



United States
CONSUMER PRODUCT SAFETY COMMISSION
 Washington, D.C. 20207

JAN 23 1997

VOTE SHEET

Date: **JAN 23 1997**

TO : The Commission
 Sadye E. Dunn, Secretary

FROM : Eric A. Rubel, General Counsel *ER*
 Stephen Lemberg, Asst. General Counsel *AP*
 Harleigh P. Ewell, Attorney, GCRA (Ext. 2217) *HE*

SUBJECT: Options for the Project on Child-Resistant Packaging of Household Products Containing Petroleum Distillates and Other Hydrocarbons

A staff briefing package concerning options for the project on child-resistant packaging of household products containing petroleum distillates and other hydrocarbons is attached. The staff recommends publishing an advance notice of proposed rulemaking ("ANPR") to obtain additional information relevant to whether the Commission should propose a child-resistant packaging standard for such products. A draft ANPR is included at Tab B of the briefing package for the Commission's consideration. Please indicate your vote on the following options.

I. PUBLISH THE ANPR AT TAB B AS DRAFTED.

 (Signature) (Date)

II. PUBLISH THE ANPR AT TAB B WITH CHANGES (please specify).

 (Signature) (Date)

III. OTHER (please specify).

 (Signature) (Date)

Attachment CPSA 6 (B)(1) Cleared
2/1/23/97
 No Adm/Pres. Bur. or
 Products identified
 E-mail

NOTE: This document has been reviewed and approved for release.
 Initial SD Date 1/23/97

BRIEFING PACKAGE

**Child-Resistant Packaging of
Petroleum Distillate-Containing Products.**

For Further Information Contact:

**Suzanne Barone, Ph.D.
Directorate for Health Sciences
(301) 504-0477 ext. 1196**

NOTE: This document has been reviewed and approved for release.
Initial SB Date 1/23/97

CP6A 6 (b)(1) Cleared
1/23/97
No Mrs/PrvtLbrs of
Products Identified

TABLE OF CONTENTS

	Page
Executive Summary	4
Background	5
Requirements Under the FHSA	6
Requirements Under the PPPA	6
Rationale for Petroleum Distillate Project	7
Poisoning Information	8
Request for Information	9
General Information	9
Scope of a Petroleum Distillate Rule	10
Information Request Mechanisms	13
Options	13
Recommendation	14

TABS

TAB A	Memorandum from Mannon A. Boudreault and Harpreet Singh, EPA, "Analyses of Unregulated Petroleum Distillates and Pine Oil Products, December 20, 1996	16
TAB B	Draft <u>Federal Register</u> Advance Notice of Proposed Rulemaking for the Special Packaging of Products Containing Petroleum Distillates or Other Hydrocarbons	49

Executive Summary

This briefing package presents the staff recommendation to begin rulemaking to require child-resistant packaging of consumer products that contain petroleum distillates. Petroleum distillates are a group of hydrocarbon-based chemicals that are refined from crude oil. Aspiration into the lung of small amounts of these chemicals can result in chemical pneumonia, pulmonary damage, and death. Petroleum distillates with low viscosity, such as gasoline, kerosene, and mineral seal oil, possess a greater potential for aspiration. Aspiration can occur when young children choke while attempting to drink such substances or during vomiting after drinking them.

Petroleum distillate-containing products, such as lamp oil, furniture polish, lighter fluid and paint solvents, that were associated with the most serious injuries and deaths to small children are currently required to have child-resistant packaging. However, petroleum distillates are not regulated under the Poison Prevention Packaging Act (PPPA) as a chemical class. Therefore some individual petroleum distillate-based consumer products are not required to be in child-resistant packaging. For example, cleaning solvents, automotive chemicals, shoe care products, and lubricants may contain large amounts of various petroleum distillates but do not require child-resistant packaging.

The staff evaluated pediatric poisoning cases involving the product classes listed above. Data from the National Electronic Injury Surveillance System (NEISS), the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS), and all other CPSC databases were reviewed. According to NEISS, there was an annual average of about 2,300 emergency room visits of children under five years of age associated with exposure to unregulated product classes that may contain petroleum distillates. At least 10 deaths of children under 5 years of age were documented from various sources since 1973 following exposure to product categories that contain petroleum distillates.

The toxicity of petroleum distillates is well defined, and poisoning data exist to show that children do access unregulated petroleum distillate-containing products. However, the staff would like additional information about the products that contain petroleum distillates that do not now require child-resistant packaging.

In addition to general information about hydrocarbon-containing products, several areas need to be addressed when defining the scope of a potential requirement for child-resistant packaging of these products. These include regulation of petroleum distillates in aerosol form, a requirement for restricted flow, the inclusion of non-petroleum derived hydrocarbons, and viscosity.

There are several mechanisms available to the Commission to collect information, including a survey, a general or specific order, a Request for Information, an Advance Notice of Proposed Rulemaking, or a Notice of Proposed Rulemaking. The staff believes that pursuing rulemaking to require child-resistant packaging of petroleum distillate-containing products is warranted. Therefore, the staff recommends that the Commission issue an ANPR to inform the public and to request information.



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

Date: **JAN 23 1997**

TO : The Commission
: Sadye E. Dunn, Secretary

Through : Eric A. Rubel, General Counsel *ER*
Through : Pamela Gilbert, Executive Director *PG*

FROM : Ronald L. Medford, Assistant Executive Director for Hazard *RLM*
Identification and Reduction
: Suzanne Barone, Ph.D. *SB*
Project Manager for Poison Prevention
Directorate for Epidemiology and Health Sciences, 504-0477
ext. 1196

SUBJECT : Child-Resistant Packaging of Consumer Products that Contain
Petroleum Distillates and Other Hydrocarbons.

This memorandum presents the staff recommendation to begin rulemaking to require child-resistant packaging of consumer products that contain petroleum distillates and other hydrocarbons having similar characteristics. A copy of a draft Advance Notice of Proposed Rulemaking (ANPR), prepared by the Office of the General Counsel, is at Tab B.

BACKGROUND

Petroleum distillates are a group of hydrocarbon-based chemicals that are refined from crude oil. Petroleum distillates include gasoline, naphtha, mineral spirits, kerosene, paraffin wax, and tar. Petroleum distillates are the primary ingredient in many different consumer products. The viscosity of the petroleum distillate-containing product determines the potential toxicity. Viscosity is the measurement of the ability of liquid to flow. Liquids with high viscosities are thick or "syrup-like" and liquids with low viscosities may be more "watery" or volatile.

The toxicity of petroleum distillates is respiratory in nature. Direct aspiration into the lung, or aspiration during vomiting, of small amounts of these chemicals can result in chemical pneumonia, pulmonary damage, and death. Petroleum

CPSA 6 (b)(1) Cleared
1/23/97
No Mfrs/Prvtlbrs
Products Identified

NOTE: This document has not been
reviewed by the Commission.
Initial *SD* Date *1/23/97*

distillates with low viscosity, such as gasoline, kerosene, and mineral seal oil, possess a greater potential for aspiration.

As discussed below, the potential for serious toxicity and death from products that contain petroleum distillates has been addressed previously by the Consumer Product Safety Commission (CPSC).

Requirements Under the FHSA

The CPSC regulates the labeling of consumer products containing petroleum distillates under the Federal Hazardous Substances Act (FHSA). The regulations under the FHSA generally require special hazard labeling for products containing 10 percent or more by weight of petroleum distillates such as kerosene, mineral seal oil, naphtha, gasoline, mineral spirits, Stoddard solvent, and related distillates (16 CFR 1500.14(a)(3) and (b)(3)). The label must bear the signal word "DANGER," the statement of hazard, "Harmful or fatal if swallowed," and the statement "Call physician immediately" (16 CFR 1500.14(b)(3)), along with the balance of the labeling required by Section 2(p)(1) of the FHSA.

This section of the FHSA regulations (16 CFR 1500.14(b)(3)) also requires labeling of other hydrocarbons, including products that contain 5 percent or more by weight of benzene and products containing 10 percent or more by weight of toluene or xylene.

Requirements Under the PPPA

The CPSC also regulates the packaging of some household products containing petroleum distillates under the Poison Prevention Packaging Act (PPPA). Under current regulations, certain consumer products containing 10 percent or more by weight of petroleum distillates, and having a viscosity less than 100 Saybolt Universal Seconds (SUS)¹ at 100°F, are subject to child-resistant packaging standards. These products include prepackaged liquid kindling and illuminating preparations (e.g., lighter fluid) (16 CFR 1700.14(a)(7)), prepackaged solvents for paint or other similar surface-coating materials (e.g., varnishes)(16 CFR 1700.14(a)(15)), and nonemulsion liquid furniture polish (16 CFR 1700.14(a)(2)). Products in these categories were responsible for many serious injuries and deaths to young children following ingestion.

The individual PPPA regulations for these three petroleum distillate-containing product categories differ in scope. The PPPA regulation for furniture polish specifically exempts pressurized spray containers (aerosols). The liquid furniture polish regulation also offers additional protection by requiring a limit of the amount of furniture polish that can flow from the bottles (restricted flow). The

regulations for furniture polish and for kindling and illuminating preparations are limited to petroleum distillates. However, the PPPA regulation for paint solvents applies to products containing benzene, toluene, or xylene, as well as to petroleum distillates.

Rationale for Petroleum Distillate Project to Require Special Packaging

The goal of the current project is to create a more consistent and comprehensive regulatory approach to child-resistant packaging for petroleum distillate-containing products. Because petroleum distillates are not now regulated under the PPPA as a chemical class, many petroleum distillate-based consumer products are not required to be in child-resistant packaging. For example, cleaning solvents, automotive chemicals, and shoe care products may contain large amounts of various petroleum distillates. The existing child-resistant packaging standards require child-resistant packaging of prepackaged kerosene for use as lamp fuel; however, a gun cleaning solvent that contains over 90 percent kerosene does not have this requirement. Mineral spirits used as a paint solvent require child-resistant packaging, but spot removers containing 75 percent mineral spirits, and water repellents containing 95 percent mineral spirits, do not. Although these consumer products are required by the FHSA to be labeled, "Harmful or fatal if swallowed," they do not require child-resistant packaging.

A rule to require child-resistant packaging of products that contain petroleum distillates would provide consistency within the PPPA and between FHSA and the PPPA. However, before issuing such a regulation, the Commission must find that "the degree or nature of the hazard to children in the availability of petroleum distillates, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance." The PPPA also requires the Commission to find that child-resistant packaging "is technically feasible, practicable, and appropriate" for petroleum distillate-containing products.

In addition to the required findings, the Commission is required to consider but not necessarily make formal findings on, (a) the reasonableness of the standard, (b) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances, (c) the manufacturing practices of industries affected by the PPPA, and (d) the nature and use of the household substance.

Under the PPPA, a notice of proposed rulemaking (NPR) may be published without having previously published an ANPR. However, before issuing a rule, in addition to complying with the requirements in the PPPA, the Commission must either assess the impact of a regulation on small businesses, or certify that there will not be a significant economic effect on a substantial number of small entities.

The Commission must also examine the potential for adverse effects on the environment.

POISONING INFORMATION

The staff evaluated pediatric poisoning cases involving product classes known to contain hydrocarbons that are not currently regulated by the PPPA. The product areas of interest include adhesives, automotive chemicals, workshop chemicals, metal polishes, spot removers or cleaning fluids, shoe polishes and lubricants. Pine oil cleaners and disinfectants were also examined, however, many of these products are regulated by the Environmental Protection Agency (EPA). Data from the National Electronic Injury Surveillance System (NEISS), the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS), and all other CPSC databases were reviewed. In addition, telephone investigations were conducted on NEISS cases involving children under 5 years of age and the household product categories listed above. The results of the data analysis is at Tab A.

