated paraffins; alkanes, C10-13, chloro; and chlorinated paraffins, C10-13.

commercial online literature databases (e.g., Dialog/ProQuest). Specifically, the contractor executed searches of 140 literature databases using the Dialog/ProQuest platform.[9]

Following a review of the source title and abstract, the contractor rated each identified source for relevance on a scale of 1 to 5, 5 being the most relevant, and obtained PDF copies of as many of the sources identified as possible, with priority given to those sources rated higher for relevance. Among all 255 sources obtained, the contractor prioritized the review of 187 complete sources.

For each PDF reviewed, the contractor highlighted information on topics of interest for the study, such as manufacturing or import activity, use of chemicals in products, lifecycle considerations, and regulatory or other trends. The report further identified all OFR chemicals discussed in the source, and where available, captured the CAS RN for each chemical and any synonyms, abbreviations, and trade names. From the 187 sources extracted and reviewed, the contractor made over 2,200 OFR identifications (for 488 unique OFRs). The summary of sources reviewed is provided in the Data Source Synthesis Excel workbook of the supplemental Market and Use Profile Supporting Files, referenced by OFR subclass.

4.3.2. Other Data Sources

The OFR Market and Use Report contains information collected from inventories and registries from the United States, Canada, Mexico, the EU, Japan, and China. In the United States, the Toxic Substances Control Act (TSCA) inventory was used to identify if an OFR substance was designated as active or inactive.[10] In addition to determining whether OFR substances appear as active substances on the TSCA chemical inventory, the contractor conducted a detailed analysis of U.S. production and import activity using data available from the EPA Chemical Data Reporting (CDR) program, and the manufacturing, processing, and waste management trends of OFR substances from the Toxic Release Inventory (TRI), as reported by industrial and federal facilities.

To determine whether individual OFR chemicals are used in consumer and/or children's products the contractor reviewed information available from the EPA's CDR and the Interstate Chemicals Clearinghouse High Priority Chemicals Data System (HPCDS). European data on OFR substances in products could not be reviewed in entirety in time for the publication of the report.

In addition, the contractor made efforts to identify OFR chemicals on several chemical business to business (B2B) or e-Commerce sites, using automated techniques to "scrape" data on OFRs from these sites. From Buyersguide.com and Chemnet.com, the contractor obtained the identity, country, and website of OFR suppliers. From Alibaba.com, they obtained the name and website of the OFR suppliers, as well as some data on quantities available and pricing.

[9] For a list of data sources searched using Dialog/ProQuest, see Exhibit 3-32 of the Market and Use Report Volume 1.

[10] Active chemicals are those that have been reported to EPA for manufacture or processing in the U.S., including those reported within a 10-year time period ending on June 21, 2016. Inactive chemicals are those that have not been reported and are, therefore, not considered to be in commercial use.

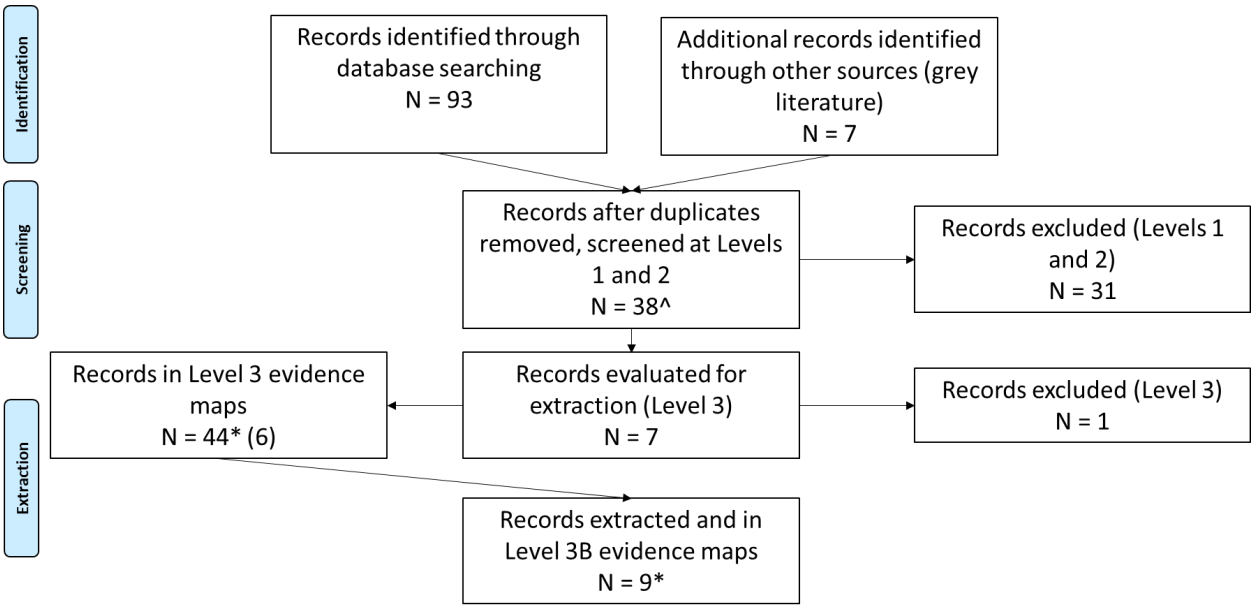
4.4. Literature Survey

The OFR literature survey was intended to gather readily available toxicity, exposure, and risk information to characterize the types and amounts of data available for chemicals (and analogs) within a class. CPSC staff defined data sources for the literature survey effort as toxicity, exposure, and chemistry databases; completed toxicity, exposure, or risk assessments; and completed literature reviews. Sources identified in the literature survey were screened to confirm utility and identify the type of data, but the actual data were not evaluated or extracted.

Detailed descriptions of the literature survey approach and process are found in the Literature Survey Guide and accompanying documentation. These documents were developed by University of Cincinnati (UC) Risk Science Center staff as part of work performed under a CPSC-sponsored contract (UC, 2022a; UC, 2022b). Development of the evidence maps followed a multilevel process to screen data sources initially identified in a defined search. Briefly, for peer-reviewed and gray literature, **Level 1** screening was used to confirm that the reference might contain information about at least one OFR chemical and that the reference was relevant to the PECO statement.[11] **Level 2** screening identified the OFR subclasses included in each reference and tagged the references for the types of data (hazard, exposure, risk). **Level 3** identified the specific OFR or analog chemicals in each reference and extracted more specific information about the types of hazard data, exposure data, or risk assessment information presented for each chemical. Finally, **Level 3B** tagging was performed on a subset of toxicity assessments, toxicity literature reviews, risk assessments, and exposure literature reviews selected from Level 3 to identify even more specific information for the chemicals in these references. Similarly, data from databases were tagged for type of data using a database logic developed to provide consistency across different data sources. Finally, the tagged information was organized into evidence maps by OFR subclass and specific chemicals. Figure 4-1 shows the numbers of records initially identified and the number of records screened or extracted at each level.

[11] PECO refers to population (P), exposure (E), comparator (C), and outcomes (O) of interest, and generally describes the scope of a literature search and subsequent analyses.

Figure 4-1. Literature Flow Diagram



Notes:
^Removal of duplicates within the subclass, and between this subclass and previous subclasses.
* PHPhD evidence maps contain additional references uploaded with other subclasses. Number in parentheses is the number of references identified by searching for the PHPhD subclass only, excluding the references identified by searching for other subclasses.

5. Scoping for PHPhDs

5.1. PHPhD Subclass Chemistry

The PHPhD subclass generally consists of chemicals containing a phenol group with halogenated substituents on the aryl ring. The presence of a sulfonyl group on two of the chemicals may lead to chemistry-based differences throughout this subclass despite structural similarities amongst the members.

Table 5-1 lists eight individual chemicals in the PHPhD subclass.

