



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Vote Sheet

Date: AUG 10 1999

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Jeffrey S. Bromme, General Counsel
Stephen Lemberg, Asst. General Counsel
Harleigh Ewell, Attorney, GCRA (ext. 2217)

SUBJECT : Options on a Draft Proposed Rule to Require Child-Resistant Packaging for Low-Viscosity Hydrocarbons

Attached is a staff briefing package discussing options concerning whether the Commission should issue a proposed rule to require child-resistant packaging for low-viscosity liquid hydrocarbons. A draft proposed rule is included at Tab G of the package, for the Commission's consideration.

Please indicate your vote on the following options.

I. APPROVE THE DRAFT FEDERAL REGISTER NOTICE AT TAB G WITHOUT CHANGE.

(Signature)

(Date)

II. APPROVE THE DRAFT FEDERAL REGISTER NOTICE AT TAB G WITH CHANGES (please specify).

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(Date)

III. DO NOT APPROVE THE DRAFT FEDERAL REGISTER NOTICE.

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Comments/Instructions:

BRIEFING PACKAGE

**PROPOSED RULE TO REQUIRE SPECIAL PACKAGING FOR
HYDROCARBONS OF LOW VISCOSITY**



For Information Contact
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Executive Summary

On February 26, 1997, the CPSC issued an Advance Notice of Proposed Rulemaking (ANPR) to request comments about whether to require child-resistant packaging of consumer products that contain petroleum distillates and other hydrocarbons. Thirty individuals and groups commented. Most of the comments focused on the scope of such a rule.

The CPSC staff has refined the scope of a potential rule based on information submitted by the commenters. The staff recommends that the rule require child-resistant packaging of prepackaged nonemulsion-type liquid household chemical products, including foods, drugs, and cosmetics that contain 10 percent or more hydrocarbons by weight with a viscosity of less than 100 SUS at 100°F. Hydrocarbons are defined as compounds that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

For some products that contain hydrocarbons at the concentration and viscosity recommended for child-resistant packaging, the risk of aspiration does not exist because of the way the product is packaged. The staff recommends excluding these types of products. These include aerosol products (i.e. pressurized spray containers) that expel the product in a mist, markers, ballpoint pens, battery terminal cleaners, and make-up removal pads that are not free-flowing.

The toxicity of hydrocarbons is well defined, and ingestions and aspirations by young children of products in classes that contain these chemicals are documented.

The staff believes that the data support the technical findings that child-resistant packing is technically feasible, practicable, and appropriate for hydrocarbon-containing products. There are many different packaging options available to manufacturers. The staff recommends an effective date of one year to allow sufficient time to convert to child-resistant packaging.

If the Commission votes to propose the rule, the staff will send the Federal Register notice to identified small businesses in the cosmetic and household chemical product business.



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

Date: AUG 10 1999

TO : The Commission
 Sayde E. Dunn, Secretary

THROUGH: Jeffrey Bromme, General Counsel *JB*
 Pamela Gilbert, Executive Director *PG*

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

SUBJECT : Child-Resistant Packaging of Consumer Products that Contain
 Hydrocarbons of Low Viscosity

This memorandum presents the staff recommendation to propose rulemaking to require child-resistant packaging of consumer products that contain hydrocarbons of low viscosity. A copy of a draft Notice of Proposed Rulemaking (NPR) prepared by the Office of the General Counsel is at Tab G.

BACKGROUND

The Poison Prevention Packaging Act (PPPA) was established to protect children from serious personal injury or illness resulting from handling, using, or ingesting hazardous household substances by requiring child-resistant packaging of these substances. As a chemical class, petroleum distillates and other similar hydrocarbon solvents are currently not required to be in child-resistant packaging. These chemicals are the primary ingredients in many different consumer products. Direct aspiration into the lung, or aspiration during vomiting, of small amounts of these solvents can result in chemical pneumonia, pulmonary damage, and death. The viscosity of the hydrocarbon-containing product determines the potential toxicity. Viscosity is the measurement of the ability of liquid to flow. Liquids with high viscosity are thick or "syrupy" and liquids with low viscosity may be more "watery". Products with low viscosity pose a greater risk of aspiration into the lungs.

The U.S. Consumer Product Safety Commission (CPSC) regulates the labeling of hazardous household substances containing 10 percent or more by weight petroleum distillates under the Federal Hazardous Substances Act (FHSA) regulations (16 CFR § 1500.14). The CPSC also requires child-resistant packaging of some household products containing petroleum distillates under the PPPA regulations (16 CFR § 1700.14). Under the current PPPA regulations,

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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., paint thinners)(16 CFR §1700.14(a)(15)), and nonemulsion liquid furniture polish (16 CFR §1700.14(a)(2)).

In addition to protecting children from serious injury from ingesting hydrocarbon-containing products, the goal of the current rulemaking is to create a more consistent and comprehensive regulatory approach to child-resistant packaging for these products. Because hydrocarbons, as a chemical class are not now regulated under the PPPA, many hydrocarbon-based consumer products are not required to be in child-resistant packaging. For example, cleaning solvents, automotive chemicals, shoe-care products, and cosmetics may contain large amounts of various hydrocarbons and are not required to be in child-resistant packaging. 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.

On February 26, 1997, the CPSC issued an Advance Notice of Proposed Rulemaking (ANPR) to request comments and information about whether to require child-resistant packaging of consumer products that contain petroleum distillates and other hydrocarbons. In the ANPR, the Commission solicited information on four specific issues: 1) the appropriate viscosity and/or percentage composition to be used as a threshold for requiring products that contain petroleum distillates to be in child-resistant packaging, 2) the inclusion of aerosol products in a requirement for the child-resistant packaging of products containing petroleum distillates or other hydrocarbons, 3) the scope of a rule to extend beyond petroleum distillates to include other hydrocarbons, such as benzene, toluene, xylene, pine oil, and limonene, and 4) the inclusion of restricted flow as an additional requirement for certain products.

The Commission also solicited information on products that may be affected by such a rule, including chemical properties, users and use patterns, current packaging and labeling, economic information, and incident reports. The Commission extended the comment period until September 1, 1997 at the request of the Chemical Specialty Manufacturers Association (CSMA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA).

The ANPR was sent to 221 trade associations and businesses believed to be involved with petroleum distillate-containing products. Thirty individuals and

¹ Saybolt Universal Seconds is a unit of viscosity.

groups submitted comments (Tab A). Four commenters (CP97-2-3, 11,12,18) supported the rule. Most of the other comments focused on which products should be subject to such a rule.

The scope of a potential rule, the comments on the ANPR, the staff's responses to the comments, and the staff's recommendation are discussed below.

RECOMMENDED SCOPE OF THE REGULATION

The CPSC staff reviewed the comments submitted in response to the ANPR. The staff's recommendation is to proceed with a PPPA rule for products that contain chemicals capable of causing chemical pneumonia and death following aspiration. The ANPR was open-ended regarding the potential scope of such a rule. The CPSC staff has refined the scope based on information submitted by the commenters. This section of this memorandum briefly outlines the staff's recommendations for the scope of the rule. The rationale for and discussion of this recommendation follows in subsequent sections.

The staff recommends that the rule require child-resistant packaging of prepackaged nonemulsion-type liquid household chemical products, including foods, drugs, and cosmetics that contain 10 percent or more hydrocarbons by weight with a viscosity of less than 100 SUS at 100°F. Hydrocarbons are defined as compounds that consist solely of carbon and hydrogen. For products that contain multiple hydrocarbons, the total percentage of hydrocarbon in the product is calculated by adding the percentage by weight of the individual hydrocarbon components.

The staff recommends that there be two separate rules, one for FHSA-regulated products and the other for Food Drug and Cosmetic Act (FDCA) - regulated products. The enforcement of the PPPA with respect to hazardous substances relies on the misbranding and prohibited acts sections of the FHSA. The enforcement of child-resistant packaging requirements applicable to foods, drugs, or cosmetics relies on comparable provisions of the FDCA.

On November 19, 1998, the staff met with interested trade associations to discuss the scope of the potential rule described above. The emphasis of the meeting was to obtain information on various products or packaging types that should be included or excluded from the rule (Meeting log, December 3, 1998). Several trade associations submitted comments in response to the meeting. The staff evaluated these comments. The following exclusions are recommended by the staff.

The staff recommends excluding products that contain hydrocarbons at the concentration and viscosity recommended for child-resistant packaging but do not present the risk of aspiration because of the way the product is packaged. For example, aerosol products (i.e. pressurized spray containers) that expel the

product in a mist do not pose the risk of aspiration. Aerosols that are expelled in a stream, however, would require child-resistant packaging under the staff's recommendation.

The staff also recommends exempting products packaged in mechanical pumps and trigger sprayers that expel product in a mist, provided that the spray mechanism is either permanently attached to the bottle or has a child-resistant attachment. This makes the misted trigger sprayer package equivalent to the aerosol can. However, if the mechanical pump or trigger sprayer expels product in a stream (either solely or as an option), the entire package must be child-resistant including the pump mechanism.

The FHSA regulations exempt from full labeling small packages, minor hazards, and special circumstances (16 CFR 1500.83(a)). Writing markers and ballpoint pens are exempted from full cautionary labeling requirements relating to toxicity if they meet certain specifications listed in the regulations. The staff is recommending that these products that are specifically exempted also be exempted from any proposed child-resistant packaging requirements. In addition, the staff also recommends that cosmetics and other household substances containing 10 percent or more hydrocarbon by weight with a viscosity under 100 SUS, such as battery terminal cleaners, paint markers, and make-up removal pads that do not have product free flowing from the packaging, be exempt from any proposed child-resistant packaging requirements.

The following section will describe some of the products that would require child-resistant packaging if the above described recommendations were adopted.

PRODUCTS THAT MAY BE INCLUDED

The staff recommendation for a child-resistant packaging standard includes all products, unless exempted, that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F. This impacts many different classes of products that currently do not require child-resistant packaging. However, not all of the products in each category would require child-resistant packaging under a proposed rule due to differences in formulations.

The staff identified several different automotive products that would require child-resistant packaging under a proposed rule, including carburetor cleaners, fuel injection cleaners, and some gasoline additives. These products are usually intended for single use, and some are currently in child-resistant packaging. Automotive lubricants, including motor oil and spray lubricants, for the most part will not be included in a proposed rule. Most, if not all motor oils have a high viscosity and the staff is not recommending including aerosols in a proposed rule.

Other household chemicals that may require packaging include spot removers and water-repellants. Several of the spot removers identified by the staff were in child-resistant packaging. However, the water repellants, especially those made for shoe care, are not currently in child-resistant packaging. Cleaning products, including some floor and metal cleaners would also be impacted by a proposed rule. Some miscellaneous sports-related products including gun cleaners and archery arrow feather water repellents were identified as containing hydrocarbons but were not in child-resistant packaging.