According to NEISS, between 1990 and 1994, there was an annual average of about 2,300 emergency room visits of children under five years of age associated with exposure to unregulated petroleum distillate-containing product categories. About five percent of the NEISS cases result in hospitalization.

Between October 1994 and May 1996, telephone investigations were conducted on emergency room-treated incidents involving children under five years of age following exposure to the categories of products listed above including pine oil. The telephone investigations resulted in 43 in-scope cases for analysis. Most of the incidents occurred in the child's home. When the incident occurred, about 50 percent of the victims gained access to the product when it was in its normal storage area rather than when the product was left outside of its normal storage area. Seventy-nine percent of the incidents involved products in the original packaging; however, most of these containers were reported as non-child-resistant.

In 1994, the Poison Control Centers reported 11,100 exposures of children under 5 years of age attributed to product categories that may contain petroleum distillates. Eighteen percent of these cases resulted in symptoms, with most being minor in nature.

At least 10 deaths of children under 5 were documented from various sources since 1973 following exposure to product categories that contain petroleum distillates and currently do not require child-resistant packaging.

REQUEST FOR INFORMATION

The toxicity of petroleum distillates is well defined, and poisoning data exist to show that children do access unregulated petroleum distillate-containing products. However, the staff would like additional information about the products that contain petroleum distillates that do not now require child-resistant packaging. Information on the following topics would be requested.

General Information

Product Information

Information about individual products will be used to identify the categories and products that would be regulated under a petroleum distillate rule. The form of the product (i.e., liquid, aerosol, etc.), the formulation, and the viscosity of the final product would be requested for the products.

Users and Use Patterns

Information about the users, the indicated use, the site of use, the frequency of use and the retention of the product would be requested to evaluate consumer use patterns for the different product categories.

Packaging and Labeling

Information about current packaging of hydrocarbon-containing products will be used to assess the technical feasibility, practicability, and appropriateness of child-resistant packaging. Information about the packaging would be requested, including descriptions of the packages, packaging sizes, container material, closure material, and closure design. To define the scope of voluntary child-resistant packaging usage, the ASTM classification of child-resistant packaging currently being used for petroleum distillate-containing products would be requested.

Market Information

Market information about products that contain petroleum distillates would be requested to evaluate the extent and the economic impact of a rule to require child-resistant packaging for all petroleum distillate-containing consumer products. Information is requested on the cost and sales of products. The impact of this requirement on small businesses must be assessed; therefore, the staff would request information about the impact of such a regulation on small businesses.

Incident Information

The staff monitors ingestions by young children of products that contain petroleum distillates. However, additional information about poisoning incidents is requested. The details of the scenarios (e.g., opened by child, product in use, etc.) resulting in poisoning incidents and the outcome of the incident would be used to assess the extent of injury from different product formulations.

Scope of a Petroleum Distillate Rule

Several areas need to be addressed when defining the scope of a potential requirement for child-resistant packaging of products containing petroleum distillates. These include regulation of petroleum distillates in aerosol form, a requirement for restricted flow, the inclusion of non-petroleum derived hydrocarbons, and viscosity. The staff is interested in collecting information and soliciting comments on these issues to help define the scope of a child-resistant packaging requirement for petroleum distillate-containing products. The general product data requested above would also be used to assess these issues.

Aerosols

Should a petroleum distillate requirement for child-resistant packaging include aerosol products that contain low-viscosity petroleum distillates?

The PPPA regulation for liquid furniture polish specifically exempts aerosol products (16 CFR 1700.14(a)(2)). The rationale given in the final rule for the exclusion of aerosol furniture polishes was that aerosols would be dealt with separately (36 FR 18012). However, there has been no further regulatory action on aerosol furniture polish. The child-resistant packaging requirements for paint solvents and kindling and illuminating solvents do not specifically exempt aerosol products. However, the staff is not aware of any paint solvent or liquid kindling or illuminating fluid sold in an aerosol form.

Inhalation of petroleum distillates has been shown to cause respiratory problems, such as asthma, pneumonia, or pulmonary edema.^{2,3,4} These medical literature cases involved prolonged or repeated exposure of adults to inhaled petroleum distillates from aerosols or vapors. However, it has been documented that under equal exposure levels, children are subject to greater inhalation risk than adults.⁵ The effect of a single acute exposure to an aerosol product containing petroleum distillates is unknown.

CPSC exposure data on aerosol products are limited. The NEISS case investigation study, described in the Poisoning Information Section above identified

4% of the cases as involving products in aerosol form. The victims in all of those cases were treated and released.

The staff would request information and comment on whether aerosol products that contain petroleum distillates should be child-resistant.

Viscosity Level

What is the appropriate viscosity for requiring child-resistant packaging of products that contain petroleum distillates?

Since the hazard associated with petroleum distillates is from aspiration and not systemic toxicity, viscosity plays a role in defining the potential hazard of a petroleum distillate-containing product. The current PPPA regulations impose a child-resistant packaging requirement on furniture polish, lighter fluid, or paint solvents, containing at least 10 percent petroleum distillates, that have a viscosity of less than 100 SUS at 100°F. This viscosity has been used to define the upper limit of the aspiration hazard because the products associated with chemical pneumonia and death had viscosities below this level.

The staff collected and measured the viscosity of several household products that contain petroleum distillates to see the range of viscosities (Table 1). These products contain over 10 percent petroleum distillates.

Table 1: The Viscosities of Petroleum Distillate-Containing Products

Product	PPPA Regulated (Y or N)	Viscosity (SUS @100°F) ^{1,6}
Motor oil (10W-30)	N	≈325
Heavy Mineral Oil	N	180
Baby Oil	N	≈70
Furniture Polish	Y	≈40
Gasoline Treatment	N	≈35
Carburetor Cleaner	N	<32 ⁷
Degreaser	N	<32 ⁷
Lighter Fluid	Y	<32 ⁷

According to the limited laboratory analysis, lighter weight oils, including some baby oils, would be included in a regulation that requires child-resistant

packaging of products containing at least 10 percent petroleum distillates with a viscosity less than 100 SUS at 100°F. There are cases of lipid pneumonia⁸ and deaths documented from lubricants (Tab A).

The exact number and variety of consumer products that would be included in a child-resistant packaging requirement for all products that contain at least 10 percent petroleum distillates and have a viscosity less than 100 SUS at 100°F is unknown. The staff would request the identification of products with at least 10 percent petroleum distillates that would be regulated at a viscosity of 100 SUS at 100°F. The staff would also solicit comments concerning the appropriateness of a viscosity level of 100 SUS at 100°F.

Restricted Flow

Should restricted flow be an additional requirement for certain products?

The child-resistant packaging regulation for furniture polish includes an additional requirement that no more than 2 milliliters of product be obtained when the container is shaken, squeezed, or activated once. This requirement was added because of the nature and use of household furniture polish. The example given in the final rule was that the container without a closure may be moved and used throughout the house (37 FR 5613). Furniture polish is the only PPPA-regulated substance with this additional requirement.

There are two conditions where restricted flow may provide the most additional protection. First, on products with usage patterns similar to furniture polish that may be left open or used frequently and not always put back into the normal storage place. Second, on products with low viscosities that are the most likely to result in injury if aspirated by children, such as products with viscosities under 50 SUS at 100°F.

There are situations where restricted flow may not be appropriate. Examples include single-use products and products where a larger volume is needed. Many automotive products fit these descriptions. The staff would request comment on this issue regarding restricted flow.

Other Hydrocarbons

Should a child-resistant packaging requirement for petroleum distillates include products that contain other hydrocarbons?

The PPPA requirement for paint solvents extends the packaging requirement to products that contain the aromatic hydrocarbons, benzene, toluene,

and xylene. The FHSA groups benzene, toluene, xylene, and petroleum distillates together because of similar inhalation and aspiration hazards.

Many of the product categories that do not now require child-resistant packaging including adhesives and automotive chemicals, contain petroleum distillates, toluene, or xylene. It is anticipated that a child-resistant packaging requirement for products that contain petroleum distillates would include products that contain benzene, toluene, xylene, or any mixture of these.

There are other hydrocarbons, not derived from petroleum, found in consumer products including terpene hydrocarbons such as turpentine, pine oil and limonene. These hydrocarbons are derived from wood and fruit and are found in cleaning products and spot removers. The PPPA and FHSA have separate packaging and labeling requirements for turpentine. It should be noted that pine oil products that claim to be disinfectants are regulated by the EPA. The number of pine oil products under CPSC jurisdiction is unknown.

The hazards associated with other hydrocarbons are similar to those seen with the petroleum-derived hydrocarbons. Should other hydrocarbons be included in a rulemaking for petroleum distillates or should they be dealt with separately?

The staff would request comments on whether other hydrocarbons with similar toxicity profiles to petroleum distillates should be included in the same PPPA rulemaking.

INFORMATION REQUEST MECHANISMS

There are several mechanisms available to the Commission to collect information. These include conducting a survey, publishing a request for information in the Federal Register, issuing a general or special order, issuing an ANPR, or issuing a notice of proposed rulemaking (NPR). Any of these mechanisms can be used to inform interested parties and to solicit specific information. An order or survey addresses the request to the industries directly involved, the other choices broaden the scope to include the general public. The ANPR or the NPR would begin rulemaking under the PPPA.

OPTIONS

The following options are available to the Commission:

1. If the Commission believes that it is appropriate to begin rulemaking to require child-resistant packaging of all products that contain petroleum distillates and that additional information is necessary before proposing a

regulation, the Commission can publish the ANPR, as drafted or with appropriate changes.

2. If the Commission believes that sufficient data exist to propose rulemaking, the Commission can direct the staff to prepare an NPR.
3. If the Commission believes that it is necessary to collect additional information prior to considering rulemaking, the Commission could direct the staff to prepare documents needed to pursue other mechanisms for gathering information (survey, orders, request for information).
4. If the Commission believes that it is not appropriate to begin rulemaking to require child-resistant packaging of all products that contain petroleum distillates at this time, the Commission can direct the staff to terminate the project.

RECOMMENDATION

The staff recommends that the Commission begin rulemaking and issue an ANPR in the Federal Register to inform the general public of the Commission's intent to require child-resistant packaging on products containing petroleum distillates and to request information useful in the rulemaking.

The staff believes that pursuing rulemaking to require child-resistant packaging of petroleum distillate-containing products is warranted. The toxicity of petroleum distillates is well defined. The poisoning data indicate that children are accessing products that contain petroleum distillates and that much of the current packaging may not be child-resistant. However, before proceeding with a recommendation to issue a proposed rule, the staff would like additional information and comments on issues related to the scope of the rule and on consumer products containing petroleum distillates.

Although not required for PPPA rulemaking, an ANPR provides an efficient means of informing the public about the Commission's intent to begin rulemaking and soliciting information and comments about products containing petroleum distillates from many different sources. Information obtained in response to the ANPR could then be used in a subsequent proposal, should the Commission decide to pursue that option.

ENDNOTES

1. Saybolt Universal Seconds is a unit of viscosity.
2. Nierenberg, D.W., et al. Mineral Spirits Inhalation Associated with Hemolysis, Pulmonary Edema, and Ventricular Fibrillation. *Arch Intern Med*, 151:14337, 1991.
3. Rodriguez de la Vega, A. et al. Kerosene-induced Asthma. *Annals of Allergy*, 64:362, 1990.
4. Glynn, K.P. and Gale, N., Exogenous Lipoid Pneumonia due to Inhalation of Spray Lubricant (WD-40 Lung), *Chest*, 97:1265, 1990.
5. Schiller-Scotland, C.F, et al. Experimental data for total disposition in the respiratory tract of children. *Toxicol. Lett.*, 72: 137, 1994.
6. The viscosity was measured at 100°F using a Brookfield viscometer calibrated in centistokes. The value was converted to SUS using ASTM conversion table, D 2161-93.
7. There are no equivalent viscosities measured in SUS for viscosities less than 1.8cs. Therefore, measurements of "less than 32 SUS" are given for cs values lower than 1.83cs, which is equivalent to 32 SUS.
8. Reyes De La Rocha, S. et al. Lipoid pneumonia secondary to baby oil aspiration: a case report and review of the literature. *Pediatric Emergency Care*, 1:74, 1985.

