

CP 97-2-24

6069  
6/17/97

**TURTLE WAX, INC.**

5655 WEST 73RD STREET  
CHICAGO, ILLINOIS 60638  
(708) 563-3600  
FAX: (708) 563-3703

HARVEY KORNHABER  
SENIOR VICE PRESIDENT  
RESEARCH AND DEVELOPMENT

July 8, 1997

Office of the Secretary  
Consumer Product Safety Commission  
Washington, DC 20207-0001

Dear Secretary:

Turtle Wax has received your Advance Notice of Proposed Rulemaking (ANPR) published in the Federal Register of Wednesday, February 26, 1997 (pages 8659 - 8663).

To date, Turtle Wax, Inc. has not received any claims involving aspiration of petroleum distillates into the lungs involving our products. Moreover, we have not received any inquiries from Poison Control Centers.

Most of the aerosol products which we manufacture are water based cleaners and emulsions which may contain low levels of petroleum distillates. These products are dispensed as water based high foaming surfactants and, therefore, do not lend themselves as ingestion or inhalation hazards.

Under-the-hood engine additives are typically one time use products and are not stored over long periods of time. These are also high viscosity liquids which do not lend themselves to being easily ingested, and all utilize a thermal seal under the cap. These seals require a sharp instrument to puncture and remove them effectively in order to use the product. In essence, it is this one-time use application in combination with a "thermal" seal and adequate labeling that minimizes accidental exposure to children. Therefore, childproof closures are unnecessary.

CPSA 6 (b)(1) Cleared

No Mfrs/PrvtLbrs or Products Identified

Excepted by ANPR

Firms Notified,

Comments Processed. 7/15/97  
SRB

Office of the Secretary  
Page Two  
July 8, 1997

In summation, it is our position that the current Consumer Product Safety Commission labeling is sufficient, and further requirements for child resistant closures are not warranted.

Sincerely,



Harvey Kornhaber

HK:tn

Certified Mail - P 962 968 998

Gabbok 9/11/97 CP97-2-6



July 11, 1997

Ann Brown  
Chairman  
Office of the Secretary  
Consumer Product Safety Commission  
Washington, DC 20207-0001

Re: Household Products Containing Petroleum Distillates and Other  
Hydrocarbons

Dear Madam Chairman:

Enclosed please find an original and five copies of the National Paint & Coatings Association's comments of the above referenced ANPR. If you have any questions regarding these comments, please do not hesitate to call me.

Sincerely,

A handwritten signature in cursive script that reads "Heidi K. McAuliffe".

Heidi K. McAuliffe

**ORIGINAL**

Before the  
U.S. Consumer Product Safety Commission

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Submission of Comments

In Re:

Household Products Containing Petroleum Distillates  
and Other Hydrocarbons

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On Behalf of the  
National Paint & Coatings Association, Inc.

Submitted by: Heidi K. McAuliffe  
Counsel, Government Affairs  
National Paint & Coatings Association, Inc.  
1500 Rhode Island Avenue, NW  
Washington, DC 20005  
202-462-6272

July 11, 1997

Before the  
U.S. Consumer Product Safety Commission

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Submission of Comments

In Re:  
ANPR for Petroleum Distillates

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On Behalf of the  
National Paint & Coatings Association, Inc.

**I. Statement of the Issue**

On February 26, 1997, the U.S. Consumer Product Safety Commission (CPSC) published an Advanced Notice of Proposed Rulemaking under the Poison Prevention Packaging Act (PPPA) targeted at household products that contain petroleum distillates, other hydrocarbons or combinations of these ingredients. Existing PPPA standards require child-resistant packaging for some products that contain threshold levels of petroleum distillates or other hydrocarbons. The Commission is seeking information on a variety of issues concerning products containing these ingredients as it considers the possibility of requiring child-resistant packaging for additional consumer products.

Petroleum distillates are a group of hydrocarbon-based chemicals that are refined from crude oil. They include gasoline, naphtha, mineral spirits, kerosene,

paraffin wax, and tar. Other hydrocarbons that are not petroleum distillates include benzene, toluene, xylene, pine oil, turpentine, and limonene.

The toxicity of petroleum distillates and these other hydrocarbons affects the respiratory system and aspiration of a small amount of these chemicals in the lung can cause chemical pneumonia, pulmonary damage and death.

Household products that contain concentrations of ten percent or more of petroleum distillates are required to have hazard warnings under the Federal Hazardous Substances Act (FHSA) as are many household products that contain ten percent or more of other hydrocarbons. Some, not all of these products, are required to be contained in child-resistant packaging under PPPA regulations.

This ANPR solicits specific information with regard to household products that are contained in aerosol packages. Although the exposure data on aerosol products is limited (the available data only refers to inhalation or prolonged exposure of adults -- there is no data available with regard to children), the Commission will consider the question of whether aerosol products should be included within any regulation applicable to products that contain petroleum distillates or other hydrocarbons.

## **II. Statement of Interest**

The National Paint & Coatings Association, Inc. (NPCA) is a voluntary, non-profit industry association originally organized in 1888 and comprised today

of over 400 member companies which manufacture consumer paint products and industrial coatings or the raw materials used in their manufacture.

NPCA membership companies collectively produce some 80% of the total dollar volume of consumer paints and industrial coatings produced in the United States. NPCA represents approximately 50% of the paint and coatings manufacturers who make or fill aerosol paint. Many aerosol paint formulas contain petroleum distillates and other hydrocarbons such as toluene and xylene.

NPCA and its Spray Paint Manufacturers Committee has been very active in regulatory affairs since the advent of activities specifically focusing on aerosol spray coatings. For instance, NPCA, through its Spray Paint Manufacturers Committee, testified on several occasions before California's South Coast Air Quality Management District when Rule 1129, the rule limiting the amount of VOCs in aerosol coatings, was promulgated. Likewise, members of our Committee were also very active in maintaining a dialogue with the Bay Area Air Quality Management District (also in California) when it was forced by a court order to promulgate a rule on aerosol coatings.

Furthermore, NPCA encouraged and actively participated in the legislative activity that vested the California Air Resources Board with sole authority to regulate aerosol coatings. And in the subsequent rulemaking in the state of California which established a statewide rule establishing VOC standards for spray paint, NPCA and the members of its Spray Paint Manufacturers Committee participated in numerous workshops, surveys, informal solicitations

and an endless series of meetings in an effort to produce a reasonable and environmentally sound regulation. As you can see, NPCA's Spray Paint Manufacturers Committee is committed to working with federal and state environmental agencies to establish reasonable, practical and technologically feasible standards for the spray paint industry.

In addition to responding directly to the ANPR's questions regarding aerosols, NPCA's Spray Paint Manufacturers Committee would like to use this opportunity to relay some information about aerosol paint products to the Commission regarding the aerosol delivery system as a package. We are delighted to have the opportunity to comment on the Advanced Notice of Proposed Rulemaking, and like the examples cited, hope it can serve as the catalyst for an ongoing, constructive dialogue in the public interest.

**III. Spray paint should not be included within any proposal to broaden the scope of products subject to the PPPA regulations.**

**A. Accidental ingestion from an aerosol container is highly unlikely because the product comes out as a spray mist -- not a collectible liquid.**

Generally speaking, an aerosol package delivers product through a valve assembly. The part of the valve assembly that delivers the paint product is the valve tip. One of the functions of the valve tip (also known in lay terms as a tip, a valve, a spray cap or an actuator) is to disperse the product in a very fine, atomized mist. The product does not stream out of the can in a manner that permits it to be collected like a liquid product.

Atomization of the paint product is one of the fundamental characteristics of spray paint. Household consumers of spray paint generally purchase the product in order to obtain a professional finish or to paint objects that have an intricate surface.<sup>1</sup> The fine atomization of the spray is what produces the professional finish and permits adequate coverage of intricate objects like wicker baskets and wicker furniture.

Because aerosol paint is delivered in an atomized mist and cannot be collected and ingested, there is no requirement for spray paint to carry a warning against ingestion under the Federal Hazardous Substances Act, 15 U.S.C. 1261-74, as amended. See also NPCA's Paint Industry Labeling Guide (Fourth Edition, Sample Labels Nos. 7 and 8.

**B. An aerosol container, by virtue of its construction, is hermetically sealed and the can's contents cannot be accessed unless it is properly activated.**

An aerosol container consists of the can, the valve assembly and the overcap. The side seam on a container is double seamed and welded and the bottom end is also double seamed and welded. The valve assembly is inserted on the top of the can and it is crimped around a curl. The container is absolutely sealed and airtight. The only way the paint product can escape is if the valve tip is appropriately depressed or the can is somehow punctured.

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<sup>1</sup> It is impossible to achieve the same professional finish or the same kind of coverage of intricate objects using liquid paint and a brush. In addition, there is no clean-up with spray paint.

**C. The warning labels that are already on containers of spray paint, as required under the Federal Hazardous Substances Act, as amended, are adequate to warn consumers of the dangers to small children.**

Some of the ingredients of spray paint are hazardous substances under the Federal Hazardous Substances Act, as amended. As such, each container is required to carry warnings with regard to the specific hazard presented in a container of spray paint. See 16 CFR Section 1500.14(a) and (b). These warnings, if heeded, instruct the purchaser/consumer to keep this product away from children at all times. Since children under five years of age, in most cases, do not read and do not have the maturity to understand and heed such warnings, manufacturers and fillers must communicate to the purchaser/consumer with clear and simple instructions regarding proper use and storage of the product.

