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*Acting Manager, Transport Airplane
Directorate, Aircraft Certification Service.*

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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

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.

DATES: Written comments and submissions in response to this notice must be received by the Commission by May 12, 1997.

ADDRESSES: Comments should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 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

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.²

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

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

² The Commission voted 2-1 to approve publication of this ANPR. Voting to approve were Chairman Ann Brown and Commissioner Thomas Moore. Commissioner Mary Sheila Gall voted to develop a Request for Information for publication in the Federal Register and to utilize other available information sources instead of an ANPR. Commissioner Gall also issued a statement concerning this vote. The statement is available from the Office of the Secretary.

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.³ 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-

³ Saybolt Universal Seconds is a measure of viscosity. The higher the SUS, the more viscous the liquid.

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 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) ⁴
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 ⁵
Degreaser	N	<32 ⁴
Lighter Fluid	Y	<32 ⁴

⁴ 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.

⁵ 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.

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-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.⁶

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. 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.⁷ Inhalation of a spray lubricant has been associated with lipoid pneumonia.⁸ 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.⁹

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 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.¹⁰ "Practicable" means that special packaging complying with the standards can utilize modern mass production and assembly line techniques.¹¹ "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.¹²

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.

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

⁶Reyes 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.

⁷Nierenberg, 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 Pneumonia due to Inhalation of Spray Lubricant, *Chest*, 97:1265, 1990.

⁸Id. (Glynn, 1990).

⁹Schiller-Scotland, C.F., et al. Experimental data for total disposition in the respiratory tract of children. *Toxicol. Lett.*, 72: 137, 1994.

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

¹¹Id.

¹²Id.

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, DC 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 May 12, 1997.

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: February 21, 1997.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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BILLING CODE 6355-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N-0038]

RIN 0910-AA01

Sunscreen Drug Products for Over-the-Counter Human Use; Amendment to the Tentative Final Monograph; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice of proposed rulemaking that appeared in the Federal Register of September 16, 1996 (61 FR 48645). The document proposed to amend the tentative final monograph (proposed rule) for over-the-counter (OTC) sunscreen drug products. The document was published with an error. This document corrects that error.