Table 5-1. List of Chemicals in PHPhD Subclass

	CAS RN	Chemical Name	Abbreviation/ Synonyms	SMILES
1	118-79-6	2,4,6-Tribromophenol	2,4,6-TBP	C1=C(C=C(C(=C1Br)O)Br)Br
2	14400-94-3	2,3,4,6-Tetrabromophenol	NA	C1=C(C(=C(C(=C1Br)Br)Br)O)Br
3	36313-15-2	2,3,4,5-Tetrabromophenol	NA	C1=C(C(=C(C(=C1Br)Br)Br)Br)O
4	39635-79-5	4,4'-Sulphonylbis[2,6-dibromophenol]	Tetrabromobisphenol S | TBBPS	C1=C(C=C(C(=C1Br)O)Br)S(=O)(=O)C2=CC(=C(C(=C2)Br)O)Br
5	42757-55-1	1,1'-Sulfonylbis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	NA	C1=C(C=C(C(=C1Br)OCC(CBr)Br)Br)S(=O)(=O)C2=CC(=C(C(=C2)Br)OCC(CBr)Br)Br
6	608-33-3	Phenol, 2,6-dibromo-	NA	C1=CC(=C(C(=C1)Br)O)Br
7	608-71-9	Pentabromophenol	PBR; Flammex 5BP	C1(=C(C(=C(C(=C1Br)Br)Br)Br)Br)O
8	615-58-7	2,4-Dibromophenol	2,4-DBP; FR-612	C1=CC(=C(C=C1Br)Br)O

SMILES = simplified molecular-input line-entry system. NA = not available or not found.

5.1.1. Physicochemical Property Summaries

The information collected to date led CPSC staff to find that experimental physicochemical data on PHPhD chemicals are limited. Three PHPhD subclass members have experimental data and all eight PHPhD members have predicted data. Well-studied chemicals in this subclass include 2,4,6-tribromophenol (2,4,6-TBP, CAS RN 118-79-6), pentabromophenol (5BP, CAS RN 608-71-9) and 2,4-dibromophenol (FR-612, CAS RN 615-58-7). From this data set, studied PHPhDs have experimental boiling points ranging from 239°C to 352°C, and predicted vapor pressures from $8.13E^{-11}$ to $4.47E^{-2}$ mm Hg. Data show water solubility values ranging from $1.66E^{-6}$ to $1.74E^{-2}$ mol/L. The experimental octanol/water partition coefficient (K_{ow}) values, which are commonly expressed as log K_{ow}, range from 3.22 to 4.13.

5.2. Market and Use Summary for PHPhDs

The OFR Market and Use Report, completed in March 2022, includes eight PHPhD chemicals.

- All eight PHPhD chemicals had market and use information.
- According to EPA data, four PHPhD chemicals were identified to be on the EPA's TSCA Chemical Substance (active) Inventory, two PHPhD chemicals were identified on the TSCA (inactive) inventory, one was on the CDR, and none were on the TRI program list.
- No PHPhD chemicals were identified in the Interstate Chemicals Clearinghouse (IC2) HPCDS.
- Six PHPhD chemicals were identified in the targeted literature search.
- All eight PHPhD chemicals had patent data.

5.2.1. PHPhDs Used in Commerce

The Market and Use Report summarizes data from a variety of sources, including U.S. and international chemical registries, scientific literature, patents, and chemical databases. To determine whether individual OFRs are currently in commerce, have been used in the past, or may be used in the future, these registries, patent data, and literature were reviewed in detail under a CPSC-sponsored contract and data were compiled from four main types of sources. Chemicals that have been in commerce appear on the (1) TSCA inventory, (2) international inventories, (3) in literature, or (4) in patent data. Table 5-2 lists the eight PHPhDs that are known to be or have been used in commerce, according to data available from these sources.

Among the eight PHPhD chemicals used in commerce, six can be found in the TSCA inventory. Four chemicals are in the TSCA active inventory and two PHPhD s are in the TSCA inactive inventory. In Table 5-2, PHPhD chemicals found in the TSCA inventory are identified as "Active" or "Inactive," accordingly.

Five other international registries were reviewed: EU REACH (2021), CANADA DSL (2021), MEXICO INSQ (2009), JAPAN CSCL (2021), AND CHINA IECSC (2013).[12] Five PHPhD chemicals appear in one or more of these international inventories. In Table 5-2, the number of international registries for the identified PHPhD chemical is listed in the "International Inventories" column.

Six PHPhD chemicals were identified in the literature through a targeted literature search.[13] In Table 5-2, the numeric value listed in the Literature Cites column is the number of sources from the targeted literature search that referenced the chemical.

All eight PHPhD chemicals were mentioned in patents. The total count of patents is provided for each chemical in Table 5-2, returned from a search of the associated Compound Identifier (CID) in PubChem.

Table 5-2. PHPhD Chemicals Used in Commerce

CAS RN	Chemical Name	TSCA	International Inventories	Literature Cites	Patents
118-79-6	2,4,6-Tribromophenol	Active	5	12	16,962
14400-94-3	2,3,4,6-Tetrabromophenol	Not found	Not found	0	18
36313-15-2	2,3,4,5-Tetrabromophenol	Not found	Not found	0	2,408
39635-79-5	4,4'-Sulphonylbis[2,6-dibromophenol]	Inactive	1	1	5,233

[12] EU REACH = European Union Registration, Evaluation, Authorisation, and Restriction of Chemicals; INSQ = Inventario Nacional de Sustancias Químicas; CSCL = Chemical Substances Control Law; IECSC = Inventory of Existing Chemical Substances Produced or Imported in China.
[13] For additional detail on the methodology used for the targeted literature search, see Section 4.3.1, Targeted Literature Search, in this scope document.

CAS RN	Chemical Name	TSCA	International Inventories	Literature Cites	Patents
42757-55-1	1,1'-Sulfonylbis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	Active	3	2	133
608-33-3	Phenol, 2,6-dibromo-	Active	0	2	2,541
608-71-9	Pentabromophenol	Inactive	3	4	2,718
615-58-7	2,4-Dibromophenol	Active	1	5	2,177

Table 5-2 shows that information on commercially used PHPhD chemicals is available from thousands of patents, numerous literature sources, and multiple chemical inventories.

5.2.2. PHPhDs Used in Consumer Products

The Market and Use Report identified the use of PHPhDs in consumer products, including children's products. To determine whether individual OFR chemicals are used in consumer and/or children's products, a CPSC-sponsored contractor reviewed the information available from the EPA's CDR,[14] the European Chemicals Agency's (ECHA) Substances of Concern in articles as such or in complex objects (Products) (SCIP) database, and the IC2's HPCDS. Data on the uses and applications of PHPhD chemicals were also found in the literature.

Targeted Literature Search. In the literature, several sources report the results of product testing, and these indicate PHPhDs have been found in a variety of consumer and/or children's products (product reported concentrations are in parentheses), such as:

- Televisions, printers, computer monitor and scanners, electrical power boards, adaptors, toys, and other household appliances (0.02% to 0.7%)
- Casings of electrical/electronic devices (0.01% to 0.8%)
- Various resins including high density polyethylene (HDPE), polypropylene (PP), coated foil, foil, NSP, PET, polystyrene (PS), acrylonitrile butadiene styrene (ABS), and PO (<0.01%)

Of the reported uses of PHPhDs in products, most chemicals were used in concentrations in excess of 1,000 ppm (0.1%); levels below 0.1% are considered contaminant by CPSC staff.[15] The following PHPhD chemicals were identified from the targeted literature search to have been used in consumer and children's products, and example uses are provided below:

CAS RN 118-79-6: Televisions, printers, computer monitor and scanners, electrical power boards, adaptors, toys, and other household appliances

[14] Data from the review of EPA's CDR for consumer products was generally incomplete, especially for children's products, and therefore are not summarized below however they are available in Section 3.2.5.1 in Volume I of the Market and Use Report.

[15] This amount corresponds with information on candidate list substances in articles for which importers and producers have to submit SCIP notification to the European Chemicals Agency (ECHA) if a substance is present in a concentration above 0.1% weight by weight (Introduction to Information on Candidate List substances in articles ECHA [echa.europa.eu]). CPSC staff rationale is that it should consider 0.1% or below to represent a contamination level given that concentrations of these chemicals when used intentionally as flame retardants are typically much higher.