Most writing instruments, including all markers and pens would be exempt from a proposed rule because they do not have free flowing hydrocarbons from the packaging.

The current PPPA regulations require child-resistant packaging of solvents for paint and other surface coatings, but it does not require child-resistant packaging of the paint and varnishes themselves. Most paints would not be included in a proposed rule because of their formulation and viscosity. However, some sealers, non-water-based varnishes and stains may require child-resistant packaging. Since the staff is not recommending including aerosols, spray paints are not included in the draft proposed rule.

There are several categories of cosmetics that would be included in a proposed rule. Tab B (Table 1) lists cosmetics in several categories that were analyzed by the CPSC staff. In general, creams and lotions are excluded from the rule because they are either too viscous or are emulsions. Most baby oils, excluding lotions and gels, would be included in a proposed rule. The inclusion of other cosmetic products is dependent on their viscosity. Some bath and suntan oils would require child-resistant packaging under a proposed rule while others would not because of their composition and viscosity. Make-up removers and nail/cuticle conditioners may or may not require child-resistant packaging depending on hydrocarbon content, viscosity, and product form. Wipes and saturated pads would be exempted from any proposed requirements.

These are the major product groups that have been identified by the staff. There may be other individual products that would require child-resistant packaging that have not been identified either by the staff or the comments on the ANPR.

The following section addresses the comments on the ANPR and provides the rationale for the staff recommendations regarding the scope of this rule.

RESPONSE TO COMMENTS

Scope of a Potential Rule

Detailed responses to all of the comments received that relate to the scope of the rule are at Tab B. This section excerpts these responses to specifically address the four questions that appeared in the ANPR. These include regulation of aerosols, viscosity, the inclusion of non-petroleum-derived hydrocarbons, and restricted flow. This section also provides the rationale for the staff's recommendation for the scope of the potential rule described above.

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

Response: There is insufficient evidence to demonstrate the aspiration hazard from self-pressurized aerosols spray mists that contain petroleum distillates. The commenters cited the results of animal studies conducted in the 1960s. The staff is not aware of new animal or human experience data that would change the conclusions that misted aerosols sprayed into the mouth do not pool in the mouth to result in aspiration (Gerarde, 1963).

The intent of this rule is to protect children from obtaining a volume of hydrocarbons in the mouth that could then be aspirated. The staff recommends that hydrocarbon-containing products in pressurized containers, that are expelled as a mist, be exempt from any proposed child-resistant packaging requirements.

Special labeling related to toxicity has been mandated under the FHSA for products that may be aspirated into the lungs resulting in chemical pneumonitis and death. Special labeling under 16 CFR §1500.14(b)(3) of FHSA related to the ingestion of hydrocarbon-containing aerosols is required only when the contents are expelled as a stream. The industry requested that all hydrocarbon-containing aerosols be exempted from the child-resistant packaging requirements. However, a large volume delivered directly into the mouth could result in aspiration. Therefore, the staff recommends that self-pressurized hydrocarbon-containing products that can be dispensed in a coherent stream be subject to child-resistant packaging requirements. It is also recommended that aerosol products, that form a stream only by the addition of an extended tube inserted into the nozzle, be excluded from the packaging requirements if, without the extender, the product is expelled as a mist. The CPSC laboratory staff determined that these products can be expelled through the extender tube at a rate of 1-2 ml/sec (Cobb, March 8, 1999). However, it is unlikely that a two or three year old child would obtain a sufficient amount of fluid via this route to cause an aspiration hazard.

Viscosity Level: What is the appropriate viscosity for requiring child-resistant packaging of products that contain hydrocarbons?

Response: Following a review of the submitted data and comments pertaining to viscosity, the staff recommends that the viscosity level where child-resistant packaging is not needed to protect children remain at or above 100 SUS at 100°F. This is the same viscosity below which the FHSA regulations require precautionary labeling for ingestion of petroleum distillate-containing products and the PPPA regulations require child-resistant packaging of three product categories (furniture polish, paint solvents and kindling and illuminating products).

Commenters and the medical literature agree that lower viscosities are associated with a greater risk of aspiration; however, there is no agreement about defining the "safe" upper level viscosity. One published review article suggests that products with viscosities of 60 to 100 SUS or greater have low aspiration potential (Litovitz and Greene, 1988). Another recent review article recommends that products with viscosities of less than 73.4 SUS require labels warning about the hazard of aspiration (Craan, 1996). A draft of a revision to the Canadian Consumer Chemicals and Containers Regulations (CCCR) adopts the level of 73.4 SUS for child-resistant packaging and cautionary labeling requirements. The current Canadian labeling and packaging requirements (CPSC97-2-23) use 70 SUS as the upper level.

The staff had concerns about this level because aspirations and resulting serious injury or death from pneumonitis and lipid pneumonia have been documented with mineral oil-based products such as baby oil (Reyes De La Rocha et al, 1985, Perrot et al, 1992, IDI 97030HCC9033). These products have viscosities in the 60-75 SUS range.

Another comment asserted that the appropriate upper level based on the animal studies by Gerarde in the 1960s was 81 SUS (Klein, July 16, 1998, Gerarde, 1963). The CPSC staff had concerns about defining the upper limit at or close to the viscosity associated with aspiration of products that resulted in deaths and serious injuries. Therefore, the staff recommends that products with viscosity levels less than 100 SUS at 100°F be packaged in child-resistant packaging. This would expand the current child-resistant packaging requirements from those limited to furniture polish, kindling and illuminating fluids, and paint solvents to include other product categories with similar ingredients that are capable of causing aspiration, pneumonitis, and death.

Other Hydrocarbons: Should a child-resistant packaging requirement include products that contain other hydrocarbons than petroleum distillates?

Response: Comments for and against including other than petroleum distillates were received. Some commenters wanted to limit the rule to petroleum distillates. Other commenters suggested that compounds with the same risk of aspiration should be regulated regardless of their source. The staff recommendation falls between these two suggestions. The staff recommends that the rule include products with solvents containing only hydrogen and carbon, commonly known as

"hydrocarbons". The term petroleum distillate is archaic and refers to mixtures of hydrocarbons that are distilled from petroleum. There has been confusion about the term "petroleum distillates" especially regarding the aromatic hydrocarbons, benzene, xylene, and toluene. The aromatics are components of some of the distillation fractions. However, the aromatics are not universally considered to be "petroleum distillates" because their toxicity profiles differ from the aliphatic chemicals. The Canadian standards currently do not include the aromatic hydrocarbons in their definition of petroleum distillates for cautionary labeling and child-resistant packaging (CP97-2-23).

The staff recommends eliminating the term petroleum distillate and defining the scope as those chemicals that contain hydrogen and carbon because it will minimize confusion by making it clear that the aromatic hydrocarbons are intended to be included in a child-resistant packaging requirement. However, this does not change the specific labeling requirements for the aromatic hydrocarbons. The Canadians have taken a similar approach. A draft of a revision to the Canadian standard eliminates the term petroleum distillate and lists chemical structures and classes to clarify what is included in the regulations.

Using the term hydrocarbon expands the coverage of the potential rulemaking beyond petroleum-derived chemicals. It also eliminates one commenter's concern about confusion over whether the chemical term "limonene" includes several different compounds. The recommended rule does not name individual compounds. Whether a product would require child-resistant packaging would depend on the total amount of hydrocarbon (by weight) and the product's viscosity.

The draft standard in Canada extends the labeling and packaging of aspiration hazards to include certain alcohols and ketones. The CPSC staff, however, does not recommend expanding the current PPPA rulemaking to include nonhydrocarbon chemicals such as terpene alcohols, ketones, or alcohols due to the diverse chemistry, toxicity and use of these chemicals. The CPSC staff recommends that these nonhydrocarbon chemical classes be evaluated separately for the need for child-resistant packaging.

Restricted Flow: Should restricted flow be an additional requirement for certain products?

Response: Restricted flow is defined in 16 CFR §1700.15(d) as "... the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is shaken or squeezed once or when the container is otherwise activated once." Restricted flow is required in addition to child-resistant packaging for liquid furniture polish because many of the ingestions occurred while the product was in use. Restricted flow alone is not adequate to protect children. It does not prevent the child from directly accessing the product if the package is not child-resistant. While restricted flow limits the amount of product a child can access each time the child attempts to ingest the

product from the container, it does not limit the number of attempts the child may make.

None of the commenters identified a product class as needing restricted flow in addition to child-resistant packaging. Several commenters mentioned that restricted flow would impede the use of products where greater volumes are necessary for use. Again, no specific products were identified.

A commenter requested that restricted flow be an alternative to child-resistant packaging for cosmetic products such as baby oil and body and bath oil. The commenter stated that older adults might have difficulty opening the child-resistant packaging with wet hands from the bath or shower. The commenter stated that many of these products already had restricted flow.

The CPSC staff examined some cosmetic products with restricted orifices. None of these products met the PPPA regulatory definition of restricted flow. The PPPA test procedures use adults aged 50 to 70 to determine adult-use-effectiveness for most packaging. This has led to the development of packaging systems that are easier for all adults to use properly (including resealing the cap). If companies have marketing concerns about consumer acceptance of bath or shower oils with child-resistant packaging, it may be appropriate to test packaging using adults with wet hands.

The staff has not identified any specific product or product category where restricted flow would add additional protection to children. The staff does not recommend requiring restricted flow for additional product categories. The requirement for restricted flow of liquid furniture polish will remain.

Injury Data Comments

Comment: Several commenters (CP97-2-6, 15,19-21) stated that the number of incidents and deaths were low and that child-resistant packaging was not justified.

Response: The CPSC staff does not recommend child-resistant packaging regulations based solely on the number of incidents. Before issuing a regulation under the PPPA, the Commission must find that "the degree or nature of the hazard to children in the availability of hydrocarbons, 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 primary goal of this and every child-resistant packaging rulemaking is to protect children from serious injury. An additional goal of the current rulemaking is to create a more consistent and comprehensive regulatory approach to child-resistant packaging for hydrocarbon-containing products. Because hydrocarbons are not now regulated under the PPPA as a chemical class, many hydrocarbon-

based consumer products are not required to be in child-resistant packaging. For example, cleaning solvents, automotive chemicals, shoe care products, and cosmetics may contain large amounts of various hydrocarbons but are not required to be packaged in child-resistant packaging. These chemicals have well-established toxicity. Household products that contain hydrocarbons are required under the FHSa to bear the cautionary label, "Harmful or Fatal if Swallowed," because of their potential toxicity while cosmetics with similar ingredients are known to be capable of causing serious injury.