T A B A



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: DEC 20 1996

TO : Suzanne Barone, Ph.D., Project Manager for Poison Prevention
Directorate for Epidemiology and Health Sciences

Through : Mary Ann Danello, Ph.D., Associate Executive Director *M. Danello*
Directorate for Epidemiology and Health Sciences
Robert E. Frye, Director *RF*
Hazard Analysis Division (EHHA)

FROM : Manon A. Boudreault, EHHA *MAB*

SUBJECT: Incident Data Related to Unregulated Petroleum Distillates and Pine Oil Products

The attached report presents estimates for possible unregulated petroleum distillates and pine oil product-related emergency room visits for children under 5. It also includes an analysis of follow-up telephone investigations for certain unregulated product categories believed to contain petroleum distillates or pine oil.

PETROLEUM DISTILLATES AND PINE OIL PRODUCTS

Manon A. Boudreault and Harpreet Singh
Hazard Analysis Division
Directorate for Epidemiology and Health Sciences
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

November 1996

CPSA 6 (b)(1) Cleared

1/23/97

No. *1123/97* Products File

CONTENTS

	PAGE
Executive Summary	i
I. Introduction	1
II. National Data	1
A. National Estimates of Pine Oil and Unregulated Petroleum Distillates Products, Emergency Room Treated Incidents	1
B. Unregulated Petroleum Distillates and Pine Oil Incidents by Specific Product Categories	2
Table 1. Possible Pine Oil and Petroleum Distillates Estimated Emergency Room Incidents, 1990-1994, Children Less Than 5 Years Old	4
Table 2. Possible Unregulated Petroleum Distillates Products and Pine Oil Preparations by Age and Diagnosis, 1990-1994, NEISS Incidents	5
III. Telephone Investigations	6
A. Methodology	6
B. Victim Characteristics	6
C. Product Characteristics	7
D. Household Environment	7
IV. Poison Control Center Data	7
Table 3. Poison Control Center Data, Possible Petroleum Distillates and Pine Oil Exposures, Children Under 5, 1994.	9
V. Discussion	10
Appendix A: Summary of Deaths	11
Appendix B: Telephone Questionnaire	13
Endnotes	27

EXECUTIVE SUMMARY

Petroleum distillates and pine oil are in some consumer products that are not presently required to be in child-resistant packaging. From 1990 to 1994, there was an estimated annual average of 2,300 emergency room visits for children less than 5 years old associated with unregulated petroleum distillate-containing products according to data from the National Electronic Injury Surveillance System (NEISS). An additional estimated 2,300 cases from pine oil are documented each year. Telephone investigations were conducted on emergency room treated incidents from these products that occurred between October 1994 and May 1996 and resulted in 43 in-scope cases for analysis. Data from the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS) and death data from CPSC data files were also reviewed.

- Of the cases reported through NEISS, most of the children injured were 1 and 2 years of age and were said to have had poisoning-related injuries primarily.
- About 5 percent of the estimated 2,300 petroleum distillate cases reported to NEISS emergency rooms resulted in hospitalization.
- Since 1973, CPSC has received reports of 5 deaths due to pine oil aspiration and at least 10 deaths from petroleum distillates involving children under age 5 (in what appeared to be unregulated products). The deaths were caused most often by chemical pneumonitis.
- The AAPCC reported 11,100 incidents attributed to unregulated products that contain petroleum distillates in 1994. Eighteen percent of these cases resulted in some physical effect. Most were considered minor; however, several major or life threatening exposures were documented.

The analysis of the 43 investigated cases show that:

- For most (about 80%) of the 43 investigated incidents, the product was in its original package and was reported as not child-resistant.
- For the cases where the original package was not child resistant, the child was exposed to the product when: the child opened the package himself (52%), the product was placed in a bucket or cup (22%), the package cap was left off or left on loosely (22%), or an older child was involved (3%).
- For the cases where products were originally in child resistant packages, the child resistant feature was not effective because the child had bitten into the package or the product had been removed from its original child resistant package and placed in another container (e.g., a pan) at the time of the incident.
- Most of the incidents occurred in the child's home. About half of the victims found the product in its normal storage area.

I. INTRODUCTION

Petroleum distillates and pine oil are in some consumer products that are not required to be in child-resistant packaging. Products such as adhesives, spot removers, shoe polishes, workshop chemicals, metal polishes, tarnish removers or preventatives, lubricants, and automotive chemicals or cleaners can contain petroleum distillates and are not currently required to be in child-resistant packaging. Pine oil-containing products are similar to petroleum distillate products and have essentially the same damaging effects to children when aspirated.

Emergency room visit data collected through the National Electronic Injury Surveillance System (NEISS) for the product categories listed above were reviewed to estimate the number of emergency room treated incidents associated with unregulated petroleum distillates and pine oil products.¹ To obtain additional information, a follow-up study was conducted on emergency room treated incidents from exposures to these product categories. Product information was obtained and product formulation was determined based on these data. Thus, a classification based on chemical content and product category was possible. Telephone investigations were conducted to better assess incident scenarios. The NEISS estimates and deaths are presented below followed by the results from the telephone investigations and data collected by the American Association of Poison Control Centers.

II. NATIONAL DATA

A. National Estimates of Possible Unregulated Petroleum Distillate-Containing Products and Pine Oil Products, Emergency Room Treated Incidents

As listed in Table 1, from 1990 to 1994, there was an estimated annual average of about 2,300² emergency room visits for children under 5 associated with possible unregulated petroleum distillates products, such as adhesives (only those containing xylene or toluene were included in this report), spot removers or cleaning fluids, workshop compounds or chemicals, metal polishes, lubricants, automotive polishes, waxes, cleaners, and chemicals. These product categories were believed to be the most likely of the unregulated product categories to contain petroleum distillates (based on verification of products and specific brand names in the POISINDEX).³ An additional estimated 2,300 cases are reported for pine oil-containing products. Children were exposed to these possible petroleum distillate and pine oil compounds through inhalation, ingestion, or eye or skin contact. On average, about 5 percent of the emergency room visits resulted in hospitalization.

As detailed in Table 2, most children injured were 1 and 2 years old. The predominant cause of injury was cited as poisoning. Although brand names were not included in all cases, the chemical contents of some specific products listed in the narratives were identified.

Since 1973, CPSC has received reports of 15 deaths due to pine oil or petroleum distillates involving children under age 5 (in what appeared to be unregulated products). Deaths attributed to gasoline or kerosene from consumer repackaged containers (i.e. gasoline cans) were not included in this analysis. The deaths were caused most often by chemical pneumonitis, are described in Appendix A and listed under each specific product category.

B. Incidents Related to Possible Unregulated Petroleum Distillate and Pine Oil Products by Specific Product Categories

Pine Oil Cleaning and Disinfectant Preparations (Product Code 0945)

Between 1990 and 1994, there were an estimated total of 11,300 children under age 5 treated in emergency rooms with illness or injuries attributed to this product code (an annual average of about 2,300, based on an average annual sample of about 55 cases).⁴ This product code captured pine oil cleaning preparations, disinfectants that did not contain pine oil, and products that both contain pine oil and are disinfectants. It is unknown how many of these injuries were due to pine oil products solely (the majority of the incidents mentioned the word "pine" in the narrative and one brand in particular was mentioned in about 65 percent of the incidents), disinfectants solely, or due to products that may have been both a pine oil product and a disinfectant. Eighty percent of the injuries were characterized as poisonings with the remaining injuries attributed to children getting the product in their eyes or on their skin which resulted in chemical burns (6%), dermatitis/conjunctivitis (6%) or other injuries (7%). Since 1973, 5 deaths involving children under 5 were reported to CPSC. The deaths were caused most often by pine oil aspiration resulting in chemical pneumonitis.

Adhesives (Product Code 0909)

Between 1990 and 1994, there was an estimated total of 3,300 children under age 5 treated in emergency rooms with illness or injuries that were attributed to adhesives (an annual average of about 660, based on an annual average sample of about 14 cases).⁵

Spot Removers or Cleaning Fluids (Product Code 0977)

Between 1990 and 1994, there was an estimated total of 2,100 children under age 5 treated in emergency rooms with illness or injuries that were attributed to this product code (an annual average of about 400, based on an annual average sample of about nine cases).⁶ Two reports of deaths due to children under 5 drinking spot remover were received since 1973.

Workshop Compounds or Chemicals (Product Code 0833)

Between 1990 and 1994, there was an estimated total of 650 children under age 5 treated in emergency rooms with illness or injuries that were attributed to this product code

(an annual average of about 100, based on an annual average sample of about two cases).⁷ Since 1973, one death was reported to CPSC due to mineral spirits that were used to clean leather.

Metal Polishes, Tarnish Removers or Preventatives (Product Code 0931)

Between 1990 and 1994, there was an estimated total of 400 children under age 5 treated in emergency rooms with illness or injuries that were attributed to this product code (an annual average of about 100, based on an annual average sample of about two cases).⁸ Since 1973, one death was reported where a child drank brass cleaner.

Lubricants (Product Code 0913)

Between 1990 and 1994, there was an estimated total of 3,300 children under age 5 treated in emergency rooms with injuries or illness that were attributed to this product code (an annual average of 660, based on an annual average sample of about 11 cases).⁹ About 700 of the estimated 3,300 visits identified one specific brand of lubricant that is used as a household lubricant. Lubricants such as motor oil were not included in this estimate. Since 1973, two deaths were reported to CPSC due to aspiration of lubricants: one was due to musical instrument oil and the other was due to chain saw oil.

Automotive Waxes, Polishes, Cleaners, and Chemicals (Product Codes 0955 and 0978)

Between 1990 and 1994, there was an estimated total of 2,000 children under age 5 treated in emergency rooms with injuries and illness that were attributed to these product codes (an annual average of about 400, based on an annual average sample of about six cases).¹⁰ CPSC received three reports of deaths from automotive cleaners or chemicals in children under 5 (since 1973). An additional report of a death occurred where a child aspirated a "degreaser" (this could either be an automotive chemical or a spot remover).

Table 1
National Data
Possible Pine Oil and Possible Petroleum Distillate Products
Estimated Emergency Room Incidents, 1990-1994
Children Less Than 5 Years Old

Product Category	Annual Average^a	1990-1994 Estimated Incidents (5 year total)	Total Hospitalized^b 1990-1994	Sample Size (Total 1990-1994 Incidents)
Pine Oil Cleaning and Disinfectant Preparations	2,260	11,320	590	273
Adhesives	660	3,300	40	68
Spot Removers or Cleaning Fluid	410	2,070	140	43
Workshop Compounds or Chemicals	130	650	40	12
Metal Polishes, Tarnish Removers or Preventatives	80	390	40	12
Lubricants	660	3,300	190	55
Automobile Waxes, Polishes, Cleaners, and Chemicals	400	1,980	120	32

^aThe NEISS estimates based on small sample sizes cited in this memorandum should be used with caution, particularly those with an annual estimate less than 1,200: the sampling variability for such estimates is large in comparison to the estimates themselves. ^bThis includes treated and transferred for hospitalization. Estimates were rounded to the nearest 10.