CAS RN 615-58-7: Plastic resins
CAS RN 608-33-3: Plastic resins
CAS RN 118-79-6: Plastic resins

HPCDS. Using the HPCDS reporting tool, private industry reports the use of chemicals of concern in products intended for use by children that are sold in select states.[16] From 2012 to 2020, 1,093 reports were submitted to HPCDS identifying the use of OFR chemicals from seven subclasses in children's products sold in two U.S. states, Washington and Oregon. No reports documented the use of PHPhD chemicals in children's products.

SCIP. ECHA maintains a database of information through the REACH regulation, which was enacted in 2007 to improve the protection of human health from risks posed by chemicals. REACH applies to consumer products as well as to the chemicals industry. The REACH regulation requires suppliers of articles (products) containing potentially hazardous chemicals, including OFRs, to communicate down the supply chain and to consumers sufficient information to allow for the safe use of those products that contain them. Any supplier of an article containing a substance of very high concern (SVHC) in a concentration above 0.1% weight by weight (w/w) on the EU market is required to submit information on that article to ECHA. This information is commonly referred to as a "SCIP notification." From data available from the European Union, SCIP notifications have supported the development of the SCIP database.

The SCIP database is an important tool of the REACH framework and helps ensure that information regarding the use of hazardous substances in products is more readily and efficiently shared within the supply chain, and that certain information regarding the use of hazardous substances in products is also available to the public.

No PHPhD chemicals were included in the SCIP database. (See Exhibit 3-30 in the Market and Use Report, Volume 1.)

CDR. According to data available from the EPA's CDR, PHPhD chemicals have been used Commercial or Consumer Products for many years. (See Table 5-3.) This table presents the commercial and consumer product uses of PHPhD chemicals because CPSC needs to know the range of the product uses for these chemicals during the scoping PHPhDs.[17]

EPA changed the names of some product use categories between 2006 and 2012, and again in 2016, and so Table 5-3 presents the names of product use categories of PHPhD chemicals in

[16] At this time, CPSC staff is unable to determine if information reported to the HPCDS for Washington and Oregon is representative. Presumably, the number of reports would go up substantially if information for all 50 states were available; however, it is not known whether the chemicals identified, and types of children's products would also change.
[17] In the global economy, supply chains are complex, and reporters to the CDR do not know (and cannot reasonably ascertain) the end use of a product. Therefore, CPSC is reviewing all product use categories of OFR chemicals reported to the CDR, but may exclude certain categories later, if there is sufficient evidence showing that these chemical substances can be found exclusively in commercial products.

the three reporting periods.[18] To handle small changes in product use category names over the period, staff used a more generic or general name to be inclusive. The designated general product use category names help maintain consistency over the period displayed in the table below without distorting product use.

According to the CDR, the most common uses of PHPhD chemicals are in other products not identified, although PHPhDs are reported to be used in batteries as well.

Table 5-3. Report Counts of Commercial and Consumer Product Uses of PHPhD Chemicals

Product Use Category	2006	2012	2016	Total
Product description, not identified	1	1	NR	**2**
Batteries	NR	NR	1	**1**
Grand Total	**1**	**1**	**1**	**3**

Notes: Data listed as "Product description not identified" may be interpreted as one of any of the other product categories reported for PHPhDs, generally. NR = not reported or not available.

In addition, the CDR provides an opportunity for firms that report the use of a chemical substance to identify if the substance could be used in children's products. However, the CDR should not be considered a complete source for identifying the use of OFR chemical substances in children's products.[19] Over the period 2006 to 2016, the use of PHPhD chemicals in children's products was considered by reporting firms to be confidential business information (CBI) or not known or reasonably ascertainable (NKRA).

5.2.3. Regulatory History and Trends for PHPhDs

OFRs have received considerable regulatory attention from governmental jurisdictions in the United States and around the world; however, the scope and applicability of these regulatory actions varies significantly. This section discusses legislative action taken in the United States at the state level and in Europe through ECHA.

The Market and Use Report provides greater detail of legislative action taken in the United States, as well as action taken by other nations. Volume 2, Appendix R of the Market and Use Report provides detailed fact sheets describing specific pieces of legislation enacted or under

[18] For the 2006, 2012, and 2016 reporting periods, chemical-specific product use reporting was only required for the principal reporting year (PRY), the latest completed calendar year preceding the submission period. Therefore, 2006 data are from PRY 2005, 2012 data are from PRY 2011, and 2016 data from PRY 2015.

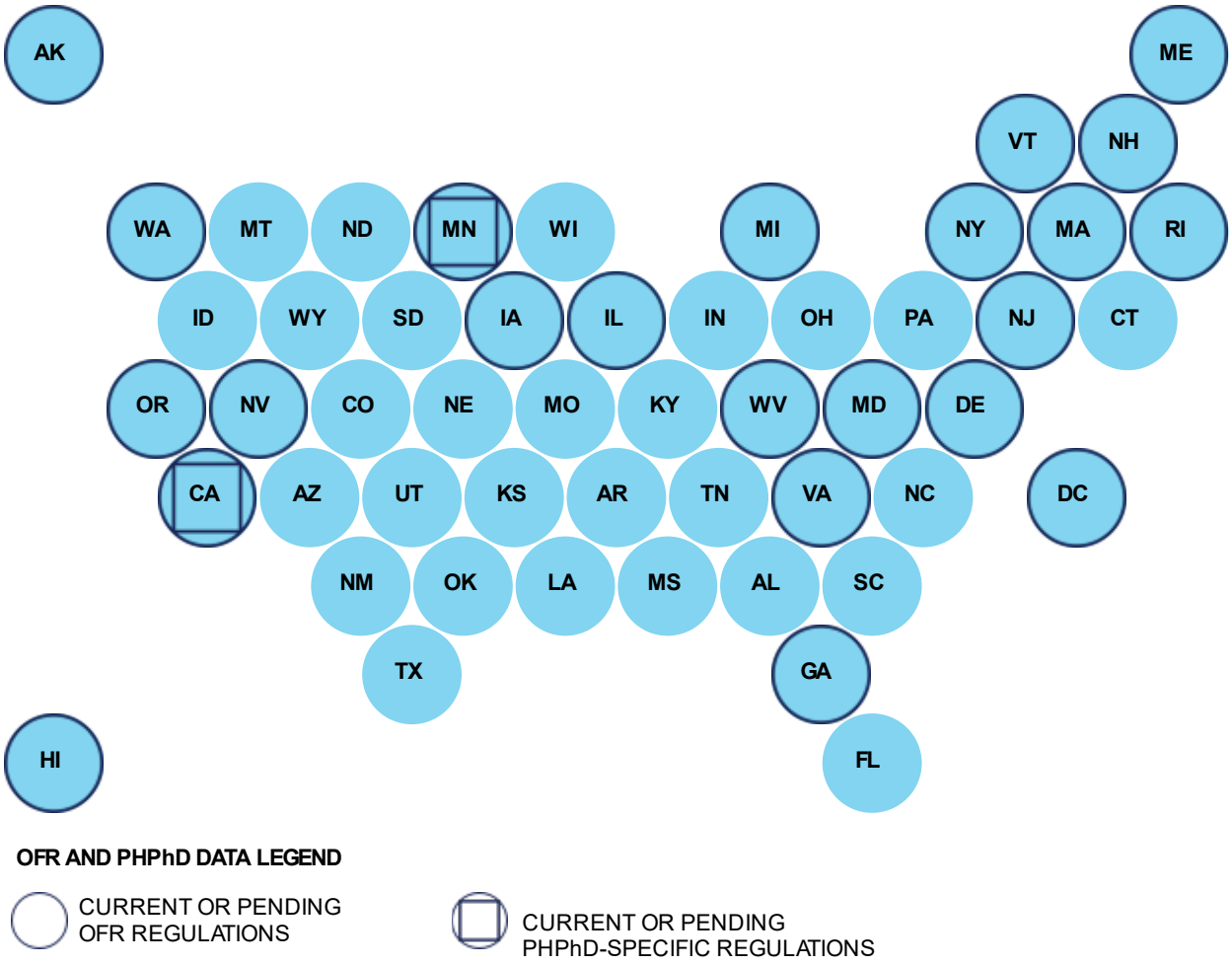
[19] The CDR rule provides reporting exemptions for chemical substances in articles, byproducts, impurities, non-isolated intermediates, certain polymers, research and development, and those produced by small manufacturers and small importers. 40 C.F.R. §§ 704.5 and 711.6. The CDR rule also exempts chemical substances manufactured in quantities of less than 2,500 pounds. *Id*. at § 711.15.

consideration since 1986 in 21 U.S. states and the District of Columbia, at the U.S. federal level, and by Canada, the EU, and Japan.[20]

According to the Market and Use Report, 22 states and the District of Columbia have current or pending OFR chemical regulations. State regulation of OFRs has tended to focus primarily on the use of these chemicals in children's products, upholstered furniture, and mattresses. (See Market and Use Report Volume 1, section 4.1.2.4 Summary of U.S. Regulatory Trends.) Among areas that have regulated the use of OFRs, 2 states, California and Minnesota, have enacted regulation of PHPhDs specifically. In the map below (Figure 5-1), states that regulate OFRs or have pending regulations are shown with circles, and states that regulate PHPhDs specifically or have pending PHPhD-specific regulations are shown with a square within the circle. For more information on the state regulation of OFRs and PHPhDs, see Volume 2 of the Market and Use Report, Appendix R.