In the ANPR, the staff presented ingestion data from various sources including the CPSC's National Electronic Injury Surveillance System (NEISS) and the Toxic Exposure Surveillance System (TESS) maintained by the American Association of Poison Control Centers (AAPCC). The staff collected additional information on the NEISS cases where possible. The data collection was limited to product categories that may contain petroleum distillates and do not currently require child-resistant packaging. The staff concluded that children access the types of products that may contain hydrocarbons. The potential for aspiration and serious injury from these chemicals is well documented. Each time a child gains access to a product without child-resistant packaging, there is the potential for ingestion, aspiration, pneumonitis, and death. The staff is recommending child-resistant packaging to protect children from accessing these products.

Packaging Comments

Comment: One commenter (CP97-2-20 and 20a) stated that there are no child-resistant/senior-friendly overcaps for aerosols. The commenter requested that the rule be clarified to say that aerosols are exempt from the senior-friendly requirements.

Response: The regulations of the PPPA contain an exemption from the senior requirements for products that must be in aerosol form and products that require metal containers with reclosable metal closures (16 CFR §1700.15(b)(2)(ii)(A)). It is unnecessary to repeat this exemption specifically in a rule for hydrocarbon-containing products. However, the staff is aware of several child-resistant overcap designs that meet the senior-friendly requirements (refer to Tab E). The staff will consider revisiting this issue in the future, but it is outside the scope of this rulemaking.

Comment: Several commenters (CP97-2-20a and 7) requested that single use products with heat seals be exempted from the requirements.

Response: Any regulated product that is intended to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening. The manufacturer may use any packaging option that meets the PPPA requirements. The CPSC staff has no data from testing packages with thermal foil seals. Manufacturers relying on heat-induction

seals may want to test the package with children and seniors to verify that the package meets the PPPA standards.

Miscellaneous Comments

Education Campaign

Comment: The CSMA and of its several members (CP97-2-20, 15) requested that CPSC work with them and others on an education campaign to encourage consumers to read product labels and follow the directions and cautions. They request this since several of the incidents occurred while the product was not in its original container and, therefore, child-resistant packaging would not have prevented the incidents.

Response: Education does not replace the need for child-resistant packaging. Child-resistant packaging prevents ingestions and saves lives directly by creating a barrier between the child and the substance. The staff agrees that education has value when used to communicate a safety message. Consumers need to be reminded to use child-resistant packaging properly. The CPSC currently partners with CSMA and other agencies and organizations to educate consumers about these issues during Poison Prevention Week. 1999 marks the 38th year of this collaborative effort. The staff recommends that the next Poison Prevention Week (Year 2000) include a message specifically about hydrocarbon-containing household chemicals and cosmetics.

Parental Responsibility

Comment: One commenter (CP97-2-4) indicated that the issue was one of parental responsibility and regulation was unnecessary.

Response: The issue of parental responsibility and child poisoning is not new. The Congressional Committee on Commerce dealt with this issue while drafting the Poison Prevention Packaging Act of 1970. The Committee report states, "...parental negligence is not the primary cause of poisonings. There are too many potentially hazardous products in the modern home to hope that all of them can be kept out of the reach of children." Child-resistant packaging creates a barrier between the child and the hazardous product when adult vigilance is insufficient. The staff recommends that the Commission propose rulemaking so that children are protected from ingesting products with the same potential aspiration hazard as other products that currently require child-resistant packaging.

Labeling

Comment: Comments (CP97-2-6, 25) were received that the labeling required under the FHSA was adequate to protect against the hazard and child-resistant packaging was unnecessary.

Response: Labels make important information available to the consumer; however, poisoning data demonstrate the inadequacy of labeling alone as an injury prevention strategy. The PPPA itself recognizes that FHSA labeling is not adequate to protect children by giving the Commission the ability to require child-resistant packaging for products that are toxic by ingestion and have to bear precautionary labeling including "Keep out of the reach of children". Human experience shows that it is unrealistic to expect labels to provide the same degree of protection as child-resistant packaging.

Garage Storage

Comment: A comment (CP97-2-1) was received that automotive products should not be included because they are stored in the garage and children do not have access to them.

Response: The PPPA applies to products distributed for sale, consumption, use, or storage in or around the household, which includes a garage. The NEISS and TESS data included in the ANPR demonstrate that children are gaining access to automotive products. These products should be in child-resistant packaging if they contain hydrocarbons and can be aspirated. Several companies voluntarily package their hydrocarbon-containing automotive products in child-resistant packaging.

Graffiti and Huffing

Comment: One commenter (CP97-2-25) stated that child-resistant packaging of aerosol paints would not prevent vandalism or inhalant abuse (huffing).

Response: The staff agrees with the commenter. The purpose of this rulemaking is to prevent children under five years of age from ingesting, handling, or using products that result in serious injury. To the extent that graffiti and huffing are done by older children, this recommended rule would have little, if any, effect on these behaviors.

Increased Risk of Injury to Children

Comment: The CTFA (CP97-2-28) commented that requiring child-resistant packaging on baby oil could result in an increase in falls from changing tables or in drowning incidents in bath tubs because parents would have to use two hands to open the package.

Response: According to the CTFA, about 70 percent of baby oil is used on adults and not babies. The comment assumes that adults who use baby oil on children are using one hand to open and squirt out the products before rubbing it on the baby. The comment also makes the assumption that two hands are required to open all child-resistant packaging. There are child-resistant designs that can be opened with one hand. In addition, containers for other baby products, including tubes or jars, often require two hands to open or use. The labeling on baby powder, for example, instructs parents to sprinkle the powder into their hands and then rub it on the baby. The staff finds it highly unlikely that baby oil in child-resistant packaging would increase the number of falls and drowning incidents.

INJURY DATA

In the ANPR, the staff reviewed child ingestions of household product categories that may contain petroleum distillates. The following section will update the ingestion data from household chemical products. The injury data reviewed in the ANPR did not include cosmetic products. This fact was commented on by the CTFA. Ingestions of cosmetics product categories including nail products, sunscreen and suntan preparations, bath oil and creams, lotions, and make-up were reviewed and the results are outline below. A separate discussion of baby oil ingestion data is also provided. More details are provided in memoranda at Tabs C and D.

Household Chemicals

The CPSC maintains the National Electronic Injury Surveillance System (NEISS) database of product related injuries that are treated in hospital emergency rooms. The NEISS data are derived from a statistical sample of hospital emergency rooms in the United States. However, many ingestion exposures are handled by Poison Control Centers and are not treated in emergency rooms. The American Association of Poison Control Centers maintains the Toxic Exposure Surveillance System (TESS) which includes calls to poison control centers. This database is not a statistical sample and the numbers of incidents cannot be used to make national estimates. The number of exposures reported in TESS represents a large percentage of the total calls to poison centers in a given year. However, the total annual number of ingestion incidents is assumed to be greater than the actual number of cases reported in TESS.

The NEISS data were examined for ingestions by children under 5 year of age for the years 1995 through 1997. The product categories examined include workshop chemicals, adhesives, lubricants, metal polishes, automotive chemicals, paints, varnishes, and shellacs, spot removers and automotive waxes, polishes, and cleaners. There were an estimated $6,800 \pm 1800$ pediatric ingestions of these products, seen in emergency rooms during the three-year period.

In addition, the CPSC purchases TESS data for children under 5 years of age from the AAPCC each year. The data purchased include reported exposure calls. Informational calls are not purchased. The data do not include trade names. They are coded for broad product categories in a single code. The CPSC staff examined unintentional ingestion incidents from categories that contain products that may require child-resistant packaging under the regulation. These include, carpet, upholstery, leather, or vinyl cleaner, automotive hydrocarbons, hydrocarbon spot removers, lubricants, other hydrocarbons, unknown hydrocarbons, other or unknown rust removers, floor wax, polish, or sealer, toluene or xylene adhesive, toluene or xylene, stains, and varnish and lacquers.

There were a total of 44,781 ingestions of these products recorded in TESS for the years 1995-1997 (12,592, 16,433, and 15,756, respectively). Of these ingestions, 612 cases were coded as aspirations. According to TESS guidelines, aspiration cases are automatically coded as ingestions in the TESS system. Of the aspiration cases, 122 resulted in "moderate" medical outcomes² and 4 in "major" outcomes³. No deaths from these product categories were reported during this time period. A number of children had specific respiratory effects that were the direct result of the aspiration of the product. These include 31 cases of pneumonitis, 5 cases of respiratory depression, and 1 case of pulmonary edema.

It should be noted that not all products in these categories contain hydrocarbons. In addition, not all hydrocarbon-containing products have a viscosity of less than 100 SUS at 100°F. For example, many of the adhesives and lubricants may have viscosities higher than 100 SUS. However, the data demonstrate that children do access household chemical products. If these products contain hydrocarbons and have viscosities less than 100 SUS at 100°F, children are at risk of aspiration and pneumonia. These data also demonstrate that aspiration of these product types does occur.

Cosmetic Products

NEISS does not have specific codes for cosmetic products; therefore, NEISS data is not included in the review of cosmetics ingestions. TESS data for the years 1995-1997 was examined for four general cosmetic categories known to have products that contain hydrocarbons. These include miscellaneous nail products, sunscreen and suntan preparations, bubble bath and bath oil, and creams, lotions, and make-up.

² Moderate effects – The patient developed signs or symptoms as a result of the exposure that were more pronounced or systemic in nature than minor symptoms. Usually some form of treatment is required.

³ Major effects- The patient exhibited signs and symptoms that were life-threatening or resulted in residual disability or disfigurement.

There were a total of 74,042 ingestions of these products recorded in TESS for the years 1995-1997 (21,850, 25,514, and 26,678, respectively). Of these ingestions, 114 cases were coded as aspirations. Of the aspiration cases, 5 resulted in "moderate" medical outcomes, 2 in "major" outcomes and one in a death from baby oil. A number of children had specific respiratory effects that were the direct result of the aspiration of the product. These include 2 cases of pneumonitis, 2 cases of respiratory depression, and 1 case of respiratory arrest.

As stated previously, not all of the products in the categories contain hydrocarbons. For example, bath oil may contain hydrocarbons, but bubble bath is usually an aqueous detergent solution that would not be covered by the recommended rule. In addition, not all of the hydrocarbon-containing products in each category would require child-resistant packaging because they have viscosities of 100 SUS or more at 100°F. Creams and lotions that are emulsions would also not be included. For example, the staff collected a convenience sample of 5 different tanning products labeled as containing mineral oil. We measured the viscosities and percentages by weight of hydrocarbons in these products. Of the five tanning products collected, one was an emulsion (lotion), two were tanning oils with viscosities in the 240 SUS range, and two were tanning oils with viscosities in the 65 SUS range. Only the latter two products would require child-resistant packaging under the recommended rule. The staff cannot extrapolate the results of this analysis to identify the percentage of products in any category that may fall within the scope of the recommended rule. The example illustrates the range of viscosities of cosmetic products in the same category.