NPCA's Paint Industry Labeling Guide (Fourth Edition)<sup>2</sup>, which provides guidance on hazard precautionary labeling requirements and industry trade practice contains sample labels for aerosol paints -- one for non-flammable aerosols and one for extremely flammable aerosols. Both of these sample labels contain the precautionary statement "KEEP OUT OF REACH OF CHILDREN" in bold, capital letters. In the sample label, the statement stands alone so that it

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<sup>2</sup> Precautionary labeling is a constantly evolving art, drawing from diverse and constantly changing sources. The purpose of the Labeling Guide is to amalgamate all of these various influences into a single document. The various influences include legislative and regulatory requirements from several governmental agencies, industry and consensus guidelines, trade practice, case law, and commercial practices. To the extent practical, the aforementioned have been considered in preparing the sample labels, tables and other statements in the Guide. Nevertheless, this information is intended to serve as a guide, not the final answer to all labeling questions. It constitutes suggestions, not directives and ultimately, the manufacturer has the final

commands attention and does not lose its message in a host of other precautionary statements.

In addition, the sample labels also contain additional statements or guidance for products that emit organic vapors. Even on cans that do not present a high risk of flammability, it is recommended that the label contain the statement "Do not breathe vapors or spray mist" along with the additional reminder that "Intentional misuse by deliberately concentrating and inhaling contents may be harmful or fatal."

These warnings are sufficient to caution consumers that the contents of spray paint could be harmful to children under five years of age and should be used and stored out of the reach of children.

**D. "Child-resistant" packaging will not prevent children from intentionally misusing aerosol products to engage in graffiti vandalism or "huffing" or "sniffing" to get high.**

The most troublesome social issue for makers and fillers of aerosol spray paint is the intentional abuse of legitimate products by children and young adults. This abuse takes the form of graffiti vandalism and "huffing" or "sniffing" which produces a momentary "high". Both of these phenoms are extremely destructive forces in our society and in both cases, the abusers/vandals use a legitimate consumer product in an inappropriate fashion. Forcing spray paint to utilize "child-resistant closures" will not deter the activities of "taggers" or children who have discovered "huffing" and "sniffing". Although "taggers" and "sniffers"

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responsibility for evaluating its formulas and communicate a fair and adequate warning as to the known hazardous properties of the product.

are getting younger and younger every year, the research generally suggests that they are older than five years of age and, therefore, will possess the strength and finger dexterity to operate a spray can even with a “child-resistant closure.” As such, this type of a device will not prevent children and young adults from engaging in graffiti vandalism or “huffing” or “sniffing.”

#### **IV. The ANPR fails to clearly identify which petroleum distillates and other hydrocarbons are at issue.**

The Advanced Notice of Proposed Rulemaking specifically references petroleum distillates such as “gasoline, naphtha, mineral spirits, kerosene, paraffin wax and tar” along with hydrocarbons that are not petroleum distillates, but that can cause similar toxic effects such as “benzene, toluene, xylene, pine oil, turpentine, and limonene” in the background information. 62 FR 8659. However, the poisoning information neglects to identify and link which petroleum distillates or hydrocarbons were involved with the reported incidents. This is particularly true with regard to the poisoning incidents which involved aerosol products. The ANPR indicates that only four percent of the NEISS case investigation study involved aerosol products (none of which required hospitalization), yet there is no indication of whether the aerosol product involved contained a petroleum distillate or a hydrocarbon or, if so, which petroleum distillate or hydrocarbon was involved. This information should be secured and examined before any effort to broaden the range of products subject to the Poison Prevention Packaging Act is initiated.

## **V. Conclusion**

NPCA commends the Consumer Product Safety Commission for its attempts to learn more about the uses, effects and packaging needs of consumer products which use petroleum distillates and hydrocarbons in an effort to better protect children. With regard to aerosol products, the Spray Paint Manufacturers Committee respectfully requests that CPSC examine more closely the poisoning incidents that involved aerosol products and clearly identify the ingredient, so that any future effort can appropriately focus its activities. The Association asks that CPSC consider the above discussion when contemplating broadening the range of products subject to the "child-resistant packaging" regulations.

In summary, we urge that aerosol spray paint should continue to fall outside of the scope of the PPPA regulations for the following reasons:

- Accidental ingestion from an aerosol container is highly unlikely because the product comes out as a spray mist -- not a collectible liquid.
- An aerosol container, by virtue of its construction, is hermetically sealed and the can's contents cannot be accessed unless it is properly activated.
- The warning labels that are already on containers of spray paint, as required under the Federal Hazardous Substances Act, as amended, are adequate to warn adults of the dangers to small children.
- "Child-resistant" packaging will not prevent children from intentionally misusing aerosol products to engage in graffiti vandalism or "huffing" or "sniffing" to get high.

NPCA is pleased to submit these comments on the above ANPR and we hope to continue to work with CPSC in the future on any matters that affect the paint and coatings industry.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi K. McAuliffe". The signature is written in a cursive, flowing style.

Heidi K. McAuliffe  
Counsel, Government Affairs

CP97-2-26

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OK  
8/7/97

**CMA**

CLOSURE  
MANUFACTURERS  
ASSOCIATION

CPSC/OFC OF THE SECRETARY  
FREEDOM OF INFORMATION  
197 JUL 23 A.M: 49

July 22, 1997

Office of the Secretary  
Consumer Product Safety Commission  
4330 East-West Highway  
Room 502  
Bethesda, Maryland 20814  
Washington, DC 20207-0001

Re: Advance Notice of Proposed Rulemaking for Household Products Containing  
Petroleum Distillates and Other Hydrocarbons, 62 Fed. Reg. 8659 (Feb. 26, 1997)

Dear Sir or Madam:

The Closure Manufacturers Association ("CMA") is pleased to submit these comments in response to the advance notice of proposed rulemaking for household products containing petroleum distillates and other hydrocarbons, 62 Fed. Reg. 8659 (Feb. 26, 1997). CMA supports the proposal to require child-resistant ("CR") packaging on products containing petroleum distillates, hydrocarbons, and combinations of these ingredients. The data presented in the CPSC's advance notice of proposed rulemaking clearly demonstrate that children are obtaining access to these products and are being poisoned by unintended consumption of them. Therefore, to the extent that the use of CR packaging will reduce this exposure and is technologically feasible for this category of products, CMA supports this and the Commission's other efforts to reduce the number of child poisonings and deaths.

Thank you for the opportunity to comment on the advance notice of proposed rulemaking. Should you have any questions regarding these comments, please do not hesitate to contact me.

Sincerely,

Darla J. Williamson

WA01A/111260.1  
1627 K Street, NW  
Suite 800  
Washington, DC 20006  
202.223.9050  
202.785.5377 (Fax)



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C.S.A. & (b)(1) Cleared  
9/1/57  
No Mins. or Lib. for  
Products  
Accepted  
[Signature]

CP92-2-27

**THE ART & CREATIVE  
MATERIALS INSTITUTE, INC.**

100 Boylston Street, Suite 1050  
Boston, MA 02116  
Tel.: 617/426-6400  
Fax: 617/426-6639

Deborah M. Fanning, CAE  
Executive Vice President

August 29, 1997

Office of the Secretary  
Consumer Product Safety Commission  
Room 502  
4330 East-West Highway  
Bethesda, MD 20814

**RE: ADVANCE NOTICE OF PROPOSED RULEMAKING (ANPR) FOR  
HOUSEHOLD PRODUCTS CONTAINING PETROLEUM DISTILLATES  
AND OTHER HYDROCARBONS, 62 Federal Register, 8659 (February 26,  
1997)**

In response to the Advance Notice of Proposed Rulemaking (ANPR) on the extension of the Poison Prevention Packaging Act (PPPA) by the Consumer Product Safety Commission (CPSC) to certain products containing petroleum distillates and other hydrocarbons, The Art and Creative Materials Institute, Inc. (ACMI) is pleased to submit the following comments. ACMI is an international non-profit association of manufacturers of art and creative materials who are committed to providing non-toxic products to children and products that have been evaluated for toxicity risks, and, if any, labeled with cautionary warnings and safe use instructions for adult consumers. ACMI's certification program began evaluating children's art materials as non-toxic in 1940 and

**LOOK FOR THESE SEALS . . . . .**



continues to this day; its program was expanded in 1982 to evaluate and properly label adult art materials.

The ANPR explains that the Commission is considering the extension of the PPPA regulations, contained in 16CFR1700.1 through 1700.20 to some additional products containing petroleum distillates or hydrocarbons because "gaps" in coverage have been identified. Some products requiring similar or identical warnings under the special labeling regulations of 16CFR1500.14 do not require child-resistant packaging under the 16CFR1700 regulations.

#### Writing and Drawing Implements Exempt Under 16CFR1500.83

While the ANPR does not expressly refer to the exemptions for writing and drawing implements contained in 16CFR1500.83 (7), (9), (12) and (38), ACMI urges CPSC, in its consideration of this subject matter to maintain these specific exemptions. Under 16CFR1500.83, CPSC has granted exemptions from labeling generally for small packages, minor hazards, and special circumstances. Those relating to toxicity and writing/drawing implements include:

- 1500.83(7) Rigid or semi-rigid ballpoint ink cartridges provided the product meets the specifications of 1500.83(7)(i), (ii) and (iii).
  