[20] As part of work performed under the CPSC-sponsored contract, CPSC staff also sought to identify legislation developed in China related to OFRs. The literature review suggests China imposes some restrictions on OFRs, which is discussed more generally in Section 4.1.3 of Volume 1 of the Market and Use Report.

Figure 5-1. U.S. States That Regulate the Use of OFR and PHPhD Chemical Flame Retardants



The sharing of data reported to states helps to improve the effectiveness of enacted legislation on potentially hazardous OFR chemicals and to address information asymmetries in the market. Increasingly, state legislation compels reporting and allows for reciprocal data-sharing agreements with trade associations, the IC2, or other independent third parties. Reported data are also shared with the public. According to data compiled in the Market and Use Report (see Appendix R of Volume 2), eight states and the District of Columbia have reporting or data-sharing requirements for OFR chemicals.

5.3. Literature Survey Results: Evidence Maps of Toxicity Data

The toxicity evidence map descriptions below are high-level observations of the Level 2, 3, and 3B literature surveys in the designated spreadsheet files.[21] The database counts indicate either the number of sources within the database (if available) or the number of entries in the database (if no information on source is available) after attempts were made to remove duplicates. The unit for PDF counts is the individual PDF file. Level 3B tagging was performed on a subset of toxicity assessments, toxicity literature reviews, and risk assessments selected from Level 3 to identify even more specific information for the chemicals in these references. Note that most of the Level 3B data are from database data, and only a subset of the PDF data sources is tagged at Level 3B.

The general observations from the Level 2, 3, and 3B reviews are:

- PHPhD members 2,4,6-tribromophenol; pentabromophenol; phenol, 2,6-dibromo-; and 2,4-dibromophenol had the highest number of data sources in each category where data were available.
- PHPhD members 2,4,6-tribromophenol; pentabromophenol; phenol, 2,6-dibromo-; 2,4-dibromophenol; and 4,4'-sulphonylbis[2,6-dibromophenol] had the most representation across exposure categories for database and PDF reviews.
- The QSAR, Read-across, Analog category (QSAR = quantitative structure activity relationships) had broad representation with 100% of PHPhD members and 94% of analogs having at least one data source at Level 3 review and similar representation at Level 3B.

5.3.1. Summary of Level 2

The "Integrated" tab of the evidence map contains summed Level 2 toxicity data counts across both PDF and database data.[22]

The literature survey identified integrated data sources (sum of databases and PDFs) for all eight PHPhD members and for 30 of 32 analogs. The PHPhD members with the most data sources were 2,4,6-tribromophenol; 2,4-dibromophenol; and pentabromophenol. Table 5-4 summarizes how many PHPhD members and analogs had different degrees of data source abundance.

[21] See evidence map files on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.
[22] See evidence map file "PHPhD Level 2 Evidence Maps 12.6.22, Tab: Integrated" on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

Table 5-4. Distribution of Toxicity Data Source Abundance Levels at Level 2

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 2 Toxicity Data Sources	
	PHPhD Chemicals (n = 8)	Analog Chemicals (n = 32)
21+	1	0
6–20	3	2
1–5	4	28
0	0	2

5.3.2. Summary of Levels 3 and 3B

The "TOX_Integrated" tabs from each file contain Level 3 and Level 3B toxicity data counts across all toxicity databases and PDFs.[23] The Level 3B tabs were divided into A, B, and C to keep the spreadsheets manageable. Integrated Level 3B counts report the sum of data sources from databases and selected PDFs (i.e., not all PDFs identified at Level 3 were reviewed at Level 3B). The integrated counts indicate the number of data sources per chemical from databases and PDFs identified and classified into seven toxicity data type categories. At Level 3B, reviewers tagged the data sources from each category with subcategories to provide additional details of specific data types. Table 5-5 and Table 5-6 summarize how many PHPhD members and analogs had different degrees of Level 3 toxicity data source abundance.

Table 5-5. Distribution of Toxicity Data Source Abundance Levels at Level 3 – Chemicals

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Toxicity Data Sources						
	PHPhD Chemicals (n = 8)						
	Animal Toxicity or Accepted Alternative	Human Toxicity	Human, Animal, or Modeled Toxicokinetics (ADME)	Experimental Mechanistic	QSAR, Read-Across, Analog	Qualitative Hazard Characterization	Quantitative Hazard Characterization
21+	1	0	1	4	8	3	1
6–20	2	0	3	1	0	0	2
1–5	3	0	4	0	0	3	3
0	2	8	0	3	0	2	2

[23] See evidence map file "PHPhD Level 3 Evidence Maps 12.6.22, Tab: TOX Integrated" and "PHPhD Level 3B Evidence Maps 12.6.22, Tab: TOX Integrated" on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

Table 5-6. Distribution of Toxicity Data Source Abundance Levels at Level 3 – Analogs

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Toxicity Data Sources						
	PHPhD Analogs (n = 32)						
	Animal Toxicity or Accepted Alternative	Human Toxicity	Human, Animal, or Modeled Toxicokinetics (ADME)	Experimental Mechanistic	QSAR, Read-Across, Analog	Qualitative Hazard Characterization	Quantitative Hazard Characterization
21+	0	0	0	2	20	2	0
6–20	2	0	2	4	0	0	1
1–5	2	0	18	3	10	2	3
0	28	32	12	23	2	28	28

Animal Toxicity or Accepted Alternative data sources were available for six PHPhD members and four analogs at Level 3 review. Four PHPhD members and two analogs had data in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail for nine subcategories: Acute Toxicity, Systemic or Repeated Dose Toxicity, Neurotoxicity, Carcinogenicity, Mutagenicity/Genotoxicity, Reproductive Toxicity/Developmental Toxicity, Irritation, Sensitization, and Endocrine Disruption. CPSC staff observed the following:

- PHPhD member 2,4,6-tribromophenol had data sources for all subcategories except Carcinogenicity.
- PHPhD member 2,4-dibromophenol had data sources for all subcategories except Carcinogenicity, Sensitization, and Endocrine Disruption.
- Mutagenicity/Genotoxicity, Irritation, Systemic Repeated Dose Toxicity, and Reproductive Toxicity/Developmental Toxicity were the subcategories with data sources for the most PHPhD members.

Human Toxicity data sources were not available for any PHPhD members and analogs at Level 3 review and in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail for the same nine subcategories used for *Animal Toxicity or Accepted Alternative* above.

Human, Animal, or Modeled Toxicokinetics (ADME [absorption, distribution, metabolism, and excretion]*)* data sources were available for all eight PHPhD members and 20 analogs at Level 3 review and in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail on seven subcategories: Human Absorption, Distribution, Excretion; Animal Absorption, Distribution, Excretion; Human Metabolism; Animal Metabolism; In Vitro; Chemical- or Class-

Specific physiologically based pharmacokinetic (PBPK) Model; and Chemical- or Class-Specific QSAR for an ADME Parameter. CPSC staff observed the following:

- PHPhD members 2,4,6-tribromophenol had data sources in all subcategories.
- The subcategory with the most data sources and for the most chemicals was Chemical- or Class-Specific QSAR for an ADME Parameter, with data sources identified for all eight PHPhD members and 20 analogs.
- Subcategory Human Absorption, Distribution, Excretion had data sources for three PHPhD Members and two analogs.