The TESS data are included to illustrate that children do access cosmetic products. If these products contain hydrocarbons and have viscosities less than 100 SUS at 100°F, children are at risk of aspiration and pneumonia. These data demonstrate that aspiration of these product types does occur.

Baby Oil

The staff was specifically interested in incidents involving baby oil. A review of the literature documented one case of serious injury following aspiration of baby oil (Reyes de la Rocha, et al, 1985). The CTFA comment documented a similar case that resulted in permanent impairment of a child. The limited details supplied by the CTFA did not directly correlate with the published case. The two cases may be the same. However, there was a death of a child following ingestion of baby oil documented by the AAPCC (Litovitz et al, 1997). The CPSC staff investigated the circumstances of the death (IDI 97030HCC9033); however, limited information was obtained. The child died 23 days after the ingestion. There was speculation that between 10 and 14 ounces of baby oil may have been ingested, although it was reported that the child was covered with baby oil. According to the AAPCC report a part of the cap was found in the child's stomach. The CTFA questioned the circumstances of this death. However, the reported

decrease in oxygen saturation and lung infiltration are consistent with aspiration pneumonitis.

The CPSC staff specifically purchased data on exposures to baby oil by children under 5 years of age that had been compiled by the AAPCC for the years 1996 and 1997. A discussion of these data is found at Tab D. Over 2,500 incidents were reported during the two-year period. Most of these cases involved ingestion. Most of the cases were managed at home. Several children exhibited symptoms and were admitted to the hospital. The CTFA also purchased this data and provided comment. Their analysis concludes that the data demonstrates the safety of baby oil.

The staff is concerned about products such as baby oil that use light weight mineral oil and have viscosities in the 60-75 SUS range. The authors of one report of a case involving baby oil conclude that, "baby oil aspiration can be one of the causes of acute respiratory distress in children" (Reyes de la Rocha, 1985). They advocate that the latent danger of baby oil needs to be publicized since it appears that baby oil is not recognized as a cause of diffuse pneumonia and respiratory distress. This was demonstrated in a recent case documented in NEISS. An infant was accidentally given baby oil. According to the mother, she was told by the poison control center and the pediatrician that the child would have diarrhea. However, three days later the child was admitted to the hospital with pneumonia. (981026HEP9021). While child-resistant packaging would not have prevented this unintentional ingestion, the case illustrates the potential dangers of the light weight mineral oil-based products with viscosities under 100 SUS.

TECHNICAL FEASIBILITY, PRACTICABILITY, AND APPROPRIATENESS

The PPPA standards for child-resistance and adult-use-effectiveness are defined in 16 CFR § 1700.15 and are based on the results of human performance tests described in 16 CFR § 1700.20. When tested according to the methods, 80 percent of tested children (41-52 months old) (based on 200 children) must not be able to access the package. In addition, most packages must be accessible to 90% of tested adults aged 50-70. The exceptions to this are products that require metal containers with metal closures or aerosols. These products must be accessible to 90% of adults tested aged 18 to 45 (16 CFR § 1700.15(b)(2)(ii)). When this memorandum refers to child-resistance it implies that the package meets the senior standard unless otherwise specified.

Before issuing a regulation under the PPPA, the Commission must find that child-resistant packaging is technically feasible, practicable, and appropriate for hydrocarbon-containing products. Technical feasibility may be found when technology exists or can be readily developed to produce packaging that conforms to the standards described above. Practicability means that packaging complying with the standards can utilize modern mass production and assembly line techniques. Packaging is appropriate when complying packaging will adequately

protect the integrity of the substance and not interfere with its intended storage or use.

The CPSC staff assessed the packaging of a range of products that may be included in the rule recommended by the staff. The staff believes that child-resistant packaging is technically feasible, practicable, and appropriate for hydrocarbon-containing products. There are currently three product categories that require child-resistant packaging if the products contain petroleum-derived hydrocarbons (16 CFR §§ 1700.14(a)(2), (7), and (15)). Child-resistant packaging that meets the standards is available and compatible with these hydrocarbon-containing products. Many of the products that would be included in the recommended rule are similar in composition and use. This section will summarize technical information to support the findings for the variety of packaging types commonly used for hydrocarbon-containing products. A detailed discussion of the technical findings for child-resistant packaging of hydrocarbon-containing products is in Tab E.

Continuous Threaded Packaging

Most packages that contain liquid products are currently sold with non-child-resistant continuous threaded (CT)(screw on) closures. These closures can be made of plastic or metal. This type of closure has been successfully modified to be child-resistant. There are several different types of child-resistant CT designs. The most common is the ASTM type IA closures. These are two piece child-resistant closures that open by "pushing and turning." These types of closures are already being used on hydrocarbon-containing products such as liquid furniture polish and mineral spirits. These and other types of CT closures are available from many different manufacturers. Stock closures are available and come in a variety of sizes, skirt lengths, and liner options. Plastic-on-metal closures are also available for products with solvents that may be incompatible with plastics.

Closures are also available that can accept brush applicators. Smaller sizes of these closures may have to be developed to accommodate the small bottles used for nail dryers and nail moisturizers. These packages are very similar to those used for methacrylic acid-containing nail primers, for which the Commission recently required child-resistant packaging for these products (64 FR 32799).

In most cases, the development of new closures or sizes will be unnecessary. However, modifications to the bottle neck finish and/or to the existing sorting and capping equipment may be necessary to change from non-child-resistant to child-resistant CT packaging.

Dispensing Packaging (Inserts and Flip-Tops)

The staff examined a convenience sample of cosmetic products that would be included in the recommended rule. Many baby oil, suntan oil, and bath oil products are currently packaged with dispensing capability. Several different packaging designs are being used, including restricted orifice plug inserts, flip-top dispensers, and finger pump dispensers.

The plug inserts and the flip caps both function by decreasing the orifice of the opening of the bottle. The plug insert fits flush with the opening of the bottle and does not interfere with the function of the closure. A child-resistant CT closure can replace the existing non-child-resistant closure as described above. The staff is not aware of any commercially available child-resistant flip-top closures for liquids. However, plug inserts with child-resistant closures can be substituted and serve the same function. Plug inserts are compatible with mineral oil-based cosmetics because several of the cosmetic products currently use plug inserts.

Manufacturers may have to change bottle neck finishes or buy plug insert equipment if they are not currently using the inserts.

Pump Dispensers

Some suntan oils are available with finger pumps. The Commission has recently addressed the child-resistance of finger pumps during the minoxidil rulemaking. In a comment in that rulemaking, a manufacturer said that it could make a child-resistant finger pump. The finger sprayer for minoxidil has to be metered to deliver a specific dose. This is not the case for hydrocarbon-containing products; therefore, the development of a finger sprayer for these products should be less complicated.

Companies using finger pumps have other options. Other products in this category use plug inserts as described above. In addition, there are several child-resistant overcaps being developed specifically for pump sprayers.

Some of these alternatives are more complex than others and would require more time and money to complete.

Aerosols and Trigger Sprayers

Any product meeting the recommended requirements that is in aerosol or trigger sprayer packaging, and is expelled as a stream must be child-resistant. Child-resistant aerosol overcaps are available on the market. There are several designs that are also senior friendly. Since the overcaps do not come in contact with the products, compatibility is not an issue.

For products that currently use a trigger sprayer, the staff is aware of a child-resistant trigger sprayer on the market and several other designs under development. The Commission addressed the issue of child-resistant trigger sprayers during the fluoride rulemaking (63 FR 29949).

Metal Container Closures

There are several designs, including snap caps and CTs that are child-resistant and can be used with metal cans. These types of closures are currently being used on lighter fluids and some paint solvents. They are commercially available and compatible with hydrocarbons.

The CPSC staff concludes that the available data support the finding that it is technically feasible, practicable, and appropriate to produce special packaging for products that contain 10 percent hydrocarbons or more by weight with a viscosity less than 100 SUS at 100°F.

EFFECTIVE DATE

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such final regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it finds that it is in the public interest to do so.

This recommended rulemaking covers diverse groups of products with diverse packaging. As outlined in Tab E, some of the packaging changes may be minimal while others may be more extensive. For example, even though there are child-resistant packages readily available, changes from tool design to product filling line equipment may be required to replace some of the non-child-resistant packaging with the various types of child-resistant packaging. In addition, there are multiple options available to manufacturers. Cost and consumer preference may play a role in determining which child-resistant feature is best suited to a product. Not all products in the same product category may take the same time to change to child-resistant packaging. However, the staff estimates that all of these packaging changes could be achieved during a one year timeframe.

Therefore, the staff recommends an effective date of one year for this rulemaking.

ECONOMIC CONSIDERATIONS

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.

A discussion of the economic considerations of requiring child-resistant packaging on household chemical products and cosmetics is at Tab F. This section summarizes information about the potential impact on small businesses for both household chemical products and cosmetics and the likely costs of packaging.

The ANPR was sent to 9 trade associations that represent over 1300 small and large companies. In addition, the ANPR was sent to over 200 individual companies identified by either CPSC or Environmental Protection Agency staff as manufacturing hydrocarbon-containing products. Thirty comments were received. These provided very little specific information about individual companies or the economic impact of converting from non-child-resistant to child-resistant packaging. The CTFA conducted a survey of over 200 members. They received responses from 20 companies and presented this information in their comment. The responders were not identified by size.

The lack of specific information submitted by commenters may be due, in part, to the fact that the ANPR did not define the scope of products to be included. General questions about appropriate viscosity and chemical content made it difficult to identify which products may be impacted, according to several commenters. Now that the staff has recommended a more defined scope, the draft proposed rule specifically solicits information about the economic impact of the rule, especially from small businesses.

As discussed previously, not every product in a given category will require packaging under the recommended scope of the rule. For example, of the suntan products, only oils would be impacted. However, not all suntan oils have a viscosity under 100 SUS. We are not able to identify the number of products or the percentage of the market for the different product categories that will be included in the rule. Additionally, some products in a category may already be using child-resistant packaging voluntarily. The staff identified some automotive products and spot removers in child-resistant packaging and identified others that are not.

Based on our previous experience with child-resistant packaging and current packaging pricing, incremental costs for child-resistant packaging typically range from \$0.005 to \$0.020 per package.

There are multiple packaging options for companies. The route a company chooses may be determined by consumer preference and cost. Makers of cosmetic products expressed concern about custom design packaging for cosmetic products. The choice to use readily available child-resistant packaging versus developing custom packaging will be up to the companies. The CTFA stated in its comment that several companies will drop products with low sales volume if child-resistant packaging is required. However, the size of the companies and dollar impact was not given.

Child-resistant packaging is widely available and that the incremental costs are small relative to the cost of most household chemicals and cosmetic products. Few firms, if any, are expected to have a significant economic burden. The effective date includes enough lead time for companies to use up existing package inventory. Therefore, the staff preliminarily concludes that there is little evidence that the proposal will have a significant economic effect on a substantial number of small entities.