- 1500.83(9) Porous-tip, ink marking devices with ink containing 10% or more by weight of toluene, xylene or petroleum distillates as defined in CFR1500.14(a)(3) and/or because the ink contains 10% or more by weight of ethylene glycol provided the product meets the specifications of 1500.83(9)(i), (ii)A or B.

1500.83(12) Containers of dry ink intended to be used as liquid ink containing a toxic substance or 10% or more by weight of ethylene glycol provided the product meets the specifications of 1500.83(12)(i), (ii) and/or (iii).

1500.83(38) Rigid or semi-rigid writing instruments and ink cartridges having a writing point and an ink reservoir containing a toxic substance and/or because the ink contains 10% or more by weight of ethylene glycol or diethylene glycol if all of the specifications of 1500.83(38)(i), (ii), (iii) and (iv) are met.

These specific exemptions were justified essentially by the very limited amount of their contents and the construction of the product that is already a form of child-resistant packaging, although not contained in the 16CFR1700 regulations.

Pens, ink cartridges and markers are constructed so that their inks are dispensed through points or nibs in a manner that does not present an aspiration risk under any reasonably foreseeable condition of manipulation or use, as specified in 1500.83(7)(i), 1500.83(9)(i)(A&B), and 1500.83(38)(i).

Pens, ink cartridges and markers contain very small quantities of ink, and thus do not present risk of exposure of large amounts of the contents, including listed hazardous substances, even for some under abusive conditions, as specified in 1500.83(7)(iii), 1500.83(9)(ii)(B), and 1500.83(38)(iii) and (iv).

Pens, ink cartridges, dry inks and markers in the certification program of ACMI are thoroughly evaluated and tested for any acute or chronic hazards under the Federal Hazardous Substances Act (FHSA), including the Labeling of Hazardous Art Materials Act (LHAMA). These evaluations are based on conservative risk and exposure assessments, which were developed by ACMI's consulting toxicologist at Duke University Medical Center and which meet or exceed requirements of LHAMA and FHSA.

ACMI and its consulting toxicologist, Woodhall Stopford, M.D., are not aware of any aspiration incidents involving these exempt products that would in any way call into question the current validity of these exemptions. For these reasons, ACMI would not see any health-related need to require exempt products to meet any additional child-resistant packaging requirements as a result of this ANPR.

If the definition of petroleum distillates or hydrocarbons under the PPPA regulations is to be expanded, ACMI would urge that the definitions be consistent in the FHSA regulations as well to avoid creating additional "gaps." For example, if a marker contained a newly-covered substance in any new PPPA regulations and the substance was not covered in the existing FHSA writing instruments exemptions, the marker would be required to comply with the PPPA regulations, even though current exemptions should apply to newly-covered substances.

#### Additional Comments by ACMI

While some ACMI members currently manufacture products that require child-resistant packaging, we are investigating other products in the ACMI certification program to which the PPPA regulations may need to be extended. Since we do not

currently have all the information required to respond to this aspect of CPSC's ANPR, we request that we be allowed to provide additional recommendations in connection with this ANPR by September 30, 1997 without any further "formal" extension being required.

Conclusion

As a major contributor to the development of ASTM D-4236, the pioneering chronic hazard labeling standard for art materials, the development of LHAMA, and a member of the Poison Prevention Week Council, ACMI is committed to the provision of safe products and information to consumers of its members' products and is pleased to submit these comments for consideration by CPSC. ACMI expects to be able to submit additional comments by September 30, 1997.

Respectfully submitted,

  
Deborah M. Fanning, CAE  
Executive Vice President

Of Counsel: Neville, Peterson & Williams  
80 Broad Street, 34th Floor  
New York, NY 10004

cc: Woodhall Stopford, M.D.  
Susanne Barone

CPSA 6 (b)(1) Cleared  
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No Mfrs, PrvtLbrs or  
Products Identified  
Excepted by ANPR  
Firms Notified,  
Comments Processed.

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

CP97-2-28

September 1, 1997

Suzanne Barone, Ph.D.  
Directorate of Epidemiology and Health Sciences  
U.S. Consumer Product Safety Commission  
EH-590  
Washington, D.C. 20207

E. EDWARD KAVANAUGH  
P R E S I D E N T

Re: Advance Notice of Proposed Rulemaking (ANPR) Regarding Household Products Containing Petroleum Distillates and Other Hydrocarbons, 62 Fed. Reg. 8659 (2/26/97)

Dear Dr. Barone:

On behalf of the members of The Cosmetic, Toiletry, and Fragrance Association (CTFA), CTFA is reporting the results of a survey of member companies that currently market one or more products that could be affected by the Consumer Product Safety Commission (CPSC) proposal to require special packaging for products containing petroleum distillates and other hydrocarbons at certain levels and meeting a specific viscosity threshold. The only cosmetic mentioned as being within the parameters for viscosity and petroleum distillate content in the Federal Register notice is baby oil. However, after interested CTFA member companies met to determine whether other cosmetics could contain 10 percent petroleum distillates and have a viscosity less than 100 Saybolt Universal Seconds (SUS), industry realized the impact of the ANPR could be greater than originally thought.

CTFA is the national trade association of the personal care products industry. Founded in 1894, CTFA has an active membership of approximately 275 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States. CTFA also represents approximately 275 associate member companies including manufacturers of raw materials and packaging.

Therefore, CTFA requested additional time to submit written comments in order to more broadly survey members of several technical committees that could manufacture products with petroleum distillates. Also, there was a need for additional time to educate the membership on what was meant by "petroleum distillate," "other hydrocarbons" and "combination of ingredients" because none of the terms were defined in the initial ANPR. The Commission agreed that it was important to have information that is as complete as possible from the cosmetics industry and extended the comment period to September 1, 1997. CTFA appreciates the additional time to respond to the ANPR.

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702

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<http://www.ctfa.org>

SECURING THE INDUSTRY'S FUTURE SINCE 1894

## **Introduction**

CTFA, as the national trade association for the personal care products industry, administered a survey to its members that may manufacture cosmetics with petroleum distillates at a level of at least 10 percent and with a viscosity of less than or equal to 100 SUS at 100 degrees Fahrenheit. CTFA sent the survey out to over 200 representatives of member companies and received responses from 20 companies, many with the largest market share within a given product category. (See survey attached, Appendix A) Fifteen companies completed surveys contributing either general policy positions and/or specific product category information. Five additional companies returned the surveys to CTFA stating that: they made no products within the percent and viscosity range, used no petroleum distillates, had a product in development, but not a currently marketed product, or the product was not for household use. The information has been reported without identification of brands or companies, only by product category.

This comment is the result of an extensive survey of the membership based on the questions provided in the ANPR. The 15 member companies who responded to the survey with specific information reported on the following categories of cosmetics: baby oil; bath oil; oil-based eye makeup remover; oil-based suntan or sunscreen products; massage oil and nail products. Generally, the companies that reported represent those with the largest sales of cosmetics and therefore, have a more extensive array of products than many companies.

## **Summary of Survey Findings**

Several facts are evident from the responses received. First, those cosmetic products besides baby oil that are manufactured with petroleum distillates, generally use mineral oil. However, the number of cosmetic product categories that use mineral oil and present a possibility of aspiration are few. For example, makeup concealer sticks, eye shadows and blushes contain mineral oil at relatively high levels, but because of their solid form, aspiration is not an issue.

Second, of the cosmetics in liquid form, few use up to 10% petroleum distillate and meet the viscosity level of less than or equal to 100 SUS. Therefore, many companies that received the survey notified CTFA staff that they did not market consumer products subject to the rulemaking.

Third, the companies that did report generally represented market leaders in the product category and therefore, their experiences with ingestions are noteworthy. Where possible, market share was specified.

Fourth, a review of the ingestion data reported by companies demonstrates that the cosmetic industry has had very few incidents involving products with petroleum

distillates. In the survey administered to member companies based on CPSC's ANPR, companies were asked to report not only the number of incidents and the outcome, but also how many units of the cosmetic were sold annually or over a specified number of years. CTFA thinks it is crucial for the Commission to consider the number and seriousness of reported incidents in relation to sales for the cosmetic to put into context any ingestions and the need for child-resistant closures (CRCs).

Fifth, companies felt strongly that an unnecessary CRC for a cosmetic product sold domestically and abroad, would have significant economic ramifications. Most companies in the cosmetics industry are now global. Sales to international markets would be negatively impacted because of a negative consumer perception in foreign countries about the safety of the U.S. product with a CRC versus the foreign competitor's product that is not child resistant. Also, a foreign competitor's packaging cost could be lower than the U.S. product with a CRC and consumers would buy the cheaper product in many cases. Also, many U.S. companies cannot afford unique packaging for the U.S. market versus packaging for international markets, where CRCs are not required. Therefore, the requirement of a CRC on a cosmetic imposed by a U.S. agency would affect global marketing adversely.

### **Cosmetics Do Not Pose an Aspiration Hazard Warranting Child-Resistant Packaging**

It is CTFA's strong position that based on the candid and complete survey responses received by the association from member companies, there is not a problem with cosmetics containing petroleum distillates and ingestions by children. Based on reviewing the surveys returned by the member companies, an important trend is evident. In the vast majority of cases, there were no ingestions reported to companies for specific product categories. If there was an ingestion at all there were only minor or asymptomatic effects; they were not aspiration incidents, which is of concern to the Commission. Where there were unfortunate serious ingestion incidents in two cases, described below, the facts indicate that a CRC would not have prevented these incidents because either the product was not stored in the original package or due to a lack of adult supervision.