Source: CPSC, National Electronic Injury Surveillance System, EHHA

Table 2
National Data
Possible Petroleum Distillate Products and Pine Oil Preparations
Percent Distribution by Age and Diagnosis, Children <5 Years Old
1990-1994

PRODUCT	VICTIM AGE	DIAGNOSES*
Pine Oil and Disinfectant Preparations	<1 year 13%	Poisoning 80%
	1-2 years 75%	Chemical Burn 6%
	3-4 years 12%	Dermatitis/Conjunctivitis 7%
		Other 6%
Adhesives	<1 year 6%	Poisoning 65%
	1-2 years 62%	Chemical Burn 4%
	3-4 years 32%	Dermatitis/Conjunctivitis 6%
		Other 25%
Spot Removers or Cleaning Fluid	<1 year 12%	Poisoning 58%
	1-2 years 85%	Chemical Burn 7%
	3-4 years 3%	Dermatitis/Conjunctivitis 11%
		Other 24%
Workshop Compounds or Chemicals	<1 year ---	Poisoning 97%
	1-2 years 93%	Chemical Burn 3%
	3-4 years 7%	Dermatitis/Conjunctivitis ---
		Other ---
Metal Polishes, Tarnish Removers or Preventatives	<1 year 4%	Poisoning 76%
	1-2 years 96%	Chemical Burn 4%
	3-4 years ---	Dermatitis/Conjunctivitis 19%
		Other ---
Lubricants	<1 year 5%	Poisoning 77%
	1-2 years 74%	Chemical Burn 7%
	3-4 years 20%	Dermatitis/Conjunctivitis 12%
		Other 4%
Automobile Waxes, Polishes, Cleaners, and Chemicals	<1 year 13%	Poisoning 69%
	1-2 years 54%	Chemical Burn 4%
	3-4 years 32%	Dermatitis/Conjunctivitis 7%
		Other 20%

* As defined in the NEISS coding Manual.

Other diagnoses include: foreign body (to eye), contusion/abrasion (e.g., corneal abrasion), aspiration, and "other".

Total may not add to 100 percent due to rounding.

Source: CPSC, National Electronic Injury Surveillance System, EHHA

PETROLEUM DISTILLATES AND PINE OIL PREPARATIONS

III. TELEPHONE INVESTIGATIONS

A. Methodology

The NEISS cases reviewed for this report included those that were coded as product code 833 (Workshop Chemicals), 909 (Adhesives), 932 (Shoe Polishes),¹¹ 931 (Chrome/Metal Polishes), 937 (Rust/Tarnish Removers)¹², 945 (Pine Oil Cleaners and Disinfectants), 955 (Automotive Chemicals), 978 (Automotive Cleaners), 977 (Spot Removers), and product 913 (Lubricants) for children under 5 years of age. They were assigned for telephone investigation. The telephone investigations were conducted on emergency room treated incidents that occurred between October 1994 and May 1996. One-hundred and sixty cases were assigned for this time period and in 85 of these cases, a telephone investigation was completed (for a response rate of 53%). Each product involved was reviewed to determine eligibility as either a pine oil product or an unregulated petroleum distillates product (based on the POISINDEX, product formulation database³). Of the 85 cases where a telephone investigation was possible, 43 cases were considered in-scope. For most products, data was available on the product type or brand to review product formulation. The percent of in-scope cases varied by product type. For the product categories reviewed as possible unregulated petroleum distillates (including adhesives containing xylene or toluene only), 36 percent were found to be in-scope. For the possible pine oil products and disinfectant category, 78 percent of the cases were in-scope. Twenty-five out of forty-three of the cases for this analysis were pine oil products rather than petroleum distillate products. Eighteen cases were petroleum distillates (six of which were xylene or toluene). In 90 percent of the cases, a parent was the respondent.

B. Victim Characteristics

Most (74%) of the poisonings were to children 1 and 2 years of age and were about evenly divided between males and females. Almost all (97%) were treated and released following the incident.

Treatment Given

Although for most incidents (80%), no one saw the child taste or swallow the product, caregivers reported the following reasons for suspecting that the child had gotten into the product: residue in/on the child's mouth; smell of the product in or on the child's mouth; child was coughing or gasping; or child was found with the bottle in his or her hands. Based on the contents of the package prior to the suspected ingestion, almost all of the caregivers in this study reported that the amount the child ingested was a small amount (a sip or swallow or less than one ounce).

About one-fourth of the children showed some physical symptoms before going to the emergency room, most often vomiting or coughing. After the suspected ingestion, most caregivers (72%) contacted someone such as a poison control center, physician or other health professional (usually it was a poison control center). About one-third of the caregivers gave some type of treatment at home, usually giving the child milk or water. Sixty percent of the parents reported that their children were treated, most often with administration of a charcoal solution, when they arrived at the hospital.

C. Product Characteristics

For most (about 80%) of the 43 investigated incidents, the product was in its original package; most packages were reported as not child-resistant. Almost all (96%) of the products were liquid with a small portion being in an aerosol or spray form. About three-fourths of the respondents identified a brand name.

For the cases where the original package was not child resistant, the child was exposed to the product when: the child opened the package himself (52%); the product was placed in a bucket or cup (22%); the package cap was left off or left on loosely (22%); or an older child was involved (3%). For the small number that were originally in child resistant packages, the child resistant feature was not effective because the child had bitten into the package or the product had been removed from the child-resistant package and placed in another container (e.g., a pan) at the time of the incident.

D. Household Environment

Although caregivers may have been nearby when the accident happened, in most (80%) incidents, it was reported that no one saw the child taste or swallow the product. It appeared that the child had relatively easy access to the product, since for about 70 percent of the incidents, the child did not climb onto any object to obtain the product. About one-third of the children found the product on a counter top or table. About the same number found the product inside a cabinet or under the sink. Some others found the product in a trash can or on the floor. About half of the products were found by the children in the kitchen/dining room or bathroom. When the incident occurred, for about half of the victims, the product had been placed in its normal storage area rather than left out. Most (80%) of the incidents occurred in the child's home.

IV. POISON CONTROL CENTER DATA

Toxic Exposure Surveillance System (TESS) data are compiled by the American Association of Poison Control Centers (AAPCC) in cooperation with the majority of U.S. poison control centers. Of the 65 reporting centers, 60 submitted data for the

entire year in 1994. Only cases where follow-up was possible were included in this report.¹³

As listed in Table 3, 1994 data from TESS showed that there were about 4,100 exposure cases attributed to pine oil and 11,100 exposure cases attributed to possible petroleum distillate-containing products that were followed by the poison control centers for the effect of the exposure. For the cases that were followed, 18 percent of the possible petroleum distillates exposures resulted in some physical effect and 26 percent of the pine oil exposures resulted in some physical effect. Most of these physical effects were considered minor. (The signs or symptoms were minimally bothersome and generally resolved rapidly with no residual disability or disfigurement.) However, cases with major symptoms (life threatening or resulted in significant residual disability or disfigurement) were documented. No deaths of child under 5 years of age following exposure to these household product categories were reported by the AAPCC in 1994.

It should be noted that 52 percent (5,791) of the 11,100 exposure cases in TESS are from products known to contain petroleum distillates or other hydrocarbons.

**Table 3 POISON CONTROL CENTER DATA
POSSIBLE PETROLEUM DISTILLATES AND PINE OIL EXPOSURES,
CHILDREN UNDER 5, 1994**

POSSIBLE PRODUCT CODE and AAPCC GENERIC CODES	Total	CASES FOLLOWED-EFFECT OF EXPOSURE				
		None	Minor	Moderate	Major	Death
Pine Oil Cleaners-Total	4,054	2987	1005	53	8	0
Pine Oil Disinfectant		2987	1005	53	8	0
Adhesives-Total	1,852	1430	407	15	0	0
Adhesives, Glues, Cements, Pastes-Other/Unknown		925	224	8	0	0
Toluene/Xylene (Adhesives Only)		505	183	7	0	0
Spot Removers-Total	1,200	946	245	9	0	0
Spot Remover/Dry Cleaning Agent-Other/Unknown		16	4	1	0	0
Spot Remover/Dry Cleaning Agent-Nonhalogen Other Hydrocarbon Carpet/Leather/Upholstery Cleaners		45 885	23 218	2 6	0 0	0 0
Possible Workshop Chemicals-Total	2,709	2131	504	67	7	0
Toluene/Xylene (excl. adhesives)		100	31	3	0	0
Hydrocarbon Other		1048	254	29	5	0
Hydrocarbon Unknown		983	219	35	2	0
Possible Chrome/Metal Polishes-Total	2,760	2393	345	21	1	0
Polishes and Waxes (excl.mineral seal oil)		2393	345	21	1	0
Rust/Tarnish Removers-Total	27	18	6	3	0	0
Rust Remover-Other/Unknown		18	6	3	0	0
Lubricants-Total	1,484	1304	171	9	0	0
Lubricating Oils/Motor Oils		1304	171	9	0	0
Possible Automotive Chemicals and Cleaners-Total	1,096	881	201	14	0	0
Auto/Aircraft/Boat Products-Other		191	44	6	0	0
Auto/Aircraft/Boat Products-Unknown		14	8	0	0	0
Other Hydrocarbon-Automotive		676	149	8	0	0

Source: American Association of Poison Control Centers Toxic Exposure Surveillance System

V. DISCUSSION

The review of injury data from various sources show that petroleum distillates and pine oil can cause severe injury and deaths to children under 5. Since 1973, CPSC has received reports of 5 deaths due to pine oil and at least 10 deaths from petroleum distillates involving children under age 5 (in what appeared to be unregulated products). Most of the deaths were attributed to chemical pneumonia following aspiration. Although the exact number of children under 5 years of age treated in emergency rooms due to unregulated petroleum distillates and pine oil products is unknown, the annual average emergency room visits for these products combined is estimated to be 4,600.

Based on the telephone investigations, 78 percent of the cases coded in the NEISS system as pine oil products were pine oil products. If this percentage is applied to the annual average NEISS estimate of emergency room visits (2,300), then the annual estimate attributed to pine oil cleaning products may be about 1,800 incidents. The AAPCC reported 4,100 exposure cases attributed to pine oil in 1994.

Determining the estimated number of children under the age of 5 who were treated in emergency rooms due to unregulated petroleum distillates products is more difficult. For the unregulated petroleum distillate products, it is unknown how many of the other general product categories in CPSC databases may contain relevant injuries or deaths, since specific information dealing with brand/formulation was limited. Also, the data search for this report focused primarily on the unregulated product categories that were believed to contain petroleum distillates incidents. Thus, the "unregulated product" petroleum distillates-related injuries and deaths cited in this report may be a substantial under-count.

While the absolute number is unknown, it is important to note that children are accessing products in the categories known to contain petroleum distillates. The AAPCC reported 11,100 incidents in 1994 from unregulated petroleum distillate-containing product categories. About 52 percent (5,791) of these incidents involved products known to petroleum distillates or other hydrocarbons. While most of these cases did not have serious outcomes, major or life threatening effects were documented in several cases.

The details of the NEISS cases from the telephone investigations describe that most children were accessing the products without child-resistant packaging from the normal storage areas. It is reasonable to conclude that child-resistant packaging could prevent some incidents with this scenario if packaging were required on petroleum distillate- and pine oil-containing product categories.