As stated above, the staff recommends that the proposed rule solicit economic information, especially from small businesses.—We have expanded our mailing list to include additional small cosmetic companies.

ENVIRONMENTAL CONSIDERATIONS

A special packaging requirement will have no significant effects on the environment since the manufacture, use, and disposal of child-resistant packaging will present the same environmental effects as nonchild-resistant packaging.

OPTIONS

The following options are available to the Commission:

1. The Commission may propose a rule requiring special packaging for products containing 10 percent hydrocarbon or more by weight and having a viscosity of less than 100 SUS at 100°F if the Commission preliminarily finds that:
 - i.) special packaging is required to protect young children from serious personal injury or illness from handling, using or ingesting the product; and
 - ii.) special packaging is technically feasible, practicable, and appropriate.
2. The Commission may decide not to propose a special packaging rule for hydrocarbons if it does not preliminarily make these findings.

RECOMMENDATION AND DISCUSSION

The staff recommends that the Commission issue a notice of proposed rulemaking to require child-resistant packaging of products containing 10 percent or more hydrocarbons by weight and having a viscosity less than 100 SUS at 100°F.

The comments and information submitted in response to the ANPR helped to refine the scope of the rule. No information was received that would change the

staff's belief that rulemaking to require child-resistant packaging of hydrocarbon-containing products is needed. The toxicity of hydrocarbons is well defined and exposure is documented. A rulemaking based on the percentage of total hydrocarbons will expand the scope to include non-petroleum-derived hydrocarbons. This will protect children from hazardous chemicals that may otherwise be excluded from PPPA rulemaking.

The staff recommends that the rule maintain the viscosity of products and percentage composition of hydrocarbons at the levels defined in the FHSA. While comments suggested lower viscosity levels for regulation, there was no compelling data submitted that warranted lowering the upper limit of safety from aspiration for these products.

Hydrocarbon-containing products with a viscosity level of less than 100 SUS at 100°F include household chemicals and cosmetics. The cosmetic trade association argued that all cosmetics should be exempted. The rationale given was that cosmetics were included incidentally in an attempt by CPSC staff to regulate hydrocarbon-containing household chemicals. While the staff recommends that household chemicals and cosmetics be regulated separately due to enforcement differences, the staff recommends that this rulemaking include cosmetics.

The cosmetic trade association argues that the aspiration hazard does not exist for cosmetic products. However, some companies warn about the possibility of serious injury on their labels, using the following: "For external use only. Keep out of children's reach to avoid drinking and accidental inhalation, which can cause serious injury. Should breathing problems occur, consult a doctor immediately." This warning is not specifically mandated by the FDA. The FDCA (21 CFR 740.1(a)) requires that, "the label of a cosmetic product bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."

The TESS database documents aspirations from cosmetic products. In addition, the reported cases of a serious injury and a death from baby oil, regardless of the circumstances and whether child-resistant packaging would have prevented them, reinforce and support the potential hazard of these products. The viscosities of these products fall in the range where aspiration may be a hazard. The poisoning data indicate that children are accessing household chemicals and cosmetics that contain hydrocarbons. The potential for serious injury exists.

There are some products that would fall within the scope of the recommended rule that do not have potential for serious injury because of their existing packaging. Fine mist aerosols, impregnated pads, pen- or marker-like applicators may contain hydrocarbons meeting the scope of this rule, but the contents are not accessible in an amount to be a hazard to children. The staff recommends exempting these from the rule. In addition, we recommend soliciting

information about any other products or packaging that should be excluded but that have not been identified.

This rulemaking has the potential of affecting a wide variety of products with diverse types of packaging. In addition to bottles with CT closures, products have various dispensing features, finger pumps, applicator brushes, trigger sprayers, metal closures, and aerosol packaging. Child-resistant packaging options are technically feasible and in most cases readily available for each of these. The Commission has addressed many of these packaging issues previously in other PPPA rulemakings. For example, finger pumps for minoxidil, applicator brushes for methacrylic acid-containing nail primers, and trigger sprayers for fluoride-containing wheel cleaners.

Child-resistant packaging is already required for products with similar chemical compositions. The packages that are currently used for furniture polish, lighter fluids, and paint solvents can be adapted for products such as spot removers, automotive products, and shoe-care products. The cosmetic products can add child-resistance while maintaining their dispensing capability. The staff believes that the data support the technical findings that child-resistant packaging is technically feasible, practicable, and appropriate for hydrocarbon-containing products.

There are many different packaging options available to manufacturers. The staff recommends an effective date of one year to allow ample time to convert to child-resistant packaging and use the existing packaging stock. This will help to minimize the costs, especially for small businesses.

In general, the increased cost of child-resistant packaging is small compared to the average cost of the household chemicals and cosmetics. We do not believe that this rulemaking will have a significant effect on a substantial number of small businesses. We base this conclusion on our previous experience with child-resistant packaging costs and the lack of comments from small businesses indicating any adverse effects. However, the staff recommends that the proposal specifically solicit information on the economic impact, especially to small businesses. The staff will specifically send the Federal Register notice, if published, to all trade associations and to companies identified by the staff as manufacturers of products that may contain hydrocarbons.

TAB A



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

MEMORANDUM

DATE: September 2, 1997

TO : EHPS

Through: Sadye E. Dunn, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Advanced Notice of Proposed Rulemaking: Household Products Containing Petroleum Distillates and Other Hydrocarbons; 16 CFR Part 1700, 62 FR 8659, February 26, 1997

ATTACHED ARE COMMENTS ON THE CP97-2

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CP97-2-1	4/3/97	Roger E. Tucker Director-Quality & Technology	Coastal Unilube, Inc. P.O. Box 2048 West Memphis, AR 72303
CP97-2-2	4/7/97	Robert L. Rod PhD (Environmental Engineer- ing), PE	Rod Products Co., Inc. 4600 Glencoe Ave, No 4 Marina del Rey, CA 90292
CP97-2-3	4/17/97	Kelly Fitzsimmons	208 South 42nd St. Philadelphia, PA 19104
CP97-2-4	5/5/97	Stuart Feen President	Plastic Bottle Corp. 28055 N Ashley Circle Libertyville, IL 60048
CP97-2-5	5/6/97	Melissa DeDonald Regulatory Affairs Administrator	Perrigo Company 502 Eastern Ave. Allegan, MI 49010
CP97-2-6	5/9/97	L. E. Hill Vice President	Quaker State Corp. 225 E. John Carpenter Fwy Irving, TX 75062
CP97-2-7	5/9/97	Sarosh Manekshaw	Pennzoil Company Pennzoil Place P.O. Box 2967 Houston, TX 77252

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 Part 1700, 62 FR 8659, February 26, 1997

CP97-2-8	5/12/97	Robert Hemphill Principal RD&C Manager	Gas Research Institute 8600 West Bryn Mawr Ave. Chicago, IL 60631
CP97-2-9	5/12/97	Jeffrey Minnette Director Regulated Markets	Rexam Closures 3245 Kansas Road Evansville, IN 47711
CP97-2-10	5/19/97	confidential	San Antonio, TX 78230
CP97-2-11	6/4/97	Renee McLeod MSN, RN, CS, CPNP, President	National Association of Pediatric Nurse Associate & Practitioners, Inc. 1101 Kings Highway, North Suite 206 Cherry Hill, NJ 08034
CP97-2-12	7/1/97	On behalf of Florida Univeristy Students	Florida International University 16501 SW 102 Ave Miami, FL 33157
CP97-2-13	7/2/97	Joseph Mattingly Director of Government Affairs & General Counsel	Gas Appliance Manu- facturers Association 1901 North Moore St P.O. Box 9245 Arlington, VA 22209
CP97-2-14	7/2/97	Mark Horton Regulatory Affairs Manager	ChemRex Incorporated Corporate Headquarters 889 Valley Park Drive Shakopee, MN 55379
CP97-2-15	7/8/97	Brenda Nuite Regulatory Project Manager, Product Safety & Regulatory Affairs	The Dial Corporation Technical-Administrative Center 15101 N Scottsdale Rd. Scottsdale, AZ 85254
CP97-2-16	7/9/97	Janet Catanach Environmental Affairs Coordinator	Exxon Chemical Company P.O. Box 3272 Houston, TX 77253
CP97-2-17	7/10/97	Kipp Coddington on behalf of Tender Corporation	Covington & Burling 1201 Pennsylvania Ave, NW P.O. Box 7566 Washington, DC 20004
CP97-2-18	7/10/97	Bohdan Dmytrasz Manager	Texaco P.O. Box 509 Beacon, NY 12508

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Part 1700, 62 FR 8659, February 26, 1997

CP97-2-19	7/11/97	Kevin Uhl Research Scientist	Amway Corporation 7575 Fulton St, East Ada, MI 49355
CP97-2-20	7/11/97	Brigid Klein Regulatory Counsel	Chemical Specialties Manufacturers Association 1913 Eye St, NW Washington, DC 20006
CP97-2-20a	12/15/98	Brigid Klein	Address same as above
CP97-2-21	7/9/97	Dennis Groh Section Supervisor	Ford Customer Service Division Fairlane Business Park #4 17225 Federal Drive Suite 140 Allen Park, MI 48101
CP97-2-22	7/10/97	Aludia Hernandez Technical and Regulatory Compliance Manager	Chase Products Company The Quality First Company 19th St & Gardner Rd Broadview, IL 60153
CP97-2-23	7/11/97 ltr dated 6/25/97	Paul Chowhan Project Officer Chemical Hazards Section	Product Safety Bureau Statistics Canada Main Building, Wing 1000 Tunney's Pasture Locator: 0301B2 Ottawa(Ontario) L1A0K9 CANADA
CP97-2-24	7/8/97	Harvey Kornhaber Sr. Vice President Research and Development	Turtle Wax, Inc. 5655 West 73rd Street Chicago, IL 60638
CP97-2-25	7/11/97	Heidi McAuliffe Counsel, Government Affairs	National Paint & Coatings Association 1500 Rhode Island Ave, NW Washington, DC 20005
CP97-2-26	7/22/97	Darla Williamson	Closure Manufacturers Association 1627 K Street, NW Suite 800 Washington, DC 20006
CP97-2-27	8/29/97	Deborah Fanning Executive Vice President	The Art & Creative Materials Institute, Inc. 100 Boylston Street Suite 1050 Boston, MA 02116

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Part 1700, 62 FR 8659, February 26, 1997

CP97-2-27a	9/30/97	Deborah Fanning Executive Vice President	The Art & Creative Materials Institute, Inc. (address same as above)
CP97-2-28	9/01/97	Catherine Beckley Assistant General Counsel	The Cosmetic, Toiletry, and Fragrance Association 1101 17th St., N.W. Suite 300 Washington, DC 20036-4702
CP97-2-28a	12/15/98	Catherine Beckley	Address same as above
CP97-2-28b	1/12/99	Catherine Beckley	Address same as above
CP97-2-29	9/02/97	Justin Powell on behalf of the Florida Chemical Company	Keller and Heckman Law Offices 1001 G Street, N.W. Suite 500 West Washington, DC 20001
CP97-2-30	12/15/98	David Baker Attorney for Writing Instrument Manufacturers Association, Inc.	Thompson Hine & Flory LLP 1920 N Street, NW Washington, DC 20036

TAB B



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

MEMORANDUM

DATE: APR 28 1999

TO : Mary Ann Danello, Ph.D., Associate Executive Director
for Epidemiology and Health Sciences *mad*

Through : Lori E. Saltzman, Director, Division of Health Sciences
Directorate for Epidemiology and Health Sciences *LS*

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

SUBJECT : Response to Comments Related to the Scope of a
Child-Resistant Packaging Requirement for Products Containing
Petroleum Distillates or other Hydrocarbons.