### **Ingestion Incidents**

One company reported a serious incident involving a product with a 60-year product history. That ingestion was the only serious incident in the marketing of that product brand. In that ingestion incident, the baby oil was not in the original container, it had been transferred to a vial stored in a sister's purse left on the floor. Therefore, one cannot conclude that the original container was inadequate to keep a child from accessing it and ingesting it since the product was transferred to a container not intended to hold that product.

In addition, CTFA reviewed a recent CPSC Epidemiologic Investigation Report (EIR) of a fatality involving ingestion of an unknown brand of baby oil by a one-year-old boy in 1996. Although the outcome of this incident was certainly tragic, the lack of information surrounding the incident and even some of the known facts do not make this a case that warrants child-resistant closures for millions of baby oil containers safely used in millions of homes. The EIR acknowledges "the information presented in this in-depth investigation [by CPSC] is very limited and came from the medical examiner's office...."

According to the EIR, investigators were unable to learn key facts about the ingestion incident. For example, they could not learn whether the product was left open after an adult used it, thereby making a CRC useless in preventing this incident, or whether the cap was closed before the ingestion. The latter is an essential fact in determining whether the child opened a closed baby oil container that did not have a child-resistant closure. "No other information was available on the bottle," according to the Report Synopsis. For more details about the incident, see Appendix B attached, CPSC Epidemiological Investigative Report.

### **Cosmetics are not Represented in the 43 Epidemiologic Investigation Reports & NEISS Data Cited in the ANPR**

Other available evidence of ingestions obtained by the Commission rules out a serious risk of injury from cosmetics with petroleum distillates and other hydrocarbons. First, of the 43 Epidemiologic Investigation Reports (EIRs) cited in the ANPR involving ingestions of products with petroleum distillates and other hydrocarbons, *none* involved a "cosmetic" as defined by the Federal Food, Drug, and Cosmetic Act or any other personal care products. Over the three-year period from 1994 through 1996, the incidents cited involved primarily other "household products." Second, the National Electronic Injury Surveillance System (NEISS) data for 1990-1994 released pursuant to an industry Freedom of Information Act (FOIA) request for information on household products with petroleum distillates, included no cosmetic product categories or ingestion incidents.

### **Results of Industry Information Survey**

#### **Part 1: General Issues to be Considered During Rulemaking**

**The following are responses received in response to the CPSC request for general information about its regulatory approach:**

##### **1. Viscosity & Percent Composition**

The ANPR asked what viscosity and/or percentage should be used as a threshold for requiring child-resistant closures (CRCs) for products with petroleum distillates. Overall, the respondents found that the less than or equal to 100 SUS

viscosity level and 10% petroleum distillate amount was reasonable for products which are appropriate to include in a regulation, but based on the survey results, cosmetics should not be among them. One company, however, stated that less than 70 SUS for its product category did not pose a lipid pneumonia risk from aspiration, based on expert studies. Several companies questioned the value of the less than or equal to 100 SUS at 100 degrees F as a measure because cosmetic products are kept at room temperature in the home and not at 100 degrees. CTFA shares that concern as well. Also, many companies do not measure product viscosity at 100 degrees F.

Other comments about the viscosity and petroleum distillate levels include: one company did not endorse an overall SUS and petroleum distillate percentage level, but suggested that the regulation should be "directed toward the specific product categories causing the greatest number of incidents." One of the companies that endorsed the less than or equal to 100 SUS and 10% petroleum distillate level reasoned that such an approach is consistent with existing CPSC regulations requiring warnings. Finally, another company suggested varying the percentage of petroleum distillate and SUS level depending on the type of petroleum distillate used in the product.

## 2. Other Hydrocarbons

Several reporting companies stated that where there were legitimate safety issues surrounding the hydrocarbons listed in the ANPR, PPPA rules could be warranted. However, those companies added that the hydrocarbons listed in the ANPR generally are not used in cosmetic products, so they lack data on most of the compounds.

The Chemical Specialties Manufacturers Association (CSMA) stated in their comments to the Commission that there should be a separate rulemaking for hydrocarbons to determine whether CRCs are necessary on products that use them. CTFA agrees that any investigation into hydrocarbons and CRCs should be separate from this ANPR.

## 3. Aerosols

Respondents unanimously stated that cosmetic products in aerosol delivery systems should not be included in a regulation requiring a CRC if the product contains petroleum distillates or other hydrocarbons. CTFA agrees aerosols should be exempted from any rulemaking involving petroleum distillates based on survey information collected from CTFA members. One company argued that because aerosols are designed to deliver only a limited, pre-measured volume of product, CRCs are unnecessary to prevent excessive ingestion. Another company argued that the aerosol valve and delivery system is already a type of restricted flow closure obviating the need for a CRC. Two companies reported they have no information of accidental aerosol exposure incidents. Another company argued that there should be an aerosol exemption under the Poison Prevention Packaging Act (PPPA) generally.

#### 4. Restricted Flow

The Commission also wanted to know whether restricted flow closures should be an "additional requirement" for certain products. The responses from companies were mixed. Two companies stated that restricted flow closures should be required if they can enhance safety. One of the three companies favoring the restricted flow orifices added that such closures should be in agreement with the products' use patterns and method of application. In a similar vein, another company added that there should be a requirement only if restricted orifices do not adversely affect product performance. The second company stated that restricted flow orifices could be an alternative to a CRC, but not an additional requirement and parameters for flow restriction would need to be defined by the Commission. Another company reported that restricted flow caps should be an option for body and bath oil products instead of, not in addition to, CRCs because of the difficulty of opening CRCs with wet hands in the bath or shower. Finally, one company stated that restricted flow caps could be a possible substitute for CRCs for certain products.

Four companies stated unequivocally that restricted flow closures should *not* be an additional requirement for cosmetics for several reasons. First, usage and product characteristics should dictate the necessity and appropriateness of flow restrictions. Second, there is no reason for restricted flow orifices based on the reporting company's records which support the safety of current packaging.

#### Part II: Additional Requests for Information

**The following section includes specific information CPSC sought in the ANPR regarding products containing petroleum distillates:**

##### **A. Product Category: Baby Oil**

The association received responses from the two companies that have approximately 42 percent of the national baby oil market, based on independent market data reports. The companies surveyed are the national market leaders with the remaining market comprised of "house brands" which are manufactured by private-label contract manufacturers. The national brand baby oil companies surveyed by CTFA supplied the following information as requested by the ANPR and any clarifying information, if needed:

##### Chemical Properties of Products with Petroleum Distillates

Both companies' baby oils were in liquid form. One company used restricted flow orifices and the other company did not. In terms of formulations, one company's product contained greater than or equal to 99% light mineral oil and 1% fragrance. Another company's product contained approximately 90% mineral oil, >1% fragrance

and other ingredients. Both products fell within the 60-70 SUS viscosity range and neither had child-resistant packaging.

### Users and Use Patterns

The companies reported that the intended use of baby oil is as a moisturizer and cleanser. The locations of use are the bathroom and nursery/children's bedroom. The length of time one brand of baby oil remains in the home is approximately one year, and the other brand reported being in homes 6 months or less. The latter company explained that the baby oil's container size often determines the time a consumer keeps it in the home. The location of storage when not in use is on dressers, in medicine cabinets and bathroom shelves.

### Current Packaging and Labeling

The baby oil package sizes were reported as 4 ounces, 9 ounces, 12 ounces and 14 ounces. The container materials used are PET plastic for one brand and PVC plastic for the other brand. Both brands' closures used polypropylene (PP). The closure designs for both products are flip-top dispenser caps with orifices. One company reported labeling that included: "Warning: FOR EXTERNAL USE ONLY. Keep out of reach of children to avoid drinking and accidental inhalation which can cause serious injury. Should breathing problems occur, consult a doctor immediately." The other company reported a warning: "Keep out of reach of children. For external use only."

For instructions, one product states: "FOR BABY: Use daily to help moisturize delicate skin and prevent drying. FOR YOU: Apply while skin is still damp from shower or bath for superior moisturizing, helping skin stay soft and smooth. Gently removes makeup from delicate eye area." The other brand's instruction statement reads: "For adults: Apply after shower for softer skin. Helps remove makeup. For baby: Use after baby's bath for smoother skin."

### Economic Information

One company reported a wholesale price of \$1.71 and a retail price of \$2.25 for its baby oil. One company reported that the expected cost of providing CRCs would be \$1 million for new molds for the bottles, increased component price (caps, etc.) and new tooling for product filling lines. In terms of the potential impact that a CRC requirement would have on the company's business, one company said that in the long term, it would mean a slight increase in the cost of closures.

The second company pointed out that older people might find the product more difficult to use/open which is a concern because an estimated 70% of baby oil use is by adults, with the remainder of the market on babies and other family members. Therefore, the majority of the users of baby oil are adults who would have a difficult time

opening the bottle with a CRC and wet hands from the bath or shower. The concern also was expressed that any adults, especially older people or people with arthritis, tend to leave open products with child-resistant closures because it is difficult to open them for each use creating an inadvertent ingestion hazard.

### Incident Information

**Table 1 - Incident Information - Baby Oil**

<b>Time Period Reported</b>	<b>Number of Incidents Combined (2 companies)</b>	<b>Outcome</b>	<b>Units Sold - U.S. Per Year</b>
1993 - 1996 & 1995 - 1996	77	No medical attention required	14.6 Million Units per year

### Explanation of Table 1

The two baby oil manufacturers reported a total of 77 ingestion incidents based on one company's 1995-1996 sales period and on the other company's 1993-1996 sales period. The two companies marketed a combination of 14.6 million units per year.