**Appendix A
UNREGULATED PETROLEUM DISTILLATES PRODUCTS AND PINE OIL DEATHS (CHILDREN UNDER FIVE)*
1973-reports received as of August 1996**

DOCUMENT NO.	STATE	DATE OF DEATH	AGE	PRODUCT	NARRATIVE
PETROLEUM DISTILLATES DEATHS					
06067969	CA	4-24-75	8 MOS.	INSTRUMENT OIL	DRANK TRUMPET VALVE OIL, CHEMICAL PNEUMONITIS.
37014619	NC	4-6-76	2 YRS.	BRASS POLISH	CHILD DRANK BRASS POLISH
40008340	OK	4-7-78	19 MOS.	DEGREASER	RESPIRATORY ARREST, ASPIRATION PNEUMONIA, HYDROCARBON INGESTION (DEGREASER).
048103065	TX	12-30-80	9 MOS.	MINERAL SPIRITS	DRANK MINERAL SPIRITS USED TO CLEAN LEATHER, NECROTIC PNEUMONITIS.
204019318	AZ	11-12-82	12 MOS.	CHAIN SAW OIL	INGESTED CHAIN SAW OIL, CHEMICAL PNEUMONITIS.
641009919	OR	5-30-86	21 MOS.	SPOT REMOVER	INGESTED SPOT REMOVER LIQUID, CHEMICAL PNEUMONITIS.
622018498	LA	6-6-86	16 MOS.	TRANSMISSION FLUID	AUTO TRANSMISSION FLUID ASPIRATION
1747046806	TN	12-09-87	15 MOS.	SPOT REMOVER	CHILD INGESTED SPOT REMOVER.
120706HCC1754	FL	4-19-92	19 MOS.	AUTO CLEANER	CHILD DIED 30 DAYS AFTER INGESTING SOME AUTOMOBILE TIRE CLEANING FLUID THAT HAD BEEN IN ITS ORIGINAL CONTAINER WHICH DID NOT HAVE A CHILD RESISTANT CAP.
130408HCC1095	NC	1-28-93	23 MOS	AUTO CLEANER	CHILD DIED AFTER VOMITING WAS INDUCED FOLLOWING THE INGESTION OF AN AUTOMOTIVE CLEANING COMPOUND CONTAINING PETROLEUM DISTILLATES.
PINE OIL DEATHS					
7751036345	VA	12-3-77	17 MOS.	PINE OIL	DRANK PINE OIL, HYDROCARBON PNEUMONIA
948004485	TX	1-11-79	8 MOS.	PINE OIL	CHILD ASPIRATED AND INGESTED PINE OIL
8048063875	TX	8-5-80	8 MOS.	PINE OIL	CHILD ASPIRATED AND INGESTED PINE OIL
8422020104	LA	4-15-84	18 MOS.	PINE OIL	ACUTE CHEMICAL PNEUMONITIS; INGESTION OF PINE OIL
8404009476	AZ	5-11-84	12 MOS.	PINE OIL	CHILD ASPIRATED PINE OIL

ADDITIONAL POSSIBLE UNREGULATED PRODUCT PETROLEUM DISTILLATES DEATHS

6001178	CA	1-7-77	12 MOS.	CLEANING SOLVENT	RESPIRATORY FAILURE, SOLVENT INHALATION, INGESTED CLEANING SOLVENT. THIS IS A POSSIBLE PETROLEUM DISTILLATES DEATH.
46005953	SD	12-1-86	14 MOS.	SPOT REMOVER OR CLEANING FLUID	INGESTED HYDROCARBON, HYPOXIC ENCEPHALOPATHY, CEREBRAL EDEMA, PULMONARY ANOXIA FROM HYDROCARBON INGESTION. THIS IS A POSSIBLE PETROLEUM DISTILLATES DEATH.

FOR THIS REPORT, DEATHS WERE INCLUDED THAT WERE IN UNREGULATED PRODUCT CATEGORIES BELIEVED TO CONTAIN PETROLEUM DISTILLATES OR PINE OIL, E., ADHESIVES, WORKSHOP CHEMICALS, METAL POLISHES, RUST/TARNISH REMOVERS, SHOE POLISHES, PINE OIL CLEANERS, AUTOMOTIVE CHEMICALS AND WAXES, WINDOW CLEANERS, SPOT REMOVERS, AND LUBRICANTS.

NOTE: SINCE CPSC HAS RECEIVED REPORTS OF ADDITIONAL PETROLEUM DISTILLATES DEATHS IN REGULATED PRODUCT CATEGORIES SUCH AS PAINT THINNERS AND LAMP OIL, THE ACTUAL NUMBER OF DEATHS DUE TO PETROLEUM DISTILLATES IS HIGHER.

Appendix B: TELEPHONE QUESTIONNAIRE

1. CASE NO.			2. INVESTIGATOR'S ID [][][][][][]			3. OFFICE CODE [][][]			EPIDEMIOLOGIC INVESTIGATION REPORT		
4. DATE OF ACCIDENT YR [][] MO [][] DAY [][][]			5. DATE INVESTIGATION INITIATED YR [][] MO [][] DAY [][][]								
6. SYNOPSIS OF ACCIDENT OR COMPLAINT _____ _____ _____ _____											
7. LOCATION (Home, school, etc.) [][][]				8. CITY [][][][][]				9. STATE [][]			
10A. FIRST PRODUCT [][][][]				11A. TRADE/BRAND NAME, MODEL NUMBER, MANUFACTURER & ADDRESS							
10B. SECOND PRODUCT [][][][]				11B. TRADE/BRAND NAME, MODEL NUMBER, MANUFACTURER & ADDRESS							
12. AGE OF VICTIM [][][]		13. SEX (Use numerical code) MALE - 1 [] FEMALE - 2 [] UNKNOWN - 3 []		14. DISPOSITION []				15. INJURY DIAGNOSIS [][]			
16. BODY PART [][][]			17. RESPONDENT(S) (Mother, Friend) []			18. TYPE INVESTIGATION ON SITE 1 [] TELEPHONE 2 [] OTHER 3 []		19. TIME SPENT [][][]			
20. ATTACHMENTS []			21. CASE SOURCE [][][]			22. REVIEWED BY [][][][]			YR [][] MO [][] DAY [][][]		
23. PERMISSION TO DISCLOSE NAMES (NON-NEISS CASES ONLY) CPSC MAY DISCLOSE MY NAME [] CPSC MAY NOT DISCLOSE MY NAME []											
24. NARRATIVE (See instructions on Other Side)						25. REGIONAL OFFICE DIRECTOR REVIEW DATE [][][] [][][] [][][]					
(USE OTHER SIDE AND ADDITIONAL SHEETS IF NECESSARY)											

TASK NO. _____
 Ingestion Data Record Sheets- 1992/1993 Oct 14, 1992

Answer by circling appropriate response or filling in answer in the space provided.

PRODUCT: _____

NEISS COMMENTS: _____

INTERVIEWER: Review NEISS case before conducting interview.

Record of Calls

Date	Day of Week	Time	Result*	Date	Day of Week	Time	Result*

*C=Completed CB=Call Back LB=Line Busy WN=Wrong Number
 NWN=Non-Working Number NA=No Answer R=Refused
 NER=No Eligible Respondent (e.g., parent, relative, guardian)

Suggested Call Back Time: Day: _____ Time _____ A.M/P.M.

1. Hello. May I please speak with _____ (parent/relative/guardian of victim)?

(Note: If respondent is available, go to Q. 2. If not available ask:)

When would be a good time to contact him/her?

(Note: If necessary, state purpose of the call. Write in above next to "Suggested Call Back Time" the best time to try again.)

SUGGESTED INTRODUCTION

2. Hello. I'm _____ working with the U.S. Consumer Product Safety Commission. We are doing a study of accidents concerning children who get into household cleaning products, solvents, and fuels.

I understand that your child was recently treated at _____ hospital emergency room because (s)he got into _____. Would you help by answering a few questions about the incident? The information you give could help us learn how to prevent this type of incident, which commonly occurs in households with young children.

Of course, your participation is voluntary. However, I want to assure you that the information will be used only for statistical totals; no names are used. This should only take a few minutes. Will you help us?

Respondent: 1 Agreed
2 Refused-->(Determine if another time or a surrogate respondent could be used.)

Respondent is: 1 Mother of victim
2 Father of victim
3 Grandmother of victim
4 Grandfather of victim
5 Sister of victim
6 Brother of victim
7 Aunt of victim
8 Uncle of victim
9 Someone else-->Specify: _____

Probe for whether respondent: 1 Witnessed or was nearby when accident happened
2 Did not witness or was not nearby when accident happened

3. First, I'd like to make sure I have the right information.
(INTERVIEWER: CORRECT INFORMATION WHERE NECESSARY.)

a. The accident happened on MO DY YR ?

b. The child is a --

1 boy
2 girl ?

c. The child's birthday is MO DY YR ?

d. The child was --

1 Treated and released from the emergency room or examined and released without treatment

-->(SKIP TO Q. 5.)

2 Treated and transferred for further treatment, but not hospitalized

3 Treated and transferred for hospitalization

-->(GO TO Q. 4a.)

4 Admitted for hospitalization

8 Died--> SPECIAL SENSITIVITY REQUIRED, (SKIP TO Q. 5.)

9 Unknown-->(ENTER CORRECT DISPOSITION, FOLLOW APPROPRIATE SKIP PATTERN FOR CORRECT DISPOSITION.)

INTERVIEWER: The following questions may have been answered in the narrative above. If so, ask again, telling respondent you are just verifying the answer. You could say: "Let's see, you told me before that ... , is that correct?"

6. Was the original container a child-proof or child-resistant one; that is, a container designed to be difficult for young children to open, a container with special instructions telling how to open it?

- 1 yes
- 2 no
- 9 don't know

7. When the accident happened was the product in its original container, in another container, or in no container at all?

A. in original container--> Ask Q. 1-4 below, as applicable.

1. At the time of the accident, was there a label on the container?

- 1 yes
- 2 no
- 9 don't know

2. Was the original cap or closure still on the container when the child got into the product?

- 1 yes -->SKIP to Q. 8.
- 2 no, different cap or closure on container -->SKIP to Q. 8.
- 3 no cap or closure on container-->Ask Q 3-4.
- 4 cap loosely replaced on container -->SKIP to Q. 8.
- 5 original container DID NOT have a cap -->SKIP to Q. 8.
- 9 don't know -->SKIP to Q. 8.

3. Was the cap off only briefly or was it usually left off?

- 1 only briefly
- 2 usually left off
- 9 don't know

4. Was the cap left off for a specific reason?

- 1 product was in use
 - 2 original cap was hard to open
 - 3 inadequate opening instructions
 - 4 other (Specify:)
-

9 don't know, not sure

B. in another container-->Describe container or package type
and its cap or closure and ask Q. 1.

1. Why was the product transferred from the original container?

- 1 product was in use
- 2 original container was too large
- 3 original container was difficult to handle
- 4 original cap was hard to open
- 5 other (Specify:)
- 9 don't know, not sure

C. in NO CONTAINER at all at time of accident--> Ask Q. 1 below.

1. Why was the product removed from the original container?

- 1 original container was too large
- 2 original container was difficult to handle
- 3 original cap was hard to open
- 4 other (Specify:)
- 9 don't know, not sure

8. It is extremely important that I correctly identify the exact product.
Do you still have the original container that the product came in?

- 1 Yes--(CONTINUE TO Q. 9)
- 2 No-->What happened to the original product container
[Read List and SKIP to Q. 11]?
 - 1 Product was not in a container
 - 2 Container broke
 - 3 Left at emergency room
 - 4 Thrown away before going to E.R.
 - 5 Thrown away after going to E.R.
 - 6 At someone else's house
 - 7 Other:Specify
 - 9 Don't know
- 9 Don't know-->(CONTINUE TO Q. 9.)

9. Would you get/look for the original container while I wait?

1 Yes (Respondent got the container.)-->(GO TO Q. 10.)

2 Yes (Respondent looked, but did not find the container.)
-->(SKIP TO Q. 11.)

3 No-->Would you get the container later if I were to call
back at a more convenient time?

1 Yes (Set up call back time; write in on page 1 above.)

Say, "Let's continue with my questions, but I'll call you
back for the product information." -->(SKIP TO Q. 11.)

2 No-->(SKIP TO Q. 11.)

10. (RESPONDENT HAS THE CONTAINER IN HAND FOR THE INTERVIEW.)