This memorandum responds to comments received in response to the Advance Notice of Proposed Rulemaking (ANPR) for household products containing petroleum distillates or other hydrocarbons. Comments related to the scope of chemicals and products to be included in a rule are addressed.

PORTABLE GASOLINE STORAGE CONTAINERS

Comment: Two commenters (CP-97-2-8 and 13) requested that the scope of this rulemaking be expanded to include portable storage containers for gasoline or other volatile petroleum distillates. The commenters discussed and provided data on injuries to children and adults that resulted from the ignition of vapors following accessing gasoline storage cans near an ignition source.

Response: The intent of this rulemaking is to protect children from serious injury from handling, using, or ingesting petroleum distillates or other hydrocarbons. However, the request to extend child-resistant packaging standards to portable storage containers is outside the scope of this rulemaking and the jurisdiction of the Poison Prevention Packaging Act (PPPA). The PPPA jurisdiction to require child-resistant packaging extends to household substances that are "hazardous substances" as defined by Federal Hazardous Substances Act (FHSA), or foods, drugs, and cosmetics as defined in the Federal Food, Drug, and Cosmetic Act (FDCA). The product discussed by the commenters is a container that is sold empty and is therefore not a "hazardous substance." However, the rule to require child-resistant packaging of hydrocarbon-containing products would apply to prepackaged containers of gasoline or kerosene not already covered under current PPPA regulations.

AEROSOL PRODUCTS

Comment: The CPSC requested information about whether or not to require child-resistant packaging of petroleum distillate-containing products in aerosol form. Several commenters (CP97-2-7, 15,18-22,25,28) responded that all aerosols should be eliminated from the scope of the rulemaking because there are no injuries or data to support that these products cause injury to children. One commenter (CP97-2-27) indicated that aerosols should be exempt, except those that form a stream.

Response: There is insufficient scientific and medical evidence to demonstrate the aspiration hazard from self-pressurized aerosols spray-mists that contain petroleum distillates. The commenters cited the results of animal studies conducted in the 1960s. No new animal or human experience data were identified that would change the conclusions that misted aerosols sprayed into the mouth do not pool in the mouth and result in aspiration (Gerarde, 1963).

The CPSC requires special labeling of petroleum distillate-containing aerosol products under 16 CFR 1500.14(b)(3)(ii) of FHSA (including the statement "Harmful or fatal if swallowed") only when the contents are expelled as a stream and not as a fine mist. A large volume delivered directly as a stream into the mouth could result in aspiration. The CPSC staff is not aware of any new data that demonstrate an aspiration hazard from petroleum distillate-containing aerosol products. The intent of this rule is to protect children from obtaining a volume of hydrocarbons in the mouth that could then be aspirated. The staff recommends that hydrocarbon-containing aerosol products that are expelled as a mist be exempted from child-resistant packaging requirements. Self-pressurized hydrocarbon-containing products that form a coherent stream rather than a fine mist would not be exempt from the packaging requirements since these products present the potential for aspiration. Aerosol products that form a stream by the addition of an extended tube inserted into the nozzle would be excluded from the packaging requirements if, without the extender, the product is expelled as a mist. CPSC laboratory staff determined that these products can be expelled through the extender tube at a rate of 1-2 mls/sec (Cobb, March 8, 1999). However, it is unlikely that a two or three year old child would access a sufficient amount of fluid to cause an aspiration hazard.

The staff recommends extending this exemption to mechanical pumps and trigger sprayers that expel product in a mist provided that the spray mechanism is either permanently attached to the bottle or has a child-resistant attachment. This makes the misted trigger sprayer package equivalent to the aerosol can. If the mechanical pump or trigger sprayer expels product in a stream (either solely or as an option), the spray mechanism must also be child-resistant.

VISCOSITY

Comment: Many commenters (CP97-2-7, 15,19,20,27) requested that the viscosity level be maintained at 100 SUS at 100 °F. A commenter (CP97-2-14) also requested that the rulemaking focus on products with viscosities that can be easily aspirated into the lung. Several other commenters suggested regulating at viscosities lower than 100 SUS at 100 °F. One commenter (CP97-2-28) stated that viscosities greater than 70 SUS do not pose a risk. Another commenter (CP97-2-16) stated that greater than 73.4 SUS should be the threshold viscosity based on a recent review (Craan, 1996).

Response: Following a review of the submitted data and comments pertaining to viscosity, the staff recommends that the appropriate viscosity level to protect children remain at a viscosity at or above 100 SUS at 100 °F. This is the same viscosity below which FHSA regulations require precautionary labeling for ingestion of petroleum distillate-containing products and the PPPA regulations require child-resistant packaging of three product categories (furniture polish, paint solvents, and illuminating products).

Commenters and medical literature agree that low viscosities are associated with a greater risk of aspiration however; there is no agreement about defining the “safe” upper level viscosity. One published review article suggests that viscosities of 60 to 100 SUS or greater have low aspiration potential (Litovitz and Greene, 1988). This suggestion was used in another recent article to recommend that products with viscosities of less than 73.4 SUS require labels warning about the hazard of aspiration (Craan, 1996). However, aspirations and resulting serious injury or deaths from pneumonitis and lipoid pneumonia have been documented with mineral oil-based products such as baby oil (Reyes De La Rocha et al, 1985, Perrot et al, 1992, IDI 97030HCC9033). These products have viscosities in the 60-75 SUS range. Another comment asserted that the appropriate upper level was 81 SUS, based on the animal studies by Gerarde in the 1960s (Klein, July 16, 1998, Gerarde, 1963). The CPSC staff had concerns about defining the upper limit at or close to the viscosity associated with aspiration of products that resulted in deaths and serious injuries. Therefore, the staff recommends that products with a viscosity level less than 100 SUS at 100 °F be packaged in child-resistant packaging.

Comment: One commenter (CP-97-2-2) indicated that it was unfounded to assume that any product containing over 10 percent petroleum distillates with a viscosity under 100 SUS is unsafe to children because food grade petroleum distillate solvents have viscosities in this range.

Response: The regulations under the FDCA allow for usage of several petroleum-derived chemicals such as white mineral oil, or odorless light petroleum hydrocarbons in food processing (21 CFR 172.878 and 172.884). In most cases, the amounts permitted are less than one percent of the final food product. For example, when white mineral oil is used in bakery products as a release agent, the amount is not to exceed

0.15 percent of bakery products (21 CFR 172.878). Trace amounts of petroleum chemicals in food products do not pose aspiration hazards. This does not mean that these chemicals are safe to children. Liquid products containing 10 percent or more by weight of these same chemicals with a viscosity less than 100 SUS at 100°F may pose an aspiration hazard if accidentally ingested by young children.

Comment: One commenter (CP97-2-28) requested that the viscosity and level for requiring child-resistant packaging vary depending on the type of hydrocarbon used in the product.

Response: The commenter provided no rationale for making a distinction between different hydrocarbons or identifying the different levels and viscosities for different hydrocarbons. The staff is recommending a level for regulation for products with 10 percent or more by weight of hydrocarbons with a viscosity of less than 100 SUS at 100°F. This level is used as the basis for warning against the aspiration risk under the FHSA for all petroleum-derived hydrocarbons. There is one distinction for benzene-containing products in the FHSA. Products that contain 5 percent or more by weight of benzene are required to bear a cautionary label stating, "Danger", "Vapors Harmful" and "Poison" as statements of hazard, and to bear a skull and crossbones because inhalation may result in blood dyscrasia which is unrelated to aspiration (16 CFR 1500.14(b)(3)(i)). The staff are not aware of any data to support the rationale for varying the child-resistant packaging requirements of products based on their hydrocarbon content and viscosity.

Comment: One commenter (CP97-2-2) stated that, "the degree of toxicity of any distillate end product is determined not by the viscosity but by the starting stock and its distillation temperature range..."

Response: The staff agrees that the toxicity of the petroleum distillates is determined by the concentration of aromatic hydrocarbons (benzene, toluene, and xylene) which can differ depending on the source of the crude oil and the distillation fraction. However, oral toxicity of petroleum distillates is an issue separate from the risk of aspiration, which is related to the viscosity and surface tension. The oral toxicity of many of the petroleum distillates is much lower than the risk of aspiration from these same hydrocarbons (Litovitz and Greene, 1988). One review documents the lethal ratio of oral doses to intratracheal doses as 140:1, suggesting that large amounts must be ingested to allow enough gastrointestinal absorption for toxicity (Victoria and Nangia, 1987). However, small amounts of the same petroleum distillate aspirated into the lung can result in death. The exceptions are the aromatic hydrocarbons (benzene, toluene, and xylene) that have greater systemic toxicity, including central nervous system involvement.

Comment: One commenter (CP97-2-1) requested that the name of the rulemaking be changed to reflect the fact that CPSC is only concerned with, "Household Products Containing Low Viscosity Petroleum Distillates and Other Hydrocarbons."

Response: The focus of this rulemaking is to protect children from the aspiration hazard associated with petroleum distillates and other hydrocarbons. Aspiration appears to occur with products that have viscosities under 100 SUS at 100°F. The term “low” is a relative term. The CPSC staff defines “low” to mean viscosities under 100 SUS at 100°F and recommends changing the name of the rulemaking to, “Household Products that Contain Hydrocarbons of Low Viscosity”.

Comment: One commenter (CP97-2-28) questioned the use of 100°F to measure viscosity since the products are used at room temperature, which is lower.

Response: Temperature plays a role in defining the viscosity of a substance and must be standardized to appropriately measure viscosity. While it is true that most products are used at room temperature, the potential aspiration of these chemicals occurs following ingestion. The temperature of 100°F gives a standard measure that approximates body temperature (98.6°F).

CATEGORY INCLUSIONS/EXCLUSIONS

Adhesives

Comment: One commenter (CP97-2-14), who manufactures adhesives, requested that adhesive products with high viscosities (over 100 SUS) be excluded.