For one company, all of the ingestion incidents involved less than 1 teaspoon of baby oil and none required further medical attention. None of the incidents involved aspirations, but were reported as possible "ingestions" of baby oil. The company reported it has an "active surveillance system" involving an 800 number where consumer affairs representatives refer calls that could potentially be ingestions to a poison control center. In turn, the center reports back to the company all outcomes. This brand of baby oil has been marketed since 1944.

A second company reported on ingestion incidents over a three-year period from 1993 to 1996. These incidents were all "asymptomatic." The company reported in detail about its internal procedures relating to alleged ingestions. First, the company's 800 number is staffed both with consumer affairs representatives and medical technicians to field consumer questions. If there is a possible ingestion, they refer the caller to the company's registered nurse on duty. The nurse then collects details about the incident and always refers the parent or adult to take the child to his or her pediatrician. Also, if there are any serious incidents, the company will receive notice from poison control centers. The latter baby oil has been marketed since 1935.

One baby oil marketer experienced one serious injury in 1985 resulting in permanent impairment of an 15-month-old child. However, the baby oil was not stored in its original container, but had been transferred to a small vial kept in a sister's purse.

## **B. Product Category: BATH OIL**

### **Chemical Properties of Products with Petroleum Distillates**

Three companies reported that they market bath oil products in liquid form. Two companies use a restricted flow orifice. The other company does not use a restricted flow orifice because the bath oil is a limited edition, promotional item marketed to use up existing packaging. No ingestions have occurred with the promotional bath oil. One company uses a small orifice on a flip-top cap; another company uses an orifice reducer to aid in the control of the amount of product delivered.

In terms of formulations, one company reported a range among its bath oils of 25%-75% mineral oil depending on the stock keeping unit (SKU), fragrances, preservatives, and color additives all under 1%. The SUS was reported to be 93. Another company has one product at 70% mineral oil, 11% petrolatum, 7% sesame oil with the rest consisting of colors, preservatives and fragrance. The latter product has a reported viscosity of 50-150 Centistokes, because the company does not measure in SUS. The company marketing the limited edition, promotional bath oil reported a viscosity below 100 SUS and the percent of mineral oil as 73%. Finally, all three companies reported not currently using CRCs on their bath oil products.

### **Users and Use Patterns**

The intended use for bath oil stated by respondents is as a moisturizer, emollient, hair conditioner and skin softener. The location of use is the bathroom, kitchen and bedroom. Companies reported a time range from 4-6 months for one brand and 6 months-2 years for another brand that the bath oil package is kept in the home. When not in use, bath oil reportedly is stored in cabinets, cupboards, tub or sink areas and dressers.

### **Current Packaging and Labeling**

Bath oil package sizes reported include 50 milliliters (ml), 125 ml and 250 ml by one company and 2 fluid ounces, 4 fl. oz., 8 fl. oz., 16 fl. oz. and 24 fl. oz. by another company. The promotional bath oil is 4 fl. oz. Two companies reported their containers are composed of HDPE plastic. Another company reported a glass container. The companies' closure materials were reported as polypropylene (PP) and urea formaldehyde resin, respectively. Closure designs included a flip top with orifice and a screw top cap.

For warnings, one company stated "Avoid contact with styrene plastic; keep out of reach of children." Another bath oil manufacturer included no warnings on the label. A third company included the warning: " If product gets into eyes, wash thoroughly with water. ADULT USE ONLY." All companies reporting included use instructions. The same company instructed: " To Use: Pour 1 or 2 capfuls under warm running water."

One company urged “[u]se beneath makeup if skin is excessively dry. Pour a few drops into bath water to smooth and soften skin.” Another company instructed users to “Pour in 1 teaspoon into tub.”

### Economic Information

For the range of wholesale and retail prices, one bath oil manufacturer did not report. Another company valued the pump bath oil at \$10 wholesale and sold it for \$17 retail. The promotional size bath oil was not sold independently, but with a gift box including several other cosmetics, so the bath oil cost/price was not reported. In terms of the cost of CRC packaging, one company reported an increase of 30 percent for total packaging costs for the one SKU. Another company estimated \$1 million to \$1.5 million if a custom design cap is needed, which is likely given the aesthetic considerations of cosmetic package design. If a custom cap is not needed, the company estimated a cost increase of \$300,000 for the first year and \$125,000 annually thereafter.

The companies were very specific as to the potential impact on their business if CRCs were required for bath oils containing 10% petroleum distillates and meeting the viscosity parameters. One manufacturer reported:

Approximately 40 percent of our business [in general] involves promotions/limited life packages. This [bath oil] product is usually sold with a pump dispenser and we would be unable to do so with a child-resistant cap. Also, there would likely be significant consumer concerns raised related to the safety of this oil versus our other bath/body oils (non-mineral oil-based and therefore not subject to this proposed rule) which could result in erosion of sales for this item. Also, it could raise concerns about why this product, which has been sold for over 20 years, is “suddenly” seen as hazardous.

Another manufacturer reported that financially, there would be added costs for re-tooling and more expensive CRC packaging. In terms of use, the ease of use would be diminished because it is used in the bath or shower where opening products with slippery hands is difficult, the same company reported. The marketer of the promotional size bath oil reported they would discontinue the product altogether.

Incident Information**Table 2 - Incident Information - Bath Oil**

<b>Time Period</b>	<b>Number of Incidents</b>	<b>Outcome</b>	<b>Units Sold per Year</b>
1996	23	Minor, no aspirations	7 Million U.S.
Past 20 Years	none (for U.S. & worldwide)	Not applicable	431,000 Worldwide 70,000 - U.S.
1996	none	Not applicable	10,000 U.S.

Explanation of Table 2

One company that sold approximately 7 million units of bath oil in 1996, reported 23 ingestion incidents for that year. According to Poison Control Center information the company keeps on file, the outcomes have been "minor, not life-threatening" and included no aspirations. The latter bath oil has been marketed for over 20 years. The other reporting company, with a smaller market share in this category, also has marketed its pump-container bath oil for over 20 years and knows of no reported ingestion incidents for either its domestic or foreign sales. The company reporting on the promotional size stated it is a one-time, limited edition product recently launched and no incidents have been reported to the company.

**C. Product Category: Eyemakeup Remover**Chemical Properties of Products with Petroleum Distillates

Each company that reported on the eyemakeup remover category marketed the product in either the liquid, pad or gel forms. One company's product came as pads impregnated with the remover liquid. Another company had a gel eyemakeup remover, and two companies marketed a liquid form of the product. The restricted flow was not applicable to the eyemakeup remover pads. The gel product used a small orifice on the tube to allow for control when dispensing the product. One company's liquid product does not currently have a restricted flow mechanism, however, the company is considering one not as an anti-ingestion measure but for product use-related reasons. Similarly, another liquid product does not have a restricted flow closure, but the package is being revised to add a volume control plug. Another company reported it uses no flow restricters.

The pad product contained less than 50% mineral oil, but viscosity was not reported. The gel product contained 78.5% mineral oil, and viscosity was reported as 1200-60,000 Centistokes, not SUS. One liquid product reported 63% mineral oil, but the viscosity was reported as "unknown." Another liquid eyemakeup remover reported a viscosity of less than or equal to 100 SUS and 9.64% petroleum distillate or hydrocarbon specified as isohexadecane. Finally, another company reported on an eyemakeup remover formulation containing 17.5% of an unspecified petroleum distillate and an estimated SUS below 100. None of these products are currently packaged in CRCs.

### Users and Use Patterns

The intended use for eyemakeup remover was reported as "cleaning" and to remove eye makeup. The location of use was the bathroom or bedroom. The estimates of time eyemakeup remover is kept in the home ranged from 2 1/2-3 months up to 2 years. Location of storage was reported as the bathroom, bedroom, drawers, dressing table, edge of bathtub, cupboard/medicine cabinet or under sinks.

### Current Packaging and Labeling

The company marketing a gel formula eyemakeup remover reported a package size of 75 ml. The tube is made of low density polyethylene (LDPE) plastic and the closure material is polypropylene (PP). The closure design is a screw-on cap. The warning on the gel's label is "Remove contact lens prior to use." Instructions for use read "With eye closed, gently spread small amount over eye area to dissolve makeup, remove with damp cotton pad or soft washcloth."

The three companies that market a liquid eyemakeup remover reported package sizes of 2 fluid ounces, 3.75 fluid ounces and 4 fluid ounces, respectively. The container material is high density polyethylene (HDPE) plastic for the 2 oz. size. PET plastic was reported as the material used for the 3.75 oz. and 4 oz. sizes. The closures for both company's products were made of polypropylene (PP) and were described as a "straight-sided screw top," "threaded screw-on closure" and screw on top with regular orifice. One company shrink wraps the entire plastic container which remains until opened by users. The 2 oz. product has no warnings, but instructions for use state: "Shake well. With eye closed, apply remover to lid and lashes using a clean cotton ball. Wait a few seconds and wipe." The 3.75 oz. product's label included "Warning: In case of eye irritations, infections or scratches, discontinue use of all eye cosmetic products and consult a physician." Instructions for use read: "Shake until blended. Apply small amount to cotton ball or pad. Gently wipe away all traces of eye makeup." The 4 oz. eye makeup remover has no warning because the product is "meant and tested for eye area use." The same label instructs users: "Shake well. Saturate cotton ball, stroke over eyes. Rinse with water."