Please read the label and tell me-- (IF LABEL IS MISSING, CHECK HERE /___/ AND CONTINUE)

a. The name of the product- (ASK FOR EXACT SPELLING)

b. The manufacturer-

c. The form of the product-

- liquid
- granules
- powder
- tablet
- ball
- other: Specify _____

d. What was the amount of the product in the container, when new?

e. The exact words and direction of the arrows on the top of the cap or directions for opening the container-

- no words
- no arrows
- no directions
- no cap

11. (RESPONDENT DOES NOT HAVE THE CONTAINER IN HAND FOR THE INTERVIEW, OR PRODUCT WAS NOT IN A CONTAINER WHEN THE ACCIDENT HAPPENED.)

a. What was the name of the product?

_____ don't know/don't recall

b. The manufacturer?

_____ don't know/don't recall

c. What was the form of the product?

- liquid
- granules
- powder
- tablet
- ball
- other: Specify _____
- don't know/don't recall

d. What was the amount of the product in the container, when new?

_____ don't know/don't recall

e. What were the words and arrow directions on the top of the cap or directions for opening the container?

- no words
- no arrows
- no directions
- no cap
- don't know/don't recall

f. The letters and numbers on the bottom of the container?

- no letters
- no numbers
- no container

f. What were the letters and numbers on the bottom of the container?

- no letters
- no numbers
- no container
- don't know/don't recall

INTERVIEWER: For the following questions, probe for specific amounts in ounces, grams, etc., if possible. If respondent doesn't recall specific amounts, specify amounts as proportion of full container, or, if necessary, in amounts expressed in teaspoons, tablespoons, cups, mouthfulls, or tastes. Record the amount in Q. 10.g.1 or Q. 11.g.1 and continue on to Q. 12. If respondent can't express an amount which the child ingested, continue probing with Q. 10.g.2. or Q. 11.g.2.

g. 1) How much of the product do you think the child tasted or swallowed?

don't know/don't recall

1) How much of the product do you think the child tasted or swallowed?

don't know/don't recall

2. What was the amount of product in the container
a) when new [read from label]?

before the child got into it?

don't know/don't recall

after the child got into it?

don't know/don't recall

2) What was the amount of product in the container
a) when new?

don't know/don't recall

before the child got into it?

don't know/don't recall

after the child got into it?

don't know/don't recall

12. Please describe how you think the child got into the container?

-
- 8 no container
 - 9 don't know

13. Did anyone actually see the child taste or swallow the product?

- 1 yes --->SKIP TO Q. 15.
- 2 no
- 9 don't know, not sure

14. How did you or someone else know or suspect that the child had gotten into the product?

- 1 residue of product in/on child's mouth
- 2 smelled product in/on child's mouth
- 3 product spilled near child
- 4 child reported ingesting product
- 5 other, Specify: _____
- 9 don't know, not sure

15. After (child's name) exposure to the product, did (s)he show any symptoms or signs of illness before going to the emergency room?
INTERVIEWER: circle more than one response, if applicable.

- 1 yes -->(SPECIFY:) --->
 - a. Child vomited
 - b. Child had fever
 - c. Child was lethargic
 - d. Child was irritable
 - e. Child was coughing
 - f. Other: Specify _____

- 2 no
- 9 don't know

16. Before going to the emergency room, did you (parent/guardian) talk to a poison control center, a physician, another health professional, or someone else?

- 1 yes -->(SPECIFY:)
 - a. poison control center
 - b. physician
 - c. health professional (specify) _____
 - d. other (specify) _____
 - e. don't know

- 2 no
- 9 don't know

17. Was some type of treatment given at home (e.g., Was child made to vomit)?

1 yes --> (SPECIFY TYPE:)

- a. Child vomited, without ipecac or other emetic administered
- b. Child vomited, ipecac administered
- c. Child vomited, other substance administered
- d. Child given milk
- e. Other, Specify: _____

2 no, child taken directly to emergency room for treatment

3 no, treatment suggested but not given at home

9 don't know

18. Was (child's name) given some type of treatment in the emergency room (e.g., given something to cause vomiting) or just observed for reactions? INTERVIEWER: circle more than one response, if applicable.

1 yes --> (SPECIFY TREATMENT(S) GIVEN:)

- a. medication given to induce vomiting
- b. stomach pumped (gastric lavage)
- c. charcoal solution administered
- d. blood tests administered
- e. other, Specify: _____

2 no, just observed

9 don't know, not sure

19. Thinking again about the day of the accident, about what time did the accident occur (probe for specific time or indicate morning, afternoon, or evening if specific time could not be recalled)?

_____ a.m.

_____ p.m.

_____ morning

_____ afternoon

_____ evening

9 don't know

20. Where did the accident happen -- in the child's own home, a relative's home, a friend's home, a sitter's home, a school, a store, or somewhere else?

1 child's home

2 relative's home --> a. grandparent

b. other relative, Specify: _____

3 friend or neighbor's home

4 sitter's home

5 someone else's home --> (SPECIFY:) _____

6 school

7 store

8 somewhere else --> (SPECIFY:) _____

9 don't know/not sure

21. When the accident happened, was the product in its normal storage place, was it left out, or was it in a trash container?

- 1 in its normal storage place
- 2 left out
- 3 in a trash container
- 9 don't know

22. In what area or room was the product when (child's name) got into it?

- 01 kitchen/dining room
- 02 living room/family room
- 03 bedroom
- 04 bathroom
- 05 closet
- 06 basement
- 07 yard
- 08 garage
- 09 outdoor structure, such as a shed
- 10 other-->(SPECIFY:)
- 99 don't know/not sure

23. Where specifically did (child's name) find the product -- on the floor or ground, under a sink, inside a cabinet or drawer, on a counter top, on a dresser top, on a shelf or somewhere else?

- 1 on floor or ground--> SKIP TO Q. 25.
- 2 under a sink--> SKIP TO Q. 25.
- 3 inside a cabinet or drawer
- 4 on a counter top
- 5 on a dresser top
- 6 on a shelf
- 7 somewhere else-->(DESCRIBE:)
- 9 don't know

24. Did the child climb onto an object such as a chair or table to reach the product?

- 1 yes: -->describe object child climbed:
 - a. chair
 - b. stool
 - c. counter
 - d. sofa
 - e. bed
 - e. toilet
 - f. sink
 - h. other:specify
- 2 no
- 9 don't know

25. Has (child's name) ever gotten into any other product that might have been dangerous or poisonous if he/she ate it (aspirin, other medicine, other chemical product)?

1 yes--> (SPECIFY TYPE OF PRODUCT:) _____

--> (SPECIFY AGE OF CHILD WHEN THIS LAST HAPPENED:)

_____ years _____ months

2 no

9 don't know

26. Did another child help-(child's name) get into the product or play some other role in this accident?

1 yes--> (DESCRIBE INVOLVEMENT OF OTHER CHILD: _____

2 no

9 don't know

27. Would you like to add any comments to your description of the accident?

___ yes, COMMENT: _____

___ no

28. INTERVIEWER: FOR THOSE RESPONDENTS WHO DID NOT HAVE THE PRODUCT CONTAINER AND WHO KNOW THE PRODUCT INVOLVED, ASK:

AT YOUR CONVENIENCE, WOULD YOU BE WILLING TO GO TO THE STORE, FIND AN IDENTICAL PRODUCT OF THE SAME SIZE AND COPY SOME INFORMATION FROM THE LABEL? IF SO, I WILL CALL YOU BACK AT YOUR CONVENIENCE. THE INFORMATION WE NEED IS:

1. Product brand name (EXACT SPELLING)

2. Type of container -- any opening instructions (Is it a child-resistant container?)

___ Respondent Agreed

___ Respondent Refused

29. If container has NOT been discarded, ASK: If we request that a CPSC field investigator contact you for further information and collect a sample of the container(s) for evaluation (The container(s) will NOT be returned to you), will you cooperate in a further investigation?.

___ Respondent agreed

___ Respondent refused

30. Thank you very much for your time. Your answers to these questions will be used in our efforts to help prevent other such accidents. If I need clarification or have forgotten to ask something important, would you mind if I call you back at your convenience?

Respondent agreed--> Best day and call back time: _____

Respondent refused _____

ENDNOTE

1. The Consumer Product Safety Commission (CPSC) operates an incident data collection system known as the National Electronic Injury Surveillance System (NEISS). The NEISS is a probability sample (91 participating hospitals) of hospital emergency rooms selected from the population of all hospital emergency rooms in the U.S. and its territories. Injuries associated with consumer products are collected on a daily basis via computer from each participating hospital. Because of the properties of a probability sample, the reported injuries represent all similar injuries treated in the U.S. and its territories.
2. Based on an average annual sample of about 55 cases involving pine oil and on an average annual sample of about 44 cases of unregulated petroleum distillate-containing products. The individual NEISS estimates based on small sample sizes cited in this report should be used with caution, particularly those with an annual estimate less than 1,200, since the sampling variability for such estimates is large in comparison to the estimates themselves.
3. Rumack BH, Hess AJ, & Gelman, CR (eds.): POISINDEX(R) System. MICROMEDEX, Inc., Englewood, Colorado (Edition expires August 31, 1996).
4. The unadjusted NEISS estimate for the product code 0945, Pine Oil Cleaning and Disinfectant Preparations, was 12,000 emergency room visits from 1990-1994 for children under 5 years of age. Cases included under the product code 0954, general-purpose household cleaners (with a word search "pine") were also reviewed and appropriate cases were included in the estimate (an additional 600 emergency room visits). Product descriptions were reviewed and product types and brand names that were included in the case narratives were checked in the POISINDEX database which lists contents and percentages of components that may make up a particular chemical product. Although for some it was unclear whether the product involved was a pine oil or disinfectant preparation, about 80 percent of the incidents mentioned the word pine.
5. The unadjusted NEISS estimate for the product code 0909, Adhesives, was 11,500 emergency room visits from 1990-1994 for children under 5 years of age. Product descriptions were reviewed and product types and brand names that were included in the case narratives were checked in the POISINDEX database. Many of the out-of-scope cases were a specific brand of fast-acting household glue. Case narratives that gave brand names were reviewed and eliminated when they were not petroleum distillate products. Narratives that did not give a specific brand name (and could not be specifically excluded) were included in the estimate as possible petroleum distillates incidents.

6. The unadjusted NEISS estimate for the product code 0977, Spot Removers or Cleaning Fluids, was 3,800 emergency room visits from 1990-1994 for children under 5 years of age. Each case narrative was reviewed for inclusion as a possible petroleum distillate product. Product descriptions were reviewed and product types and brand names that were included in the case narrative were checked in the POISINDEX database. Case narratives that gave brand names were reviewed and eliminated when they were not petroleum distillate products. Narratives that did not give a specific brand name (and could not be specifically excluded) were included in the estimate as possible petroleum distillate incidents
7. The unadjusted NEISS estimate for the product code 0833, Workshop Compounds or Chemicals, was 2,200 emergency room visits from 1990-1994 for children under 5 years of age. Each case report was reviewed for inclusion as a possible petroleum distillate product. Product descriptions were reviewed and product types and brand names that were included in the case narrative were checked in the POISINDEX database. Case narratives that gave brand names were reviewed and eliminated when they were not petroleum distillate products. Narratives that did not give a specific brand name (and could not be specifically excluded) were included in the estimate as possible petroleum distillate incidents.
8. The unadjusted NEISS estimate for the product code 0931, Metal Polishes, Tarnish Removers or Preventatives was 900 emergency room visits from 1990-1994 for children under 5 years of age. Each case report was reviewed for inclusion as a possible petroleum distillate product. Product descriptions were reviewed and product types and brand names that were included in the case narrative were checked in the POISINDEX database. Case narratives that gave brand names were reviewed and eliminated when they were not petroleum distillate products. Narratives that did not give a specific brand name (and could not be specifically excluded) were included in the estimate as possible petroleum distillate incidents.
9. The unadjusted NEISS estimate for the product code 0913, Lubricants, was 5,200 emergency room visits from 1990-1994 for children under 5 years of age. Each case report was reviewed for inclusion as a possible petroleum distillate product. Product descriptions were reviewed and product types and brand names that were included in the case narrative were checked in the POISINDEX database. Case narratives that gave brand names were reviewed and eliminated when they were not petroleum distillate products. Narratives that did not give a specific brand name (and could not be specifically excluded) were included in the estimate as possible petroleum distillate incidents.
10. The unadjusted NEISS estimate for the product codes 0955 and 0978 combined, Automotive Waxes, Polishes, Cleaners or Chemicals, was 4,900 emergency room visits from 1990-1994 for children under 5 years of age. Each

case narrative was reviewed for inclusion as a possible petroleum distillate product. Product descriptions were reviewed and product types and brand names that were included in the case narrative were checked in the POISINDEX database. Cases that gave brand names were reviewed and eliminated when they were not petroleum distillate products. Cases that did not give a specific brand name (and could not be specifically excluded) were included in the estimate as possible petroleum distillate incidents.