Response: All of the products identified by the commenter have viscosities over 100 SUS, although, the temperature at which the measurements were taken was not specified. Any hydrocarbon-containing adhesive with a viscosity over 100 SUS at 100 °F would not require child-resistant packaging under this potential rule.

Cosmetics

Comment: Commenters (CP97-2-5, 28) indicated that cosmetics should be exempt because they use mineral oil and do not pose an aspiration hazard warranting child-resistant packaging.

Response: The staff is concerned about the risk of aspiration from hydrocarbon-containing products that have viscosities under 100 SUS at 100°F regardless of the source of the hydrocarbon. The cosmetic industry discussed various cosmetic product categories that contain mineral oil and that fall within the target viscosity. The products include baby oil, massage oil, bath and body oil, suntan oil, nail enamel drier and make-up removers. It should be noted that sun screens (those that make SPF claims) are considered to be over-the-counter (OTC) drugs and not cosmetics. Mineral oil laxatives are also OTC drugs. The CPSC staff measured the viscosity and the amount of hydrocarbons of various representative products within these cosmetic classes. The results are in Table 1.

Table 1: Viscosities of Representative Cosmetic and Drug Samples.

Sample number	Product Type	% Distillate	Viscosity (SUS)at 100°F
98-594-0403	Baby oil	97.5	70.4
96-400-9187	Baby oil	NM	72.1
98-594-0404	Baby oil (gel)	NM	>500
98-594-0405	Baby oil (lotion)	NM	NM
98-594-0406	Mineral Oil Laxative	97.5	354.5
98-594-0407	Mineral Oil Laxative	100	341.2
98-594-0408	Bath and Body oil	50	116
98-594-0409	Bath/Body oil	82.5	83.9
98-594-0410	Massage Oil	2.5	148.5
98-594-0411	Potpourri/body oil	25	52.4
98-594-0412	Cuticle softener	97.5	361.5
98-594-0413	Cuticle conditioner	?	134.5
98-594-0414	Nail Enamel Drier	55	41.7
98-594-0415	Nail Enamel Drier	85	37.7
98-594-0416	Eye Makeup remover (lotion)	NM	81.9
98-594-0417	Eye Makeup remover	95	74.45
98-594-0418	Eye Makeup remover (lotion)	NM	NM
98-594-0419	Mascara remover	100	167.3
98-594-0420	Tanning Lotion	NM	NM
98-594-0453	Tanning Oil	100	241
98-594-0454	Tanning Oil	100	242
98-594-0455	Tanning Oil	100	66.49
98-594-0456	Tanning Oil	100	64.7

NM = not measured? = Uncertain of % due to method for determination.

Baby oil has a viscosity of approximately 70 SUS. The makers of baby oil are aware of the potential aspiration hazard. The FDCA regulations do not mandate requirements for baby oil. However, 21 CFR 740.1(a) requires that, "...the label of a cosmetic product bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." Both of the baby oil samples examined by the CPSC staff contained the following warning statement: "For external use only. Keep out of children's reach to avoid drinking and accidental inhalation, which can cause serious injury. Should breathing problems occur, consult a doctor immediately." A commenter provided the same information.

Products in the cosmetic categories may have varying viscosities depending on the type or weight of mineral oil used as the product base. For example, some tanning oils have viscosities in the mid 60 SUS range, while others have viscosities over 200 SUS. Not all products in the same category have viscosities under 100 SUS. Therefore, some but not all suntan products, bath oils, and massage oils would require child-resistant packaging under the recommended rule. The nail enamel drier had the lowest viscosities of the cosmetic product categories examined (below 50 SUS).

The focus of this rule is liquid hydrocarbon-containing products with viscosities below 100 SUS. Cosmetic products are available in various forms including lotions, gels, creams, and saturated pads. Lotions are emulsions and would be exempt from the child-resistant packaging requirements under the staff-recommended definition. Creams and gels are too viscous and would not require child-resistant packaging under the recommended rule. Wipes, impregnated pads, marker-type dispensers and any other cosmetic product that does not contain free flowing hydrocarbon would be exempted from the child-resistant packaging requirements. These products are comparable to chemical products that are currently exempted from full cautionary labeling under the FHSA regulations, described below.

Limonene

Comment: Several commenters (CP97-2-2, 29) requested that limonene not be included in a rule. The main rationale for exclusion is that limonene is a "natural" product derived from fruit that is used as a food additive. A commenter (CP97-2-29) also stated that the term limonene is associated with several different chemical structures, some of which are not hydrocarbons. They requested that limonene not be considered with petroleum-derived chemicals.

Response: The CPSC staff is recommending that any product that contains over 10 percent by weight of any combination of hydrocarbons with a viscosity less than 100 SUS measured at 100 °F require child-resistant packaging. This recommended definition addresses the commenters' concerns that the term limonene is associated with various chemical entities. If the hydrocarbon fraction of a product (in appropriate viscosity range) is greater than 10 percent by weight, that product would be included regardless of the source of hydrocarbon. The commenters stated that orange juice and

many cosmetics and cleaning products contain "limonene" in low or trace amounts for fragrance. These products would not be included in the rule as long as the total hydrocarbon content was under 10 percent (if in appropriate viscosity range).

The CPSC staff evaluated the likelihood of aspiration of an orange oil product that contained approximately 85 percent limonene according to the material safety data sheet. This product was not soluble in water. The study results indicated that the product was an aspiration hazard (R-863-7325). The results reinforced the staff's concern that hydrocarbons can be aspiration hazards regardless of the source.

Motor Oil

Comment: Several commenters (CP97-2-6, 7,18) requested that motor oil be exempted from child-resistant packaging requirements.

Response: The viscosity of a motor oil (10W-30) product examined by the CPSC staff had a viscosity over 100 SUS at 100°F. Any motor oil or other lubricating oil with a viscosity over the threshold level would not require child-resistant packaging. However, measuring the viscosity at the temperature of 100°F is crucial.

Single-Use-Products

Comment: Comments (CP97-2-1, 6,7,20,24) were received requesting that products intended to be totally used in a single application should not be required to be child-resistant.

Response: Any regulated product that is intended to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for the first opening, since the package must be effective for the life of the product. The manufacturer may use any packaging option, which meets these requirements. In addition, the package should be labeled conspicuously that the entire contents should be used immediately upon opening.

Canada is considering requiring the following statement on single use products, "USE ENTIRE CONTENTS ON OPENING. THIS CONTAINER IS NOT CHILD-RESISTANT ONCE OPENED." The CPSC staff believes that this statement is appropriate if a non-reclosable child-resistant closure is used, because it educates the consumer about the status of the package. However, this type of labeling will not eliminate the requirement for child-resistant packaging beyond the first opening for products commonly used for more than one application. For example, an automotive additive would not necessarily be a "single-use-product" if only a portion of the contents is added to certain engine sizes.

Spray Paint

Comment: A comment (CP97-2-25) was received that requested that aerosol spray paints be exempted because it is dispensed in a fine atomized mist.

Response: The staff agrees that products packaged in pressurized spray containers, whose contents expelled in a mist and not in a stream, should be exempted from the child-resistant packaging requirements.

Petroleum Distillates

Comment: Comments (CP97-2-15, 19,20) were received requesting that different chemical classes be regulated separately. For example, only include petroleum distillates now and propose separate rules for limonene or pine oil or other chemical agents or classes.

Response: The staff agrees with this comment to an extent. We agree that other chemical classes such as terpene alcohols, ketones, or alcohols should be evaluated and if necessary, regulated separately. We do not agree, however, that other solvents containing only hydrogen and carbon be handled separately. The term petroleum distillate is archaic and refers to mixtures of chemicals that are distilled from petroleum. There has been confusion about the term "petroleum distillates" especially regarding the aromatic hydrocarbons, benzene, xylene, and toluene. While they are components of some of the distillation fractions, they are not universally considered to be "petroleum distillates" especially since their toxicity profiles differ from the aliphatic chemicals. The Canadian standards currently do not include the aromatic hydrocarbons in their definition of petroleum distillates for cautionary labeling and child-resistant packaging (CP97-2-23). Eliminating the term petroleum distillate and defining the scope as those chemicals that contain hydrogen and carbon will minimize this confusion. Hydrocarbons with the same risk of aspiration may be derived from synthesis, further refinement of petroleum-derived chemicals, or from non-petroleum sources such as citrus fruit. The aspiration hazard remains and the staff believe that child-resistant packaging is warranted.

Pharmaceutical Grade Substances

Comment: A comment (CP97-2-28) was received that requested that products made of pharmaceutical-grade white mineral oils should be exempted from the child-resistant packaging requirements.

Response: White mineral oils are available in three grades, medicinal (pharmaceutical), food, and technical (Debska-Chwaja and Eckard, 1995). The grades are determined by quality and purity. Pharmaceutical grade has the highest purity. These grades are further classified by viscosity as either light mineral oil or mineral oil. Pharmaceutical grade mineral oil is used as a laxative. This product has a viscosity of approximately

350 SUS. The current Canadian standards exempts consumer products from child-resistant packaging requirements if the product contains pharmaceutical grade mineral oil or light liquid paraffin and no other petroleum distillate (CCCR Section 39, revised 1996). The CPSC staff finds no justification for this exemption unless the product has a viscosity over 100 SUS. The process for producing pharmaceutical grade oils eliminates contaminants; however, the aspiration hazard still exists for those light mineral oils with viscosities below 100 SUS at 100 °F.

Writing Instruments, Markers, and Related Products

Comments: Several comments (CP97-2-17, 27,28,30) were received requesting that writing instruments, writing markers, battery terminal cleaner applicators, and related products be exempted from child-resistant packaging requirements.

Response: The CPSC staff agrees that products that do not contain free flowing hydrocarbon should be exempted from the child-resistant packaging requirements since they do not pose an aspiration hazard to young children. Under the FHSA regulations, (16 CFR 1500.83(a)) many of these types of products are exempted from hazard labeling requirements, i.e. writing markers. The staff is recommending that these specifically exempted products, as well as cosmetics and other household chemical products, such as battery terminal cleaners and paint markers, that do not have free flowing hydrocarbons from the packaging not require child-resistant packaging.

EPA GUIDELINES

Comment: One commenter (CP97-2-2) suggested that CPSC adopt Environmental Protection Agency (EPA) guidelines for toxicity as defined in FIFRA.

Response: The EPA is responsible for the child-resistant packaging of pesticide products. The FIFRA regulations reference the test methods defined by the PPPA in 16 CFR 1700.20; therefore the same child-resistant packaging can be used for consumer products and pesticides. However, the determination of what requires child-resistant packaging is very different under FIFRA than the PPPA. In FIFRA, (40 CFR 157.22) child-resistant packaging is determined by toxicity and use criteria. Any pesticide, for residential use, that meets any of the toxicity criteria must be packaged in child-resistant packaging.