The impregnated pad form product did not report on its packaging and labeling, most likely because it poses no aspiration risk.

### Economic Information

The marketer of the gel eyemakeup remover stated that the wholesale price is \$3.30, while the retail price is \$5.50. The expected cost of a CRC would be several thousand dollars for custom cap tooling for the product - a 35% estimated increase in packaging costs alone. Marketer feared that sudden presence of a CRC would cause the oil-based form of eyemakeup removers (versus non-oil) to be put at a competitive disadvantage because consumers would perceive the product as "unsafe" and would not buy it.

Another marketer of the liquid eyemakeup remover reported the "manufacturer's suggested retail price" as \$3.82. The cost of a CRC on the container would make the current cap cost of 1.5 cents increase to 3 cents each. There are, however, other considerations when determining the cost of packaging changes. It is important for the Commission to recognize that packaging aesthetics is an integral element of cosmetics and are a key factor in packaging decisions and ultimately, consumer purchases. Most changes to closures on cosmetics must be custom designed which is very costly. For example, "future product would require significant development to make the CRC look attractive" as needed for aesthetics of cosmetic package, reports one manufacturer. The impact of a mandatory CRC would be to discontinue the product because its sales do not outweigh costs of redoing package.

Another company sells an eyemakeup remover for \$14.00 retail with wholesale costs of \$7.00-\$8.50. The company did not have available expected costs for providing CRCs. They reported, however, that the potential impact on production assembly equipment would be large and would involve retooling or replacing the existing closure system. Finally, another liquid eyemakeup remover marketer reported a retail price of \$13.50, but included no CRC cost predictions.

Finally, the marketer of the eye pad form reported no economic impact estimates for product because it is unlikely to require a CRC because of a lack of aspiration danger due to the fact that pads soak up the container's contents.

Incident Information**Table 3 - Incident Information - Eyemakeup Remover**

<b>Time Period</b>	<b>Number of Incidents</b>	<b>Outcome</b>	<b>Units Sold</b>
1985 to Present	No known ingestions	Not applicable	20,000-25,000 units/year
1987-1994 - co. files 1994 to Present - in-house electronic database	No ingestions	Not applicable	Not reported by company
1996	10 (reported to Poison Control Center)	2 - No effects; 8 unknown, but presumed minor because no further inquiry by consumer	1,136,000 units sold in 1996
1996	No incidents	Not applicable	10,000 units sold in 1996

Explanation of Table 3

The gel form eyemakeup remover marketer reports "no known ingestions" in the 12-year marketing history of the product and sells approximately 20,000 to 25,000 units annually. One eyemakeup remover marketer reports that after checking an in-house database begun in October 1994 and files kept prior to the database, there have been no ingestions reported. The product was first marketed at least since 1987, perhaps earlier. Another eyemakeup remover marketer reported 10 incidents during 1996 with two no effects and eight unknown because of no further contact by the consumer with the company. Presumably if one of the incidents were serious, the company would be notified by the Poison Control Center that tracks incidents involving their products or by the consumer through the consumer affairs office or company 800 phone number. The company sold approximately 1,136,000 units in 1996. Finally, another company reported that they know of no accidental ingestions and sold an estimated 10,000 units for the past year that it was marketed.

#### **D. Product Category: Suntan/Sunscreen Oil-Based Product**

##### Chemical Properties of Products with Petroleum Distillates

Two companies that market an oil-based suntan/sunscreen product reported that they sell their products in liquid form. The suntan/sunscreen oils do not have restricted flow closures because they may not permit optimal delivery of the product during use, may reduce consumer convenience and may increase costs.

In terms of formulation of the company's suntan oil, it contains 52% light mineral oil with a viscosity "below 100 SUS." The other company's suntan/sunscreen oils contain 90% mineral oil and have a viscosity of 100-150 Centistokes. Neither of the suntan oils marketed by the reporting companies have CRCs currently.

##### Users and Use Patterns

The suntan oils' intended use is as a sunscreen or suntanning product to be used at the beach and pool. One company's sunscreens reportedly are kept in the home an average of approximately six months. The other company's sunscreen is kept in the home an average of two years. When not in use, the suntan oils are stored in the bathroom and closets.

##### Current Packaging and Labeling

One company's sunscreen oil is sold in a 4 ounce package. The container material is PET plastic with a polypropylene (PP) plastic closure. The closure design is a flip top. Another company markets two products, both 8 ounces in PET plastic containers. The closure material used is polypropylene (PP) with a threaded cap for one package and a pump closure is used for another package. Neither product has a CRC.

One company's product reported both warnings and instructions for use on the label. The warning reads: "For external use only, not to be swallowed. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Discontinue use if signs of irritation or rash appear. If irritation or rash persists, consult a doctor. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately." The instructions read: "Adults and children 6 months of age and over: Apply liberally 15 minutes before sun or water exposure. To maintain sunburn protection, reapply often. Children under 2 years of age should use sunscreen products with a minimum SPF of 4. Children under 6 months of age: consult a physician."

A second manufacturer's sunscreen and suntan oils were labeled: "Caution. For external use only." The instructions for use state: "Apply generously and evenly before sun exposure. Reapply after."

### Economic Information

In terms of the range of wholesale and retail prices, the factory price for one sunscreen oil is \$3.99, while the retail price is \$5.99 to \$6.99. The expected cost of providing a CRC on this sunscreen oil is estimated to be \$13,000 in research and development costs and capital costs of \$150,000-\$200,000 for plugger/sorter. The impact on the company's business would be a slight increase in the cost of goods.

The other company selling both a pump and a capped product reports retail prices of \$8.00 - \$10.00. Wholesales costs were not reported. The company was unable to estimate costs of providing CRCs for the suntan/sunscreen oils. The business impact could be restricting the forms of the product available to consumers, a high cost to consumers, and increasing the complexity of doing business because the marketer heavily relies on outside packaging vendors and product formulators.

### Incident Information

In 1996, the first year after acquiring the product from another company, approximately 120,000 of the company's sunscreen oils were sold and no ingestion incidents were reported to the company. The second company's sun oil products have been marketed for 15 years and the company has no ingestion incidents on file.

## **E. Product Category: Massage Oil**

### Chemical Properties of Products with Petroleum Distillates

One company reported on its massage oil which is a product-line extension of a brand of a fragrance. The massage oil reportedly contains 68% mineral oil, 5-10% avocado oil, fragrance and miscellaneous non-petroleum distillate ingredients. The viscosity was not reported. The company uses restricted flow closure for the massage oil to aid in product delivery. The product does not have a CRC currently.

### Users and Use Patterns

The intended use of the massage oil is to aid in giving body massage by rubbing with the hands onto skin. The company reported the location of use to be bathroom or bedroom.

### Current Packaging and Labeling

The massage oil container is 200 ml or 6.7 fluid ounces. The container material is aluminum. The closure material is polyethylene (PE) liner with aluminum overcap. The closure design is a screw-on cap with restricted flow opening, but no CRC. The product label bears no warnings, but instructions for use state: "Light, freshly scented oil for relaxing body massage. Spread oil onto hands and gently massage into skin."

### Economic Information

The reported retail price for the massage oil is \$26. In terms of potential impact of mandatory CRC, the marketer stated the product would be dropped because the small sales do not make it worth the investment to refit with special packaging.

### Incident Information

The company reported no ingestion incidents in the 18 months the massage oil has been marketed.

## **F. Product Category: Quick-Dry Nail Product or Nail Treatment Product**

### Chemical Properties of Products with Petroleum Distillates

Two companies reported on Quick Dry Nail Products and a Nail Treatment Product under the "other products" category of the survey. The manufacturer of one quick dry nail product reports that the bottle has a type of closure that could be interpreted to be "restricted flow." Specifically, the bottle has a wiper on the bottle's neck to remove excess product from the brush for ease of application. The other reporting company's two products, a nail treatment product and a quick dry nail product, do not have restricted flow orifices. None of the nail products reported having CRCs.

One quick dry nail product contains two types of mineral oil at 74.7% and another at 25%, with fragrance and another non-petroleum distillate ingredient. The company reported viscosity of 10-15 Centistokes, because the company does not use SUS as a measurement. The other company's nail treatment liquid contains 15% mineral oil with an estimated SUS of 89-100 and its quick dry product contains 51% cyclomethicone and 18% mineral oil with an SUS of approximately 45-55.

### Users and Use Patterns

The intended use of the quick dry nail product is to dry the surface of nail lacquer on the finger or toenail. The nail treatment product's intended use is to condition nails. The location of use for all the nail products was reported as the bedroom, living room or other rooms in the home. One quick dry product is kept in the home for 6 months to 2 years. The other company had no data on length of time kept in the home for its two nail products. The location of storage when not in use is the bathroom cupboard for all nail products.

### Current Packaging and Labeling

One quick dry nail product is sold in a very small size, a 12 ml. bottle. Likewise, the other company's nail treatment and quick dry product are sold in 11 ml. or .4 fl. oz. All three nail products sold by the two companies use glass containers with polypropylene (PP) screw-top cap closures. One company uses a dropper and a typical nail polish cap with built-in brush for its quick dry product.