11. A NEISS estimate was not computed for product code 932, shoe polishes. In the NEISS comments from 1990-1995, only 3 cases were received for children under 5, and it was unclear from the narratives whether or not the products contained petroleum distillates. In the one case where a telephone investigation was possible, the shoe polish did contain petroleum distillates.
12. A NEISS estimate was not computed for product code 937, Rust/Tarnish Removers. In the NEISS narratives from 1990-1995, the products described in the incidents to children under 5 appeared to contain acids rather than petroleum distillates. A telephone investigation was not completed for a case involving this product code (where the product formulation could have been verified).
13. These cases were categorized as : "no effect"-the patient developed no symptoms as a result of the exposure; "minor effect"- the patient exhibited some symptoms as a result of the exposure, but they were minimally bothersome to the patient, i.e., the symptoms usually resolved rapidly and usually involved skin or mucous membranes; "moderate effect"-the patient exhibited symptoms as a result of the exposure which was more pronounced, more prolonged or more of a systemic nature than minor symptoms; "major effect"-the symptoms were life threatening or resulted in significant residual disability or disfigurement.

TAB B

DRAFT
1/22/97

Billing Code 6355-01

CONSUMER PRODUCT SAFETY COMMISSION

**Household Products Containing Petroleum Distillates and
Other Hydrocarbons**

**Advance Notice of Proposed Rulemaking; Request for Comments
and Information**

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission ("CPSC" or "Commission") has reason to believe that child-resistant packaging may be needed to protect children from serious illness or injury from products that contain either petroleum distillates or other hydrocarbons or combinations of these ingredients. This advance notice of proposed rulemaking ("ANPR") initiates a rulemaking proceeding under the Poison Prevention Packaging Act ("PPPA"). Existing PPPA standards require child-resistant packaging for some products that contain petroleum distillates or other hydrocarbons. The Commission desires information on a variety of issues concerning products containing petroleum distillates or other hydrocarbons as it considers the

possibility of requiring child-resistant packaging for additional consumer products that contain these substances.

The Commission solicits written comments from interested persons concerning the risks of injury or illness associated with household products containing petroleum distillates and other hydrocarbons, the regulatory alternatives discussed in this notice, other possible means to address these risks, and the economic impacts of the various regulatory alternatives.

DATE: Written comments and submissions in response to this notice must be received by the Commission by [insert date that is 75 days after publication].

ADDRESS: Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207-0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504-0800. Comments should be captioned "ANPR for Petroleum Distillates."

FOR FURTHER INFORMATION CONTACT: Suzanne Barone, Directorate for Epidemiology and Health Sciences, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0477, ext. 1196.

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

1. *Introduction.* Petroleum distillates are a group of hydrocarbon-based chemicals that are refined from crude oil. Petroleum distillates include gasoline, naphtha, mineral spirits, kerosene, paraffin wax, and tar. They are the primary ingredient in many consumer products, including certain furniture polishes, paint solvents, adhesives, and automotive chemicals. As explained below, the presence of such petroleum distillates in products may contribute to the products' toxicity.

A number of consumer products contain hydrocarbons that are not petroleum distillates, but that can cause similar toxic effects. These other hydrocarbons include substances such as benzene, toluene, xylene, pine oil, turpentine, and limonene.

The toxicity of petroleum distillates and other hydrocarbons affects the respiratory system. Aspiration of small amounts of these chemicals directly into the lung, or into the lung during vomiting of an ingested chemical, can cause chemical pneumonia, pulmonary damage, and death. Petroleum distillates with low viscosity, such as gasoline, kerosene, and mineral seal oil, possess the greatest potential for aspiration.¹

¹ Liquids with high viscosity are thick and more like syrup, while liquids with low viscosities are thin and more watery. See Table 1.

As explained below, all household products that contain 10 percent or more of petroleum distillates, or of benzene, toluene, xylene, or turpentine, are required to have hazard warnings by regulations under the Federal Hazardous Substances Act ("FHSA"). Some other products that contain hydrocarbons may be required to be labeled by more general FHSA requirements. Some, but not all, of these products are also required to be in child-resistant packaging under PPPA regulations.

The purpose of this notice is to commence a rulemaking proceeding to examine whether additional products containing petroleum distillates or other hydrocarbons should be in child-resistant packaging.

II. THE POSSIBLE NEED FOR ADDITIONAL REGULATION

1. *Poisoning information.* The Commission evaluated pediatric poisoning cases associated with product classes that are known to include products that contain hydrocarbons, and that are not currently required to be in child-resistant packaging. Such product areas include adhesives, automotive chemicals, workshop chemicals, metal polishes, spot removers, cleaning fluids, shoe polishes, and lubricants. The CPSC staff reviewed data from various sources, including the National Electronic Injury Surveillance System ("NEISS"), and the American Association of Poison Control Centers' ("AAPCC") Toxic Exposure Surveillance System ("TESS").

According to NEISS, between 1990 and 1994 there was an annual estimated average of about 2,300 emergency room visits of children under 5 years of age associated with exposure to product categories that are not required to be in child-resistant packaging and that include products containing petroleum distillates. About 5 percent of these cases resulted in hospitalization.

Between October 1994 and May 1996, a CPSC contractor conducted telephone investigations on incidents reported through NEISS that were treated in hospital emergency rooms and involved children under 5 years of age who had been exposed to products in the categories described above. The telephone investigations produced 43 cases for analysis. Of these, 18 involved petroleum distillates and 25 involved products containing the hydrocarbon pine oil. Most of the incidents occurred in the child's home. About 50 percent of the victims accessed the product from its normal storage area rather than from another location. Seventy-nine percent of the incidents involved products in the original packaging. Most of these containers were reported to be non-child-resistant.

In 1994, the Poison Control Centers ("PCC's) reported 5,791 exposures of children under 5 years of age that were attributed to product categories that included only products that contain petroleum distillates or other hydrocarbons. Of these, 1130 cases reported symptoms, most of which were

minor (exhibited some symptoms that were minimally bothersome to the patient, i.e. the symptoms usually resolved rapidly and usually involved skin or mucous membranes). Ninety-three of these cases reported moderate outcomes (exhibited symptoms that were more pronounced, more prolonged, or of more of a systemic nature than minor symptoms). In addition, 7 cases reported major symptoms (life-threatening or resulted in significant residual disability or disfigurement). A number of other PCC product categories may also include products that contain petroleum distillates or other hydrocarbons.

The Commission is aware of 10 reported deaths since 1973 of children under 5 following exposure to products that contained petroleum distillates and for which child-resistant packaging is not currently required. Six of these reports indicated that the deaths were caused by chemical pneumonitis or aspiration.

The death and injury data discussed above suggest that the safety of young children could be improved if additional products that contain petroleum distillates and other hydrocarbons are required to be packaged in child-resistant packaging.

2. Existing regulatory requirements.

a. Applicable requirements under the Federal Hazardous Substances Act ("FHSA"). The CPSC regulates the labeling of hazardous household products under the FHSA, 15 U.S.C. 1261-

1278. Currently, FHSA regulations require specified aspiration hazard labeling for products containing 10 percent or more by weight of benzene, toluene, xylene, or petroleum distillates such as kerosene, mineral seal oil, naphtha, gasoline, mineral spirits, Stoddard solvent, and "related" distillates. 16 CFR 1500.14(a)(3), (b)(3). The label must bear the signal word "DANGER," the statement of hazard "Harmful or fatal if swallowed," and the statement "Call physician immediately." 16 CFR 1500.14(b)(3). A similar labeling requirement applies to products containing 10 percent or more of turpentine because of the aspiration hazard. See 16 CFR 1500.14(b)(5).

In addition, section 2(p)(1) of the FHSA requires any household product that is "toxic" to bear specified hazard labeling. 15 U.S.C. 1261(p)(1). Any product that presents an aspiration risk from hydrocarbons is required to bear the labeling specified by section 2(p)(1), regardless of whether a regulation specifically applies to that product.

b. *Applicable requirements under the Poison Prevention Packaging Act ("PPPA").* The CPSC also regulates the packaging of many household products containing petroleum distillates or other hydrocarbons under the PPPA, 15 U.S.C. 1471-1476. PPPA regulations require that products be sold in child-resistant packaging.

Currently, some consumer products containing 10 percent or more by weight of petroleum distillates, and with a

viscosity less than 100 Saybolt Universal Seconds ("SUS") at 100°F, are subject to the PPPA's child-resistant packaging standards.² The particular types of petroleum distillate products that require child-resistant packaging under the PPPA include (1) prepackaged liquid kindling and illuminating preparations (e.g., lighter fluid) (16 CFR 1700.14(a)(7)), (2) prepackaged solvents for paint or other similar surface-coating materials (e.g., varnishes) (16 CFR 1700.14(a)(15)), and (3) nonemulsion liquid furniture polish (16 CFR 1700.14(a)(2)). Child-resistant packaging is also required for certain solvents containing 10 percent or more of benzene, toluene, or benzene, and with a viscosity less than 100 SUS at 100°F. 16 CFR 1700.14(a)(15). In addition, products containing 10 percent or more of turpentine are required to be in child-resistant packaging. 16 CFR 1700.14(a)(6).

c. Varying scope of the FHSA and PPPA regulations.

While FHSA labeling regulations apply generically to products that contain 10 percent or more petroleum distillates or other hydrocarbons, only certain specified products are required to be in child-resistant packaging under the current PPPA regulations. Therefore, a number of household products containing petroleum distillates or other hydrocarbons are not required to be in child-resistant

² Saybolt Universal Seconds is a measure of viscosity. The higher the SUS, the more viscous the liquid.

packaging. For example, cleaning solvents, automotive chemicals, shoe care products, and floor care products may contain large amounts of various petroleum distillates. These products are not required to be sold in child-resistant packaging, but some of them are required to be labeled under the FHSA. See 16 CFR 1500.14(a)(3), (b)(3).

In addition, there are some anomalies under the current PPPA regulations concerning which products are required to be in child-resistant packaging. For example, the existing standards require child-resistant packaging of prepackaged kerosene for use as lamp fuel. 16 CFR 1700.14(a)(7). However, a gun cleaning solvent that contains over 90 percent kerosene does not have this requirement. Mineral spirits used as a paint solvent require child-resistant packaging, 16 CFR 1700.14(a)(15), but such packaging is not required for spot removers containing 75 percent mineral spirits or water repellents containing 95 percent mineral spirits. Yet, all of these consumer products are required by the FHSA to be labeled "Harmful or fatal if swallowed." 16 CFR 1500.14(b)(3).

A rule to require child-resistant packaging of all household products that contain petroleum distillates and have specified characteristics would create a more consistent regulatory approach and afford greater protection against poisonings.

III. ISSUES TO BE CONSIDERED DURING THE RULEMAKING

During this rulemaking, the Commission will consider the following major issues.