Experimental Mechanistic data sources were available for five PHPhD members and nine analogs at Level 3 review. Five PHPhD members and five analogs had data in the databases and PDFs at Level 3B review.[24] This category had two subcategories at Level 3B review separating those data sources that make a connection to a mode of action (MOA) and a potential health effect from those that do not.[25] CPSC staff observed the following:

- Four PHPhD members had data sources in both subcategories. These were 2,4,6-tribromophenol; phenol, 2,6-dibromo-; pentabromophenol; and 2,4-dibromophenol. The hit counts in subcategory Study Makes Connection to MOA and Potential Health Effect were large, with hundreds of data sources per chemical per subcategory.
- The remaining PHPhD member with a data source in this category, 4,4'-sulphonylbis[2,6-dibromophenol], had one PDF source in the subcategory Study Does Not Makes Connection to MOA and Potential Health Effect.
- Five analogs had data sources in the subcategory Study Makes Connection to MOA and Potential Health Effect.
    - Two analogs had data sources in both subcategories. These were phenol, 2,6-dibromo- and 2-bromophenol.

QSAR, Read-Across, Analog data sources were available for all eight PHPhD members and 30 of 32 analogs at Level 3 review and in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail across the same nine subcategories used for *Animal Toxicity or Accepted Alternative* above. CPSC staff observed the following:

[24] See "TOX_DB" and "TOX_PDF" tabs of evidence map file on the CPSC Organohalogen Flame Retardant Chemicals Assessment website The 3B data counts for Experimental Mechanistic data are presented only in the "TOX_DB" and "TOX_PDF" tabs and not in the "TOX_Integrated" tab, because PubChem Bioassay data did not contain enough information to distinguish between the Level 3B tags for mechanistic data.
[25] Many database sources could not be tagged for Level 3B because it was not clear whether a connection was made to MOA.

- No data sources for PHPhD members or analogs were identified for Neurotoxicity. The vast majority of data with the QSAR, Read-across, Analog tag are from the Danish QSAR Database, which does not include any data that are taggable as Neurotoxicity.
- PHPhD members 2,4,6-tribromophenol; 2,4-dibromophenol; pentabromophenol; phenol, 2,6-dibromo-; and 4,4'-sulphonylbis[2,6-dibromophenol] had data sources in all subcategories except Neurotoxicity.
- Subcategories Acute Toxicity, Carcinogenicity, Mutagenicity/Genotoxicity, Reproductive Toxicity/Developmental Toxicity, Irritation, and Endocrine Disruption had data sources for all PHPhD members and at least 20 analogs.
- Fifteen analogs had at least one data source in all subcategories except Neurotoxicity.

Qualitative Hazard Characterization data sources were available for six PHPhD members and four analogs at Level 3 review and in the databases and PDFs at Level 3B review. In contrast with all other data types, a tag for Qualitative Hazard Characterization indicates that a review/assessment was attempted, not necessarily that data were found (e.g., if a review/assessment clearly stated that authors looked for data for endpoint X for chemical Y but found none, chemical Y was tagged for Qualitative Hazard Characterization for endpoint X, but not as any other data type.) This category was separated into the same nine subcategories used for *Animal Toxicity or Accepted Alternative* above for Level 3B review. CPSC staff observed the following:

- PHPhD members 2,4,6-tribromophenol; 2,4-dibromophenol; and pentabromophenol and analog 4-bromophenol had data sources for each of the nine subcategories.
- Subcategory Acute Toxicity had the highest counts of data sources for PHPhD members and analogs.
- Analog 2-bromophenol had data sources in all subcategories except Neurotoxicity and Endocrine Disruption.

Quantitative Hazard Characterization data sources were available for six PHPhD members and four analogs at Level 3 review. Five PHPhD members and four analogs had data in the databases and PDFs at Level 3B review. At Level 3B review, this category was further divided into seven subcategories: Acute Toxicity, Systemic or Repeated Dose Toxicity, Neurotoxicity, Carcinogenicity, Reproductive Toxicity/Developmental Toxicity, Sensitization, and Endocrine Disruption. CPSC staff observed the following:

- PHPhD member 2,4,6-tribromophenol had data sources available in the most subcategories. These were Acute Toxicity, Systemic Repeated Dose Toxicity, Neurotoxicity, and Reproductive Toxicity/Developmental Toxicity.
- Two PHPhD members (2,4-dibromophenol and pentabromophenol) and the analog 4-bromophenol had data sources in the subcategories Acute Toxicity, Systemic or Repeated Dose Toxicity, and Reproductive Toxicity/Developmental Toxicity.

5.4. Literature Survey Results: Evidence Maps of Exposure Data

The exposure evidence maps below describe high-level observations of the Level 2, 3, and 3B literature surveys in the indicated spreadsheet files.[26] Level 3B tagging was performed on a subset of 25 toxicity exposure literature reviews selected from Level 3 to identify even more specific information for the chemicals in these references. The database counts indicate the number of entries in the Multimedia Monitoring Database (MMDB). The unit for PDF counts is the individual PDF file. PHPhD analogs were not included in the exposure evidence map analyses because exposure to the analogs is outside the scope of the current project.

The general observations from the Level 2, 3, and 3B reviews are:

- PHPhD members 2,4,6-tribromophenol; pentabromophenol; and 2,4-dibromophenol had the highest number of data sources in each category where data were available.
- PHPhD members 2,4,6-tribromophenol and 2,4-dibromophenol had the most representation across exposure categories for database and PDF reviews.

5.4.1. Summary of Level 2

The MMDB database and PDF searches identified exposure data sources for all eight PHPhD members.[27] The PHPhD members with the most data sources were 2,4,6-tribromophenol; 2,4-dibromophenol; and pentabromophenol. Table 5-7 summarizes how many PHPhD members had different degrees of data source abundance. The PDFs provided more total data sources and covered more PHPhD members than the database.

Table 5-7. Distribution of Exposure Data Source Abundance Levels at Level 2

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 2 Exposure Data Sources
	PHPhD Chemicals (n = 8)
21+	1
6–20	2
1–5	4
0	1

5.4.2. Summary of Levels 3 and 3B

The "EXP_Integrated" tabs from each file contains Level 3 and 3B exposure data counts.[28] The Level 3 integrated counts indicate the number of data sources per chemical from the MMDB database and identified PDFs. Level 3 counts were classified into six exposure data type

[26] Exposure evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.
[27] Exposure evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.
[28] Exposure evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

categories. Integrated Level 3B counts report the sum of data sources from MMDB and selected PDFs. At Level 3B, reviewers tagged the data sources to subcategories to provide additional details of specific data types. Table 5-8 summarizes how many PHPhD members had different degrees of Level 3 exposure data source abundance.

Table 5-8. Distribution of Exposure Data Source Abundance Levels at Level 3

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Exposure Data Sources					
	PHPhD Chemicals (n = 8)					
	Environmental Monitoring	Biomonitoring/ Personal Monitoring	Source Characterization	Epidemiology – Population Group	Modeled Concentrations	Modeled Human Dose
21+	0	1	0	0	0	0
6-20	2	0	3	0	0	0
1-5	2	4	3	0	2	1
0	4	3	2	8	6	7

Environmental Monitoring data sources were available for four PHPhD members at Level 3 review. Three PHPhD members had data in the database and PDFs at Level 3B review. This category was separated into six subcategories for Level 3B review: Indoor/Personal Air, Indoor Dust, Outdoor Air, Food/Dietary, Soil, and Drinking Water.

- PHPhD member 2,4,6-tribromophenol had sources in all of the subcategories.
- PHPhD member 2,4-dibromophenol had data sources in the Outdoor Air and Food/Dietary subcategories.
- PHPhD member pentabromophenol had a data source for Outdoor Air only.