There are no warnings or instructions for use on the label of one company's quick dry product. However, another company's quick dry product warns: "Caution: Flammable. Keep from Heat and Flame." Also, there is no warning on the latter company's nail treatment product. The nail treatment product instructs users to: "Apply to nails and cuticles and massage in slowly." The instructions for use on one of the quick dry products is "Apply as finishing coat over nail color."

### Economic Information

The reported range of wholesale is \$4.80 and retail price is \$8.00 for one quick dry nail product. The other company reported a wholesale cost of \$2.00 and a retail price of \$3.60 for its quick dry product and its nail treatment product. The marketer of the more-expensive quick dry nail product reported that the expected cost of providing CRCs would be several thousand dollars for custom cap retooling and an estimated 40% increase in packaging cost. The mandatory CRC would have a large potential impact on sales volumes related to consumer concerns about product safety. The other company reported the costs for its two nail products would be "uncertain." That same company stated that they would discontinue the two nail products if CRCs were required.

### Incident Information

One company's quick dry nail product reportedly has been marketed for 12-13 years and the company has no reported ingestions. The other company's nail products have been marketed since before 1990, when the company acquired the product line. Based on its electronic database that tracks ingestion incident information, there have been no incidents since 1994 when the database went on line.

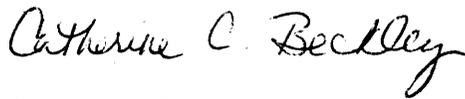
### Conclusion:

Although the CTFA survey of its members identified a number of cosmetic products with a wide variety of formulas, packages, and labels, serious incidents were rare and none of those appeared resolvable by a requirement for child-resistant packaging. Furthermore, requiring child-resistant packaging for cosmetics would impose severe burdens on the manufacturers of these products, especially where commercially available closures are not readily adapted to many cosmetic packages or where a cosmetic is marketed globally. A number of companies felt the burden was so

severe, they would be forced to discontinue the product if subject to regulation. In addition to the burdens on existing products, CTFA members expressed concerns that a future regulation as outlined in the ANPR could pose a barrier to innovative products not yet conceived of or those in development.

Based on the excellent safety record of FDA-regulated cosmetics and the burden a CRC requirement would impose as demonstrated by CTFA's extensive survey of its members, the NEISS data on products with petroleum distillates and the Commission's 43 investigative reports relied on and cited in the ANPR, cosmetic products containing petroleum distillates should not be subject to a rule mandating child resistant closures.

Respectfully submitted,



Catherine C. Beckley  
Assistant General Counsel

cc: Chairman Brown  
Commissioner Gall  
Commissioner Moore  
Dr. Barone  
Mr. Wilbur

**CTFA SURVEY FOR WRITTEN COMMENTS TO CPSC ON PETROLEUM  
DISTILLATE & OTHER HYDROCARBON ADVANCE NOTICE OF  
PROPOSED RULEMAKING (ANPR)**

**CONFIDENTIAL**

**Please note: All information collected by CTFA will be kept confidentially from other member companies and will be reviewed only by CTFA attorneys. No information provided by your company will be identified as from your company, nor will your affected brands be referenced. Therefore, please be as complete as possible in your responses, because CTFA's comment on behalf of industry will only be as good as the information collected. Thank you for filling out the survey.**

**SURVEY BEGINS HERE:**

**COMPANY NAME:** \_\_\_\_\_

**Contact person:** \_\_\_\_\_ **Phone:** \_\_\_\_\_ **Fax:** \_\_\_\_\_

**Note: Include only products currently marketed for which there is ingestion information/records**

**Questions/Information Sought by CPSC in Fed. Register Notice**

**Part 1: General**

**Note: If you require more space than is allotted for a question, please attach the rest of your response on a separate page. Identify which question you are answering on that sheet of paper.**

- 1. If there were a regulation, what, if any, should be the viscosity and/or percentage used as a threshold for requiring petroleum distillates to be in child-resistant closures?**
- 2. Should aerosol products be included in a requirement for child-resistant closures of products with petroleum distillates or other hydrocarbons? Specifically, does your company have any information on single acute exposure to aerosol products with petroleum distillates?**
- 3. Should Poison Prevention Packaging Act (PPPA) regulations extend only to petroleum distillates or should such regulations also extend to other hydrocarbons, such as benzene, toluene, xylene, turpentine, pine oil and limonene?**

4. Should restricted flow be an additional requirement for certain products? Why or why not?

**Part II: Additional Requests**

The following questions will be approached on a product-by-product basis.

**Question 1: Chemical properties of products with petroleum distillates**

**Category: BABY OIL**

FORM: Liquid: \_\_\_\_\_ Aerosol: \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

[My question: Do you use restricted flow closures for this product?

Yes \_\_\_\_\_ No \_\_\_\_\_

FORMULATION (CPSC says "include amount of each component") :

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Category: BATH OIL**

FORM: Liquid: \_\_\_\_\_ Aerosol: \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

Do you use restricted flow closures? Why? Why not?

FORMULATION (CPSC says "include amount of each component"):

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Category: EYE MAKEUP/GENERAL MAKEUP REMOVER (oil-based)**

FORM: Liquid: \_\_\_\_\_ Aerosol \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

Do you use restricted flow closures? Why? Why not?

FORMULATION (CPSC says "include amount of each component"):

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Category: BODY OIL SPRAYS**

FORM: Liquid: \_\_\_\_\_ Aerosol \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

Do you use restricted flow closures? Why? Why not?

FORMULATION (CPSC says "include amount of each component") :

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Category: SUNSCREEN/SUNTAN OIL-BASED PRODUCTS**

FORM: Liquid: \_\_\_\_\_ Aerosol \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

Do you use restricted flow closures? Why? Why not?

FORMULATION (CPSC says "include amount of each component") :

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Category: LIQUID SOAPS (mostly industrial-strength, petroleum-based)**

FORM: Liquid: \_\_\_\_\_ Aerosol \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

Do you use restricted flow closures? Why? Why not?

FORMULATION (CPSC says "include amount of each component") :

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Category: ANY OTHER PRODUCT NOT LISTED ABOVE**

FORM: Liquid: \_\_\_\_\_ Aerosol \_\_\_\_\_ Other, if so, what? \_\_\_\_\_

Do you use restricted flow closures? Why? Why not?

FORMULATION (CPSC says "include amount of each component") :

VISCOSITY \_\_\_\_\_ SUS (not Centistokes) and Percent \_\_\_\_\_

[My question: Are any of your products in this category child-resistant now?]

Yes \_\_\_\_\_ No \_\_\_\_\_

**Question 2: Users and use patterns of cosmetics with petroleum distillates or hydrocarbons**

**Category: BABY OIL**

INTENDED USE[S] (e.g., as moisturizer) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

**Category: BATH OIL**

INTENDED USE (e.g., as moisturizer) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

**Category: EYE MAKEUP/GENERAL MAKEUP REMOVER (oil-based)**

INTENDED USE[S] (e.g., as moisturizer) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

**Category: BODY OIL SPRAYS :**

INTENDED USE[S] (e.g., as moisturizer) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

**Category: SUNSCREEN/SUNTAN OIL-BASED PRODUCTS**

INTENDED USE (e.g., as moisturizer) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

**Category: LIQUID SOAPS (mostly industrial-strength, petroleum-based)**

INTENDED USE[S] (e.g., as hand cleaner) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

IS PRODUCT USED BY CONSUMERS [IN HOME] OR ONLY IN HOME BY WORKERS FOR REPAIR OR CLEANING? [REPAIR USE LIKELY NOT APPLICABLE TO COSMETICS]

**Category: ANY OTHER PRODUCT NOT LISTED ABOVE**

LIST PRODUCTS \_\_\_\_\_ (If you need more room, attach sheet)

\_\_\_\_\_

INTENDED USE[S] (e.g., moisturizer) :

LOCATION OF USE (e.g. bathroom, kitchen) :

HOW LONG IS PACKAGE KEPT IN HOME (average/estimate) :

LOCATION OF STORAGE, WHEN NOT IN USE :

IS PRODUCT USED BY CONSUMERS [IN HOME] OR ONLY IN HOME BY WORKERS FOR REPAIR OR CLEANING? [REPAIR USE LIKELY NOT APPLICABLE TO COSMETICS]

**Question 3: Current Packaging & Labeling**

**Category: BABY OIL**

***Describe current packaging:***

1. Packaging sizes :
2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

1. Any warnings?
2. Any instructions for use?

**Category: BATH OIL**

***Describe current packaging:***

1. Packaging sizes :

2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

1. Any warnings?
2. Any instructions for use?

**Category: EYE MAKEUP/GENERAL MAKEUP REMOVER**

***Describe current packaging:***

1. Packaging sizes :
2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

1. Any warnings?
2. Any instructions for use?

**Category: BODY OIL SPRAYS**

***Describe current packaging:***

1. Packaging sizes :
2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

***Describe current packaging:***

1. Packaging sizes :
2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

1. Any warnings?
2. Any instructions for use?

**Question 4: Economic Information**

**Category: BABY OIL**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**Category: BATH OIL**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**Category: EYE MAKEUP/GENERAL MAKEUP REMOVER (oil based)**

1. Any warnings?
2. Any instructions for use?

**Category: SUNSCREEN/SUNTAN OIL-BASED PRODUCTS**

***Describe current packaging:***

1. Packaging sizes :
2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

1. Any warnings?
2. Any instructions for use?

**Category: LIQUID SOAPS (mostly industrial-strength, petroleum-based)**

***Describe current packaging:***

1. Packaging sizes :
2. Container material :
3. Closure material :
4. Closure design :
5. If child resistant package, ASTM classification :

***Labeling:***

1. Any warnings?
2. Any instructions for use?

**Category: ANY OTHER PRODUCT NOT LISTED ABOVE**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**Category: BODY OIL SPRAYS**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**Category: SUNSCREEN/SUNTAN OIL-BASED PRODUCTS**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**Category: LIQUID SOAPS (mostly industrial-strength, petroleum-based)**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**Category: ANY PRODUCT NOT LISTED ABOVE**

Range of wholesale & retail prices?