The FIFRA Toxicity Criteria include:

- (1) The pesticide has an acute oral LD₅₀ of 1.5g/kg or less;
- (2) The pesticide has an acute dermal LD₅₀ of 2000 mg/kg or less;
- (3) The pesticide has an acute inhalation LC₅₀ of 2 mg/liter or less;
- (4) The pesticide is corrosive to the eye or causes corneal involvement or irritation persisting for 21 days or more;
- (5) The pesticide is corrosive to the skin or causes severe skin irritation at 72 hours; or
- (6) The pesticide or device has such characteristics that, based upon human

toxicological data, use history, accidental data or such other evidence as is available, the Agency determines there is serious hazard of accidental injury or illness which child-resistant packaging could reduce.

Companies submit toxicity data to the EPA as part of premarket registration and certify that their packaging is child-resistant if required. Criteria 1 through 5 used by EPA do not address the aspiration hazard associated with hydrocarbons. EPA would have to rely on Criterion 6, human data. This regulatory approach would be similar to that used previously under the FHSA, which relied on human experience data to issue special labeling requirements for petroleum distillate-containing products (16 CFR 1500.14). Currently, the EPA has not adopted this approach and does not require child-resistant packaging of products based on the aspiration hazard.

While the CPSC staff believes that a regulatory approach for child-resistant packaging based on toxicity has merit, it is much more difficult to implement under the PPPA where there is no premarket clearance, certification, or requirement for toxicity testing. The PPPA requires that the Commission find that special packaging is required to protect children from serious injury or serious illness and that child-resistant packaging is technically feasible, practicable, and appropriate. These findings do not preclude the Commission from defining criteria. The FHSA defines the toxicity of products based on specific criteria. However, it is difficult to apply these criteria to child-resistant packaging requirements because the PPPA also regulates foods, drugs, and cosmetics that have different requirements under the FDCA.

FHSA LABELING

Comment: One commenter indicated that any product that required "Danger" labeling under the FHSA should require child-resistant packaging.

Response: The CPSC staff agrees with this recommendation in part. This suggestion is similar to the one described above except that this commenter wants to rely on the FHSA definition of highly toxic to determine the need for child-resistant packaging. Danger labeling is required on products defined under the FHSA as highly toxic and/or extremely flammable. The commenter is not suggesting requiring child-resistant packaging based on flammability.

While this approach has merit, the same shortcomings described above exist. The PPPA regulates the child-resistant packaging of foods, drugs, and cosmetics in addition to hazardous substances for household use. A rule linked specifically to FHSA labeling would include only products regulated by the FHSA. Cosmetics containing the same ingredients would not be covered because of differences in the requirements and definitions of the FDCA. In addition, the PPPA requires that the Commission make certain findings before requiring child-resistant packaging. The requirement for cautionary labeling may support the finding that the product is capable of causing serious injury and illness in children. However, additional findings that child-resistant

packaging is technically feasible, practicable, and appropriate must also be made under the PPPA before the Commission can require child-resistant packaging.

RESTRICTED FLOW

Comment: A commenter requested that restricted flow be an alternative to child-resistant packaging for cosmetic products such as baby oil and body and bath oil that is opened with wet hands. The commenter stated that 70% of baby oil is used by adults and there was concern that older adults may have difficulty opening the child-resistant packaging with wet hands from the bath or shower. They also said that adults might leave the bottles open if they have difficulty opening them.

Response: Restricted flow is defined in 16 CFR 1700.15(d) as "...the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once." It is required in addition to child-resistant packaging for liquid furniture polish because many of the ingestions occurred while the product was in use. Restricted flow alone is not adequate to protect children, it does not prevent the child from directly accessing the product if the package is not child-resistant. While restricted flow limits the amount of product a child can access each time the child attempts to ingest the product from the container, it does not limit the number of attempts the child may make.

The CPSC staff examined some cosmetic products with restricted orifices. None of these products met the PPPA definition of restricted flow. Packaging changes would be necessary in order for these products to meet the PPPA definition of restricted flow. It is unclear if the commenters incorrectly believed that the restricted orifice closures used currently on many cosmetic products were the same as restricted flow. We should note that other commenters felt strongly that restricted flow may interfere with the use of cosmetic products.

The PPPA test procedures use adults aged 50 to 70 to determine adult-use-effectiveness for most packaging. This has led to the development of packaging systems that are easier for all adults to use properly (including properly resealing the cap). The current non-child-resistant packaging of cosmetic products provides virtually no protection for children. CPSC staff has data documenting that over 90 percent of children can access this type of packaging (CPSC-C-84-1111, November 1985). If companies have marketing concerns about consumer acceptance, it may be appropriate to test adults with wet hands.

Comment: Comments (CP97-2-19,28) were received requesting that restricted flow not be an additional requirement for products because it may interfere with use of the products.

Response: The CPSC staff is not recommending requiring restricted flow for additional products categories at this time. However, the requirement for restricted flow of liquid furniture polish will remain.

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TAB C



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

MEMORANDUM

DATE: APR 30 1999

TO: Suzanne Barone, Ph.D., Pharmacologist, EHHS

Through: Mary Ann Danello, Ph.D., Associate Executive Director
Directorate for Epidemiology and Health Sciences *mad*

Susan Ahmed, Ph.D., Director, Division of Hazard Analysis *DKT for SA*

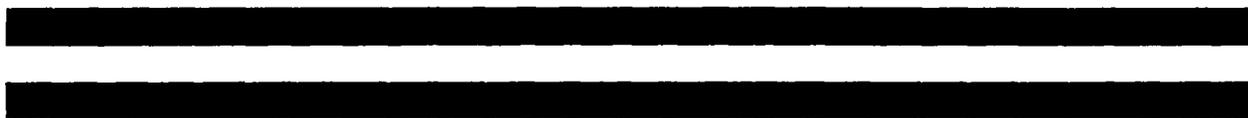
FROM: C. Craig Morris, Ph.D., EHHA *CCM*

SUBJECT: Pediatric Hydrocarbon Ingestions and Aspirations

Per your request, attached is a report on pediatric hydrocarbon aspiration-related injuries during calendar years 1995, 1996, and 1997. Data sources include the U.S. Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) and the American Association of Poison Control Centers' Toxic Exposure Surveillance System (TESS).



Pediatric Hydrocarbon Ingestions and Aspirations



April 1999

C. Craig Morris, Ph.D.
U.S. Consumer Product Safety Commission
Directorate for Epidemiology
Division of Hazard Analysis
4330 East West Highway
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Executive Summary

This report documents a high incidence of pediatric exposure to cosmetics and household chemical product groups that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. Data sources include the U.S. Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) and the American Association of Poison Control Centers' Toxic Exposure Surveillance System (TESS).

NEISS data for 1995 through 1997 yielded an estimated total number of pediatric ingestions involving household chemicals of about $6,800 \pm 1,800$. NEISS household chemical data are not directly comparable to TESS data, because NEISS product code categories do not correspond to TESS generic code categories. NEISS does not currently distinguish different cosmetic products, so cosmetic-related injuries reported to NEISS are not included in this report.

From 1995 through 1997, there were 118,823 pediatric ingestion exposures reported in TESS, with 74,042 related to cosmetics, and 44,781 related to household chemicals. During the same period, there were 726 reported aspiration exposures, with 114 related to cosmetics, and 612 related to household chemicals.

TESS data indicated that children 12 to 36 months old are most likely to be involved in pediatric hydrocarbon ingestion and aspiration exposure incidents, with children 12 to 23 months old more frequently involved than children 24 to 36 months old. Children 12 to 23 months old were involved in 46.1% of *cosmetic ingestions*, 43.3% of *household chemical ingestions*, 53.5% of *cosmetic aspirations*, and 48.4% of *household chemical aspirations*. Children 24 to 36 months old were involved in 29.1% of *cosmetic ingestions*, 33.9% of *household chemical ingestions*, 21.1% of *cosmetic aspirations*, and 34.6% of *household chemical aspirations*.

TESS data indicated the potential for severe medical consequences following pediatric hydrocarbon aspiration exposure. Of the 726 aspirations in the cosmetics and household chemicals groups, 127 resulted in a moderate medical outcome, 6 resulted in a major medical outcome, and 1 resulted in a fatality. Specific respiratory effects resulting from aspiration of these cosmetics or household chemicals groups were documented including 76 positive X-ray findings, 33 cases of pneumonitis, 1 case of pulmonary edema, 7 cases of respiratory depression, and 1 case of respiratory arrest.

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Pediatric Hydrocarbon Ingestions and Aspirations

This report describes pediatric hydrocarbon ingestions and aspirations reported in the U.S. for calendar years 1995 through 1997. A previous report presented related analyses for calendar years 1990 through 1994 [1]. Data sources include the U.S. Consumer Product Safety Commission's (CPSC) National Electronic Injury Surveillance System (NEISS) and the American Association of Poison Control Centers' (AAPCC) Toxic Exposure Surveillance System (TESS).

NEISS Hydrocarbon Ingestion Data

Method

The NEISS collects data on hospital emergency room-treated injuries via a probability sample of hospitals in the United States and its territories [2,3]. This report presents NEISS data on products that frequently contain hydrocarbon compounds known to pose an aspiration hazard to young children. NEISS selection criteria were: *product codes* 833 (workshop compounds or chemicals), 909 (adhesives, excluding tapes), 913 (lubricants), 931 (metal polishes, tarnish removers, or preventatives), 955 (automotive chemicals, excluding antifreeze, lubricants, waxes, and windshield wiper fluids), 960 (paints, varnishes, or shellacs), 977 (spot removers or cleaning fluids), 978 (automotive waxes, polishes, or cleaners); *diagnosis* 68 (poisoning); *body part* 85 (all parts of body, more than 50% of body); *age* under 5 years old; and *treatment date* 1 Jan 1995 through 31 Dec 1997. Estimates for 1995 and 1996 were adjusted to correct for sampling frame deterioration [4]. The generalized variance was used for 95% confidence intervals [5].

Estimated Injuries

Table 1 gives estimated hydrocarbon-ingestion injuries to children under 5 years old by product group for 1995 through 1997. There were an estimated $6,800 \pm 1,800$ total injuries.

Table 1. *Estimated Hydrocarbon-Ingestion Injuries to Children under 5 Years Old for 1995 through 1997*

Product Group	Code	Estimated Injuries
Workshop compounds or chemicals	833	128
Adhesives, excluding tapes	909	1,463
Lubricants	913	687
Metal polishes, tarnish removers, or preventatives	931	322
Selected automotive chemicals	955	1,183
Paints, varnishes, or shellacs	960	1,849
Spot removers or cleaning fluids	977	698
Automotive waxes, polishes, or cleaners	978	468
Total		6,798

Source: U.S. Consumer Product Safety Commission, 1999.