Biomonitoring/Personal Monitoring data sources were available for five PHPhD members at Level 3 review. Three PHPhD members had data in the database and PDFs at Level 3B review. This category was separated into five subcategories for Level 3B review: Blood/Serum, Urine, Breast Milk/Lipids, Skin/Dermal, and Human (Other).

- PHPhD member 2,4,6-tribromophenol had data sources in all of the subcategories except Skin/Dermal.
- PHPhD member 4,4'-sulphonylbis[2,6-dibromophenol] had one data source each in the Blood/Serum and Breast Milk/Lipids subcategories.
- PHPhD member 2,4-dibromophenol had a data source in the Blood/Serum subcategory.

Source Characterization data sources were available for six PHPhD members at Level 3 review and in the database and PDFs at Level 3B review. This category was separated into four

subcategories for Level 3B review: Product Testing: Content Only, Product Testing: Emission/Migration Data, Nonexperimental Product or Chemical Specific Modeling Inputs, and Other Qualitative or Quantitative Description of Product Use or Class/Chemical.

- PHPhD members 2,4,6-tribromophenol; 4,4'-sulphonylbis[2,6-dibromophenol]; 1,1'-sulfonylbis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]; pentabromophenol; and 2,4-dibromophenol each had data sources in the Nonexperimental Product or Chemical Specific Modeling Inputs and Other Qualitative or Quantitative Description of Product Use or Class/Chemical subcategories.
- PHPhD member phenol, 2,6-dibromo- had one data source for the subcategory Nonexperimental Product or Chemical Specific Modeling Inputs.
- Subcategories Product Testing: Content Only, Product Testing: Emission/Migration Data had no data sources for PHPhD members.

Environmental Epidemiology[29] data sources were available for no PHPhD members at Level 3 review or in the Level 3B review. The subcategories were Children; Adult, Non-Occupational; and Other, Specify (with Suggestions).

Modeled Concentrations data sources for two PHPhD members were identified at Level 3 review and in the database and PDFs at Level 3B review. The subcategories were Indoor Concentration, Outdoor Concentration, and Dietary/Food. PHPhD members 2,4,6-tribromophenol and 2,4-dibromophenol each had one data source in the Outdoor Concentration subcategory.

Modeled Human Dose data sources were available for one PHPhD member at Level 3 review and in the database and PDFs at Level 3B review. The subcategories were Children; Adult, Non-occupational; and Other, Specify (with Suggestions). PHPhD member 2,4,6-tribromophenol had one hit for the subcategory Other, Specify (with Suggestions).

5.5. Literature Survey Results: Summary of Existing Human Health Risk Assessments

None of the "Database" (DB) tabs at Levels 2, 3, or 3B reported risk assessment data sources. Therefore, the Integrated and PDF data counts for Human Health Risk Assessments are identical at all levels. In the files that reported PDF data sources, human health risk assessments were included in the tabs for spreadsheets displaying toxicity data sources.

5.5.1. Summary of Level 2

The "Integrated" tab contains summed Level 2 risk data counts from PDF sources.[30] No risk data were found in the databases. Ten PHPhD members and no analogs had PDF data sources for risk at Level 2 review. Table 5-9 summarizes how many PHPhD members had different

[29] The category *Environmental Epidemiology* here was identified as "*Epidemiology – POP Group*" in the "EXP_Integrated_C" tab of the Excel file, which can be found on the CPSC Organohalogen Flame Retardant Chemicals Assessment website). The change was made in this document for clarity.
[30] Risk evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

degrees of data source abundance. 2,4,6-Tribromophenol had the only human health risk assessment available.

Table 5-9. Distribution of Human Health Risk Data Sources Abundance Levels at Level 2

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 2 Risk Data Sources
	PHPhD Chemicals (n = 8)
21+	0
1–5	1
0	7

5.5.2. Summary of Levels 3 and 3B

The ”Integrated” tab for the Level 3 file contains the *Human Health Risk Assessment* counts from PDF data sources.[31] The “TOX_PDF” tab for Level 3B contains the *Human Health Risk Assessment* counts from 25 PDFs that were selected for 3B extraction. The counts indicate the number of PDFs identified per chemical for each Noncancer and Cancer risk assessment. Table 5-10 summarizes how many PHPhD members and analogs had different degrees of Level 3 human health risk data source abundance.

Human Health Risk Assessment data were available for one PHPhD member and no analogs at Level 3 review and in the 25 selected PDFs at Level 3B review. The subcategories used were Noncancer Risk and Cancer Risk, with 25 Noncancer Risk and nine Cancer Risk assessments identified. Staff noted the following observations:

- PHPhD member 2,4,6-tribromophenol had one Noncancer Risk and no Cancer Risk data sources.
- None of the 32 analogs had risk assessment data sources.

Table 5-10. Distribution of Human Health Risk Data Sources Abundance Levels at Level 3

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Risk Data Sources
	PHPhD Chemicals (n = 8)
21+	0
1–5	1
0	7

[31] Risk evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

5.6. Literature Survey Results: Key References

Among the literature survey results are several references from authoritative sources. These references include a toxicological profile by the Agency for Toxic Substances and Disease Registry, technical reports from the National Toxicology Program, EPA assessments and evaluations, Health Canada assessments, European Union risk assessment reports, International Agency for Research on Cancer evaluations, and Organisation for Economic Co-operation and Development assessments. These references primarily addressed 2,4,6-tribromophenol. Tetrabromobisphenol S (TBBPS) was included in one report. These two chemicals are among the PHPhDs[32] most frequently noted in the Market and Use Report as found in consumer products, as well as in the literature survey results generally. These reports suggest the existence of data about these chemicals, including hazard and potential exposures, and may be useful references for CPSC staff evaluations of these and other PHPhDs.

6. Scoping Determination and Next Steps

6.1. Scoping Determination

Informed by initial review of the market and use research, evidence maps, and availability of physicochemical data for the PHPhD subclass and its analogs, and the criteria described in Section 3.1, Criteria for Scoping Determination, CPSC staff concludes, at the time of writing, that the PHPhD subclass has sufficient data to proceed with risk assessment. However, this subclass may need to be combined with other similar subclasses as data sufficiency is borderline.

The criteria for sufficiency for hazard assessment for the subclass require that the subclass and analogs must have at least one data-rich chemical, multiple chemicals with some data, and a minority of chemicals that are “no data” substances.

CPSC staff concludes that the PHPhD subclass includes one data-rich chemical and that a majority of PHPhD chemicals and some analogs have some data. The evidence maps show that many PHPhD chemicals have data in the Animal Toxicity or Accepted Alternative category, including among acute, systemic or repeated dose toxicity, or reproductive/developmental studies. In addition, a majority of PHPhD chemicals and some analogs have data in the experimental, mechanistic, and QSAR categories, all of which may be used to support further analyses, including performing read-across analyses for predictions among class members with less available data. However, there are no human toxicity studies available for any subclass member or analog and only one chemical (2,4,6 tribromophenol) has a previously completed risk assessment.

The criteria for sufficiency for exposure assessment for the subclass require that the subclass must have at least one data-rich chemical and multiple chemicals with some data. CPSC staff concludes that the subclass includes up to three data-rich chemicals and that a majority of

[32] The two PHPhDs included in one or more key references are (by CAS RN): 39635-79-5; 118-79-6.

chemicals have some data. In addition, according to available data sources, all of the eight PHPhD chemicals have market information for use in commerce.

Following the determination that the PHPhD subclass has sufficient data to proceed with risk assessment, the sections below outline the next steps that CPSC staff plans to take. Below, CPSC staff provides plans for analysis to complete a class-based risk assessment. The first analysis plan describes how CPSC staff will consider data in the development of a class-based hazard identification and dose-response assessment for select endpoints. The second analysis plan describes how CPSC staff will consider data in a class-based human exposure assessment. The last step of both analysis plans is identical in that CPSC staff will consider how to combine class-based human exposure estimates with class-based toxicity reference values in a class-based risk assessment.