1. *Viscosity and percentage composition.* As noted above, the PPPA's child-resistant packaging standards currently apply to certain specified consumer products containing 10 percent or more by weight of petroleum distillates, and with a viscosity less than 100 SUS at 100°F. Products associated with chemical pneumonia and death have had viscosities below this level. Again, liquids with low viscosities are more likely to be aspirated than more syrup-like liquids with high viscosities.

The Commission's staff collected a limited number of household products that contain petroleum distillates and measured their viscosities. The results are listed in Table 1.

Table 1: The Viscosities of Products Containing Petroleum Distillates

Product	PPPA Regulated (Yes or No)	Viscosity (SUS @100°F) ³
Motor oil (10W-30)	N	≈325
Heavy Mineral Oil	N	180
Baby Oil	N	≈70
Furniture Polish	Y	≈40
Gasoline Treatment	N	≈35
Carburetor Cleaner	N	<32 ⁴
Degreaser	N	<32 ⁴
Lighter Fluid	Y	<32 ⁴

The staff's initial laboratory analysis, summarized in Table 1, shows that lighter weight oils, including some baby oils, would be included in a regulation that required child-

³ The staff measured the viscosity at 100°F using a Brookfield viscometer calibrated in centistokes (cs). The value was converted to SUS using Table 1 of ASTM D 2161-93, Standard Practice for Conversion of Kinematic Viscosity to Saybolt Universal Viscosity or to Saybolt Furol Viscosity.

⁴ There are no equivalent viscosities measured in SUS for viscosities less than 1.8 cs. The viscosity of 1.83 cs is equivalent to 32 SUS.

resistant packaging of all products containing at least 10 percent petroleum distillates with a viscosity less than 100 SUS at 100°F. There are reported cases of lipoid pneumonia and deaths from aspiration of lubricants, including baby oil, a spray lubricant, chain saw oil, and trumpet valve oil.⁵

The Commission will consider whether a viscosity criterion should be included in any regulation requiring child-resistant packaging for products containing petroleum distillates or other hydrocarbons. If such a criterion is to be included, the Commission will also consider at what level it should be set.

2. *Other hydrocarbons.* The CPSC's FHSA regulations for petroleum distillates require labeling of some products containing other hydrocarbons, including products that contain 10 percent or more by weight of benzene, toluene, or xylene. 16 CFR 1500.14(a)(3), (b)(3). FHSA labeling is required because these substances have an aspiration hazard similar to petroleum distillates.

A number of household products contain low-viscosity hydrocarbons other than petroleum distillates. These hydrocarbons include benzene, toluene, xylene, and terpenes. For example, terpene hydrocarbons derived from wood or fruit are in products such as turpentine, pine oil, and limonene.

⁵ Reyes De La Rocha, S. et al. Lipoid pneumonia secondary to baby oil aspiration: a case report and review of the literature. *Pediatric Emergency Care*, 1:74, 1985.

Pine oil and limonene are found in cleaning products and spot removers, as well as disinfectants. (Products marketed as disinfectants are not regulated by the CPSC; they are regulated as pesticides by the Environmental Protection Agency ("EPA").) Although pine oil and limonene cleaning products and spot removers require FHSA labeling, they are not currently required to be in child-resistant packaging.

The Commission will consider whether there is a need for a special packaging standard applicable to products containing hydrocarbons other than petroleum distillates.

3. *Aerosols.* The PPPA regulation for furniture polish excludes products in aerosol form. The rationale for excluding aerosol furniture polishes was that aerosols would be addressed separately. 36 FR 18012 (September 8, 1971). However, there has been no further regulatory action on aerosol furniture polishes.

The child-resistant packaging requirements for paint solvents and kindling and illuminating preparations do not specifically exempt aerosol products. See 16 CFR 1700.14(a)(7), (a)(15). However, the Commission is not aware of any paint solvent or liquid kindling or illuminating fluid sold in an aerosol form.

CPSC exposure data on aerosol products are limited.⁶

⁶ Nierenberg, D.W., et al. Mineral Spirits Inhalation Associated with Hemolysis, Pulmonary Edema, and Ventricular Fibrillation. *Arch Intern Med*, 151:14337, 1991. Rodriguez de la Vega, A. et al. Kerosene-induced Asthma. *Annals of Allergy*, 64:362, 1990. Glynn, K.P. and Gale, N., Exogenous Lipoid

Inhalation of a spray lubricant has been associated with lipoid pneumonia.⁷ The NEISS case investigation study, described above, identified 4 percent of the cases as involving products in aerosol form. However, none of the people in these aerosol cases was hospitalized.

The cases described in the medical literature that resulted from the inhalation of petroleum distillates from aerosols or vapors involved prolonged or repeated exposure of adults. However, children are subject to greater inhalation risks than are adults, for equal exposure levels.⁸

The Commission will consider whether aerosol products should be included within any regulation applicable to products containing petroleum distillates and other hydrocarbons.

4. *Restricted flow.* The PPPA regulation for liquid furniture polish includes an additional requirement that no more than 2 milliliters of product shall be obtained when the container is shaken, squeezed, or activated once. 16 CFR 1700.14(a)(2). This requirement was included, in part, because an open container of polish may be moved and used

Pneumonia due to Inhalation of Spray Lubricant, *Chest*, 97:1265, 1990.

⁷ *Id.* (Glynn, 1990).

⁸ Schiller-Scotland, C.F, et al. Experimental data for total disposition in the respiratory tract of children. *Toxicol. Lett.*, 72: 137, 1994.

multiple times throughout the house before the container is closed. 37 FR 5613 (March 17, 1972). Furniture polish is the only PPPA-regulated substance with a restricted-flow requirement.

The Commission will consider whether other products should be subject to a restricted flow requirement.

IV. RULEMAKING PROCEDURE

In order to issue a regulation under the PPPA, the Commission would have to find that "the degree or nature of the hazard to children in the availability of [petroleum distillates and other hydrocarbons], by reason of [their] packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance." 15 U.S.C. 1472(a)(1). The Commission would also have to find that child-resistant packaging "is technically feasible, practicable, and appropriate" for products containing petroleum distillates or other hydrocarbons. 15 U.S.C. 1472(a)(2).

According to the PPPA's legislative history, "technically feasible" means that technology exists to produce packaging that conforms to the standards.⁹

"Practicable" means that special packaging complying with the standards can utilize modern mass production and

⁹ S. Rep. 845, 91st Cong., 2d Sess. 10 (1970).

assembly line techniques.¹⁰ "Appropriate" means that packaging complying with the standards will adequately protect the integrity of the substance and not interfere with its intended storage or use.¹¹

In addition to the required findings, the Commission is required to consider, but not necessarily make formal findings on, (a) the reasonableness of the standard, (b) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances, (c) the manufacturing practices of industries affected by the PPPA, and (d) the nature and use of the household substance. 15 U.S.C. 1472(b).

A rulemaking proceeding under the PPPA is subject to the requirements of the Administrative Procedure Act. Therefore, the proceeding can be commenced by publication of a notice of proposed rulemaking ("NPR"), without having previously published an ANPR. However, in this proceeding, the Commission is publishing an ANPR in order to obtain additional information before deciding whether to propose a special packaging standard for products that contain petroleum distillates or other hydrocarbons.

¹⁰ *Id.*

¹¹ *Id.*

V. COMMENTS REQUESTED CONCERNING THE SCOPE OF A RULE

The Commission is seeking information on issues relevant to defining the scope of any child-resistant packaging requirement for products containing low-viscosity petroleum distillates and other hydrocarbons. These issues include the following:

1. What, if any, viscosity and/or percentage composition should be used as a threshold for requiring products that contain petroleum distillates to be in child-resistant packaging?

2. Should aerosol products be included in a requirement for the child-resistant packaging of products containing petroleum distillates or other hydrocarbons? The Commission seeks information on the possible effects to a young child of a single acute exposure to an aerosol product containing petroleum distillates.

3. Should PPPA regulation extend only to petroleum distillates or should such regulation also extend to other hydrocarbons, such as benzene, toluene, xylene, turpentine, pine oil, and limonene?

4. Should restricted flow be an additional requirement for certain products?

VI. ADDITIONAL REQUESTS FOR INFORMATION

The Commission believes that information on the following issues would also be helpful as it considers whether child-resistant packaging should be required for the

entire class of consumer products that present an aspiration hazard because they contain petroleum distillates or other hydrocarbons.

1. *Chemical properties.* Information concerning the chemical properties of individual consumer products that contain petroleum distillates or other hydrocarbons will be used to compare products that do not currently require child-resistant packaging with those that do. The Commission requests information about the form (e.g., liquid or aerosol), formulation (including the amount of each component), and viscosity of each product.

2. *Users and use patterns.* The Commission would like information about consumer use patterns for various types of products containing petroleum distillates or other hydrocarbons. The Commission requests information concerning: the intended use of the product (e.g., as a shoe waterproofer, carpet cleaner, upholstery spot remover); the location(s) where it is used (e.g., in a garage, a kitchen, a bathroom); the frequency of use (e.g., daily, monthly, seasonally); how long a package of the product is retained in the home (e.g., used just once or stored for long periods between uses); and the location(s) where it is stored when not in use. In addition, is the product used by consumers (more than occasionally) or is the product only used in the home by workers, such as repair or cleaning persons?

3. *Current packaging and labeling.* Information about the packaging of products that contain petroleum distillates will be used to assess the technical feasibility, practicability, and appropriateness of child-resistant packaging. The Commission requests information describing current packaging, such as packaging sizes, container material, closure material, closure design, and ASTM classification if the package is child-resistant. Information is also requested about whether the product has labels with warnings and instructions for use.

4. *Economic information.* Economic information will be used to evaluate the impact of requiring child-resistant packaging for all products containing petroleum distillates or other hydrocarbons. The Commission requests information about sales of these products and about the range of wholesale and retail prices. Further, the Commission seeks comments on the expected cost of providing child-resistant packaging for these products. In addition, the Commission requests information about the potential impact that such child-resistant packaging requirements would have on businesses, especially small businesses.

5. *Incident information.* Although the Commission monitors data on ingestions by young children of products that contain petroleum distillates and other hydrocarbons, the Commission seeks additional information about such poisoning incidents. This information will be used to assess

the extent of injury from different product formulations. The Commission requests information concerning the details of scenarios resulting in poisoning incidents, and the outcome of the incident.

Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207-0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland 20814; telephone (301) 504-0800. All comments and submissions should be received no later than [insert date that is 75 days after publication].

VII. TRADE SECRET OR PROPRIETARY INFORMATION

Any person responding to this notice who believes that any information submitted is trade secret or proprietary should identify all such information at the time of submission. The Commission's staff will receive and handle such information confidentially and in accordance with section 6(a) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. 2055(a). Such information will not be placed in a public file and will not be made available to the public simply upon request. If the Commission receives a request for disclosure of the information or concludes that its disclosure is necessary to discharge the Commission's responsibilities, the Commission will inform the person who submitted the information and provide that person an

opportunity to present additional information and views concerning the confidential nature of the information. 16 CFR 1015.18(b).

The Commission's staff will then make a determination of whether the information is trade secret or proprietary information that cannot be released. That determination will be made in accordance with applicable provisions of the CPSA; the Freedom of Information Act ("FOIA"), 5 U.S.C. 552b; 18 U.S.C 1905; the Commission's procedural regulations at 16 CFR Part 1015 governing protection and disclosure of information under provisions of FOIA; and relevant judicial interpretations. If any part of information that has been submitted with a claim that the information is a trade secret or proprietary is found to be disclosable, the person submitting the material will be notified in writing and given at least 10 calendar days from the receipt of the letter to seek judicial relief. 15 U.S.C. 2055(a)(5) and (6); 16 CFR 1015.19(b).

Dated: _____, 1997.

Sadye E. Dunn, Secretary
Consumer Product Safety Commission