6.2. Next Steps for Class-Based Hazard Assessment

6.2.1. Analysis Plan

CPSC staff plans to actively work on the remaining list of activities outlined below. Many of these activities can be undertaken concurrently, as resources are available. Before completing a hazard analysis, CPSC staff expects to consider and analyze data that could inform hazard identification and dose response as follows, if resources are available:

1. CPSC staff, in coordination with the Division of Translational Toxicology (DTT) at the National Institute of Environmental Health Sciences, is working on a comprehensive literature search. Available toxicity information from PHPhD class members and analogs will be further summarized and integrated after this search is complete. After the search, staff will refine the list of data-rich PHPhDs, data-rich PHPhD analogs, PHPhDs with some toxicity information, and PHPhDs with no toxicity information.
2. CPSC staff plans to complete a systematic evidence map that will be based on a scoping review in coordination with DTT. This evidence map will include a wide range of toxicity data (e.g., animal, human, mechanistic, QSAR, read-across, new approach methodologies [NAMs][33]) from the comprehensive literature search.
3. CPSC staff will refine the NAS analog list and characterize analog substances for the PHPhD class that are both chemically and toxicologically similar and have any amount of empirical toxicity information. Analog substances that are data poor, and not sufficiently similar to PHPhD class members to be associated with them, will be deprioritized. CPSC staff's initial survey shows that toxicity and toxicokinetic data are available for four analogs.
4. CPSC staff will estimate major metabolites of PHPhD class members by interpreting results from the major metabolite prediction tools, such as GLORYx and the OECD

[33] NAMs include any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals. NAM studies may include studies using human or animal cells and tissues (i.e., in vitro assays, ex vivo studies), toxicity testing using alternative animal species, such as zebrafish and nematodes, and a variety of computational modeling approaches.

QSAR toolbox, and comparing these results with data presented in the literature. CPSC staff will consider predicted and measured metabolites to inform class-based approaches for hazard identification.

5. CPSC staff plans to use a read-across approach that incorporates multiple types of data (i.e., animal, human, mechanistic, QSAR, read-across). Data rich PHPhD class members and analogs with available toxicity data can be used to read-across to PHPhD class members with insufficient data to estimate toxicity reference values for one or more endpoints of concern. The initial CPSC literature survey suggests that toxicity endpoints that are likely higher priority for the PHPhD class are acute toxicity, systemic/repeat-dose toxicity, reproductive toxicity/developmental toxicity, and mutagenicity/genotoxicity.
6. CPSC staff will identify a smaller number of endpoint(s) and studies that are candidates for identifying points of departure (POD) and generating toxicity reference values for multiple PHPhD class members. PODs may be developed using a wide range of toxicity studies (e.g., animal, human, NAM, QSAR, read-across). CPSC staff will identify studies with a range of reported doses and associated contextual information when developing dose-response information. Benchmark dose modeling will be used as appropriate.
7. CPSC staff will compare these values with toxicity reference values developed by other organizations for PHPhD class members.
8. CPSC staff will explore the variability and uncertainty associated with dose response values for PHPhD chemicals within the class.
9. CPSC staff will use information developed in a class-based hazard assessment and dose-response assessment to support a class-based risk assessment for PHPhDs.

6.2.2. Initial Human Health Hazard Observations for Class-Based Assessment of PHPhDs

The primary objective of completing a literature survey for a subclass of OFRs is to array available information and determine whether a class-based assessment is possible. CPSC staff considers class-based exposure assessment possible for any class if data on consumer uses and physicochemical properties are available. However, CPSC staff considers class-based hazard assessment as highly data dependent. Thus, whether a class-based risk assessment is possible depends on the availability of different types of human hazard data. When sufficient human health hazard data were identified from the literature survey, this section of the scope document includes initial observations informed by review of select data sources.

The acute oral toxicity of PBP is higher than that of 2,4-DBP and 2,4,6-TBP. No guinea pigs died in a 2,4-DBP range-finding study at 3,000 mg/kg, and one of two rats died at 2,000 mg/kg 2,4-DBP (EFSA, 2012). Acute oral LD50 values in rats for 2,4,6-TBP ranged from 1,486 to >5,000 mg/kg (ECHA, 2018; EFSA, 2012). The acute oral LD50 of PBP was reported to be 302 mg/kg in female rats and 251 mg/kg in male rats (EFSA, 2012). Exposure of Spartan rats to 50,000 mg/m^3 2,4,6-TBP for 4 hours resulted in clinical signs of toxicity, but no deaths (U.S. EPA, 2009). The kidney (proteinuria) was identified as a target of PBP following a single oral

exposure; the liver may also have been a target, but the effects were considered to have been confounded by stress (EFSA, 2012).

Repeat dose in vivo data for this subclass are primarily limited to 2,4,6-TBP. A combined repeat-dose and developmental/reproductive screening toxicity test provides the most reliable repeat-dose data on 2,4,6-TBP. Signs of kidney toxicity, including hyaline casts, tubular dilatation, papillary necrosis, and increased serum creatinine, were observed in male rats. Although the histopathology suggests alpha 2μ-globulin nephropathy, an effect specific to male rats, the increased creatinine suggests an effect on glomerular function, which is not generally associated with alpha 2μ-globulin nephropathy. This observation suggests that 2,4,6-TBP causes some kidney effects that are relevant to humans, although serum chemistry was not evaluated in females, and so the relevance could not be confirmed (U.S. EPA, 2009). Liver effects observed in this study and in a 28-day study of 2,4,6-TBP were considered adaptive (ECHA, 2016).

2,4,6-TBP caused decreased neonatal and fetal viability in the combined repeat-dose and developmental/reproductive screening toxicity test and in an oral pilot teratology study, respectively (U.S. EPA, 2009). The developmental effect occurred at a dose above the maternal LOAEL or at a dose with much less maternal toxicity. In an inhalation pilot teratology study, there were no respiratory effects, but embryo lethality and delayed sternal ossification were observed at a concentration below the maternal LOAEL. The inhalation study suggests that the developing fetus may be a sensitive target, but it is limited by inadequate reporting and poor characterization of the particle size distribution (U.S. EPA, 2009).

2,4,6-TBP was negative for gene mutations in *Salmonella typhimurium*, *Escherichia coli,* and *Saccharomyces cerevisiae.* 2,4,6-TBP induced chromosomal aberrations in Chinese hamster lung cells (U.S. EPA, 2009), but was negative in an in vivo micronucleus test up to the maximum tolerated dose (OECD, 2003). PBP was negative for gene mutation in *S. typhimurium* in the presence or absence of metabolic activation (EFSA, 2012), but it is not clear from the available data whether it was tested to sufficiently high doses.

A number of in vitro studies have explored receptor binding and other mechanistic endpoints with 2,4-DBP; 2,4,6-TBP; and PBP (ECHA, 2016). Binding to the estrogen receptor and androgen receptor has been observed for 2,4-DBP and 2,4,6-TBP, but generally with low to moderate affinity. More importantly, 2,4,6-TBP may interfere with steroid synthesis or metabolism, potentially leading to estrogenicity or anti-androgenicity. 2,4-DBP; 2,4,6-TBP; and PBP all bind to the human plasma transport protein transthyretin (TTR) with high affinity (IC50 values of 1400, 67.2 and 11.5 nM, respectively). However, no corresponding in vivo effects have been seen and these chemicals have not been evaluated using an Integrated Approach to Testing and Assessment (IATA).

Overall, there are some limited data consistent with similar effects (TTR binding leading to thyroid effect) among the three brominated phenols investigated. However, data are limited even for the most data-rich subclass member (2,4,6-TBP) and nearly absent for other subclass members, making it difficult to proceed with a class-based assessment, although it may be possible to combine this subclass with another subclass.

6.3. Next Steps for Class-Based Exposure Assessment

6.3.1. Analysis Plan

CPSC staff plans to actively work on the remaining list of activities outlined below. Many of these activities can be undertaken concurrently, as resources are available. Before completing a hazard analysis, CPSC staff expects to consider and analyze data that could inform hazard identification and dose-response as follows, as resources permit:

1. CPSC staff, in coordination with DTT staff, is working on a comprehensive literature search. Available exposure information from PHPhD class members will be further summarized and integrated after this search is complete. After the search, staff will refine the list of data-rich PHPhDs, PHPhDs with some exposure and use information, and PHPhDs with no exposure and use information.
2. Using the market and use research, CPSC staff expects to compile a list of PHPhD chemicals that have been or could be used in consumer products. While all eight chemicals had some market-use information, three PHPhD chemicals had more market and use information that could be used to inform analyses for PHPhD chemicals with less information. CPSC staff will characterize uses for PHPhDs according to available information and consider temporal trends when developing exposure scenarios.
3. CPSC staff will characterize the uses identified in the market and use research and combine this information with likely exposure pathways and populations exposed to define unique combinations of exposure scenarios for chemical substances within the class. Depending on available information, CPSC may be able to quantify exposure scenarios for between three and eight PHPhD subclass members.
4. Exposure pathways with likely higher potential for PHPhD class members include ingestion of dust, ingestion of drinking water, and ingestion of food. Exposure pathways with likely lower potential for PHPhD class members include inhalation of ambient air and ingestion of soil. CPSC staff will review available environmental monitoring data to determine a range of potential concentrations to which people could be exposed. There are six chemicals in the class with source characterization data, four chemicals in the class with environmental monitoring data, and four chemicals in the class with both types of data.
5. CPSC staff plans to review measurement techniques and analytical methods and assess how they have changed over time with regard to identification and quantification of PHPhD chemicals. Lack of detection in older studies may be due to older analytical methods with higher detection limits, whereas presence in newer studies may be due to newer analytical methods with lower detection limits. CPSC staff plans to evaluate reported methods and how they influence likely distributions of OFRs in different environmental media or biological matrices.
6. CPSC staff will explore the connection between consumer product sources and reported levels in environmental media by estimating environmental concentrations for a range of uses and determining whether these estimates fall within the range of reported environmental monitoring data. CPSC staff plans to consider indoor exposure modeling,

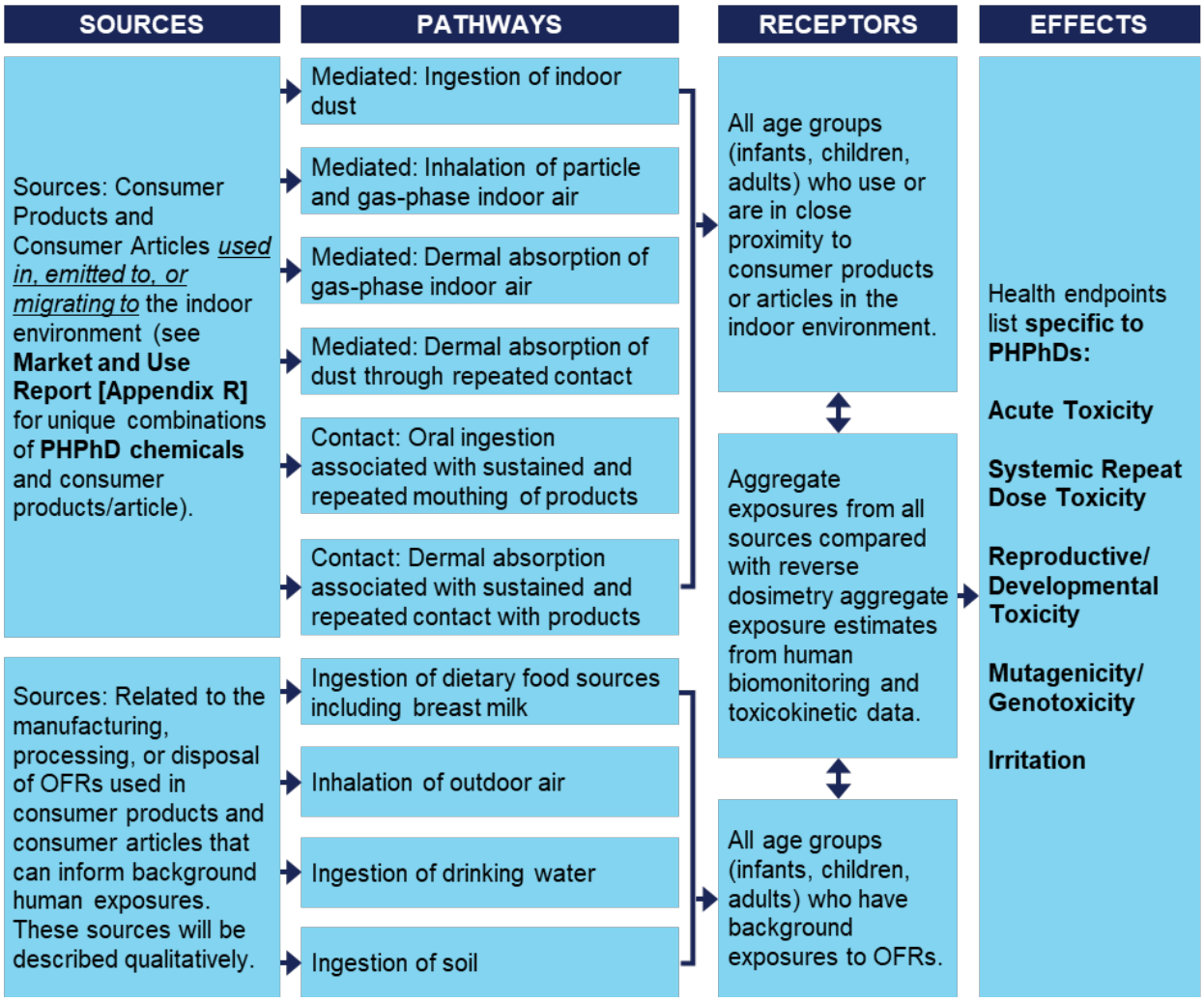
modeling approaches specific to semi-volatile organic compounds (SVOCs), and product-testing measurement techniques that characterize emissions or migration of OFRs from products into the indoor environment. When environmental monitoring is not available for comparison, CPSC staff will estimate environmental concentrations for the range of reported uses. There are two chemicals in the class with source characterization data and no corresponding environmental monitoring data.

7. CPSC staff will explore the connection between reported or estimated environmental concentrations and reported exposures from human biomonitoring data. First, doses will be estimated using reported or estimated environmental concentrations and population specific exposure factors and activity patterns. Second, doses will be estimated using reported human biomonitoring data and reported or estimated toxicokinetic data. There are five PHPhD class members with both environmental monitoring data and human biomonitoring data.
8. CPSC staff plans to use multiple approaches to estimate exposures and doses for multiple age groups and populations. CPSC staff plans to develop both deterministic and probabilistic estimates of dose, as data allow. CPSC staff will explore the variability and uncertainty associated with exposure and dose estimates for the population groups included in the human exposure assessment.
9. CPSC staff will use information developed in a class-based exposure assessment to support a class-based risk assessment for PHPhDs.

6.3.2. Conceptual Exposure Model

A conceptual exposure model visually represents connections between sources, pathways, receptors, and health effects. Figure 6-1 shows the conceptual exposure model for the PHPhD subclass. Sources are grouped into (i) those that can be related back to consumer products and (ii) all other sources that can inform background exposures. These sources will be part of a generic background exposure scenario. Each product/source will be part of an exposure scenario and quantified. Exposure pathways similarly are grouped into pathways related to emission or migration from consumer products and pathways related to occurrence in nonconsumer product-related media. Receptors include human populations of all age groups for which human biomonitoring data will be used to inform ranges of aggregate exposures from all sources. Finally, human health effects most likely to be considered for PHPhDs are listed.

Figure 6-1. PHPhD Conceptual Exposure Model



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8. Appendix: Supporting Files

The following supporting files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website. They can also be found on Docket No. CPSC-2015-0022.

Literature Survey Guide: Approaches Taken to Develop Evidence Maps from Readily Available Databases, Completed Assessments, and Literature Reviews

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Market and Use Report: Characterizing OFR Chemistries, Sources, and Uses in the U.S. and International Markets, Volumes 1 and 2 (Appendices)

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Market and Use Profile Supporting Files

Industrial Economics Incorporated (IEc). (2022). *Characterizing organohalogen flame retardant (OFR) chemistries, sources, and uses in United States and international markets: Attachment A: Standard operating procedure for producing data source outputs* [Attachment A_Data SOP.pdf]. U.S. Consumer Product Safety Commission.

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