Expected cost of Providing Child-Resistant Packaging for This Product?

Potential impact that Child-Resistant Packaging Requirement would have on your business, especially small business?

**VERY IMPORTANT !!!**

**Question 5: Incident Information**

Any ingestion incidents known to your company?

**Baby oil** — Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Estimated number of units sold yearly: \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

---

Any ingestion incidents known to your company?

**Bath oil** — Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Estimated number of units sold yearly: \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

---

Any ingestion incidents known to your company?

**Eye Makeup/General Makeup Remover (oil-based)** — Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Estimated number of units sold yearly: \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

-----

Any ingestion incidents known to your company?

**Body oil sprays** --- Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Estimated number of units sold yearly: \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

-----

Any ingestion incidents known to your company?

**Sunscreen/Suntan Oil-Based Products** --- Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Estimated number of units sold yearly: \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

-----

Any ingestion incidents known to your company?

**Liquid Soaps (mostly industrial-strength, petroleum-based)** Yes \_\_\_\_\_ No \_\_\_\_\_  
If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

-----

Any ingestion incidents known to your company?

**Other Products Not Listed Above**

Type of Product: \_\_\_\_\_

Any incidents? Yes \_\_\_\_\_ No \_\_\_\_\_ If yes, how many? \_\_\_\_\_ When? \_\_\_\_\_

Estimated number of units sold yearly: \_\_\_\_\_

Outcome of each case, if any:

How long has this product been marketed?

**END OF SURVEY**

**If you have additional comments, please add below:**

2 MAY 1997

1. TASK NUMBER 970304HCC9033		2. INVESTIGATOR'S ID 8938		EPIDEMIOLOGIC INVESTIGATION REPORT
3. OFFICE CODE 830	4. DATE OF ACCIDENT YR MO DAY 96 08 30	5. DATE INITIATED YR MO DAY 97 04 02		
6. SYNOPSIS OF ACCIDENT OR COMPLAINT A one year old male died from aspiration of baby oil which resulted in hydrocarbon (mineral oil) pneumonitis. The child was lying in a bed next to a television. The mother, who had just changed the baby's diaper, placed a 16 ounce bottle of baby oil on the television next to the bed where the child was lying. She left the room and went downstairs. When she returned, she found her son on the floor lying on his back in a puddle of baby oil. He had ingested approximately 10-14 ounces of baby oil.				
7. LOCATION (Home, School, etc.) Women's Shelter Home 51		8. CITY Alton		9. STATE IL
10A. FIRST PRODUCT Baby Oil 1915		10B. TRADE/BRAND NAME Unk.		10C. MODEL NUMBER Unk.
10D. MANUFACTURER NAME AND ADDRESS Unk.				
11A. SECOND PRODUCT N/A		11B. TRADE/BRAND NAME		11C. MODEL NUMBER
11D. MANUFACTURER NAME AND ADDRESS N/A				
12. AGE OF VICTIM 212	13. Sex Male-1		14. DISPOSITION Expired in Hospital-8	15. INJURY DIAGNOSIS Poisoning-68
16. BODY PART (S) INVOLVED All Parts Of Body 85	17. RESPONDENT Medical Examiner's Office-3		18. TYPE OF INVESTIGATION On-Site-1	19. TIME SPENT (OPERATIONAL HOURS) 8.0
20. ATTACHMENT(S) Medical Examiner's Report-2	21. CASE SOURCE MECAP - 12		22. SAMPLE COLLECTION NUMBER NONE	
23. PERMISSION TO DISCLOSE NAMES (NON NEISS CASES ONLY) CPSC MAY DISCLOSE MY NAME- CPSC MAY NOT DISCLOSURE MY NAME-XX				
24. REVIEW DATE 5-19-97	25. REVIEWED BY 8130		26. REGIONAL OFFICE DIRECTOR	
27. DISTRIBUTION				

CPSA 6 (b)(1) Cleared

No Mfrs/Prvtlbls ID

CPSC FORM 182 (REVISED 10/93) Products Identified

FORM NO. 3041-0029

2AC/ Excepted by  
Firm Notified,  
Processed

28 MAY 1997

970304HCC9033

### SYNOPSIS

A one year old male died from aspiration of baby oil which resulted in hydrocarbon (mineral oil) pneumonitis. The child was lying in a bed next to a television. The mother who had just changed the baby's diaper placed a sixteen ounce bottle of baby oil on the television next to the bed where the child was lying. She left the room and went downstairs for short time. When she returned, she found her son, on the floor, lying on his back, in a puddle of baby oil. He had ingested approximately ten to fourteen ounces of baby oil.

### PRE-INCIDENT

The information presented in this in-depth investigation is very limited and came only from the medical examiner's office, even though the site where the incident occurred was visited by this investigator.

A trip was made to the shelter home where the mother and one year old male child had stayed, but they had left to live in another state. The woman in charge was very reluctant to give out any information that was not already obtained.

The mother, and her one year old son, were living in a shelter for women. Because of limited information, it could not be determined if the child had been ill and taking medication, or if he had any physical abnormalities.

### INCIDENT

The mother and her son were living upstairs at the shelter. She had been changing the baby's diaper so she put the bottle of baby oil on a TV next to the bed where the child was lying. The mother stated that she went downstairs to the kitchen on the second floor for a couple of seconds. When she returned to her bedroom she noticed that the victim was lying on the floor on his back covered with baby oil. Other creams and clothing which also were on the floor. The baby had ingested approximately ten to fourteen ounces of baby oil and had aspirated it into his lungs.

### POST-INCIDENT

The victim was taken to a local hospital that afternoon in Illinois and, later that evening, transferred to a children's hospital in Missouri. The victim was placed on Extracorporeal Membrane Oxygenation until his death twenty three days later. The cause of death was chemical pneumonitis caused by aspiration of the baby oil.

POST-INCIDENT CON'T

According to the St. Louis City Medical Examiner report, the Women's Shelter filed a complaint three days later with the Division of Family Services Hotline against the mother for "inadequate supervision". The report states that the mother did not have any prior charges for child neglect in the state of Illinois. It goes on to say that she had a history of drug abuse and neglect in the state of Missouri and that she had other children which had been taken away from her in Missouri because of neglect.

PRODUCT INFORMATION

The product involved in this incident was baby oil contained in a sixteen ounce "flip top type" plastic bottle. The bottle had two ounces of oil remaining in it when it was recovered. Many attempts were made by this investigator to obtain the bottle, but to no avail. The mother has left the area, and the hospital could not provide any information due to confidentiality restrictions. It was stated in the report that the mother was "on the run" from the Division of Family Services in Missouri. The mother of the deceased did not know when or where she purchased the bottle. No other information was available on the bottle.

STANDARDS INFORMATION

No standards information was available on this sixteen ounce baby oil plastic flip top bottle.

ATTACHMENTS

1. Medical Examiner's Report

IDI 970304HCC 9033 - Attachment #1-1/6

St. Louis City Medical Examiner

Case Type: BR

Day: Monday

Date: 09/23/96

Time: 10:45 AM

Case No.: 96-2031

Received From: [REDACTED]

Phone No.: 577-5600

Notifying Agency/Institution: [REDACTED]

Children's Hospital

DECEASED [REDACTED]

Phone No. : [REDACTED]

Race: Black

Sex: Male

Age: 1 years

DOB: 07/12/95

Marital Status: Never Married

SSN: [REDACTED]

Address: [REDACTED]

City: Alton

State: IL

Occupation: Pre-School Age Child

Zip: 62202

Next of Kin: [REDACTED]

Phone No.: [REDACTED]

Address: [REDACTED]

City: Alton

State: IL

Relationship: Mother

Zip: 62202

Notified: 09/23/96

By: [REDACTED]

Police Agency: No Police Involved

During App/Cust?

	Date	Time	Location	By
Illness	08/30/96	04:15 PM	[REDACTED] Alton, IL (62202)	
Pronounced	09/23/96	10:31 AM	[REDACTED] Children's Hospital (IN-PT)	Physician: [REDACTED]

Manner of Death: Accident

Type of Death: Asphyxia: Other Asphyxia: Aspiration of oil;

How Injury Occurred: Suffocation

Injury at Work: No

Premises: Miscellaneous: Shelter for women

Deaths Associated with Incident: No Other Deaths Associated with Incident

Activity of Decedent: Lying Down [Reclining]

Depth of Investigation (Investigator): Telephone

Pathologist: No Pathologist Involved

Death Certificate Signed By: St. Louis City Medical Examiner

Date: 11/08/96

Records Being Sent From: [REDACTED]

Notes:

Investigator: [REDACTED]

Printed: 11/21/96 at 09:34 AM

St. Louis City Medical Examiner

Case Type: BR  
Case No.: 96-2031

IDI 970304HCC 9033 - Attachment # 1-216

X-Rays Requested: None

Case Disposition: Death at hospital resulting from apparent other than natural causes, remains released but Medical Examiner case. Family has granted permission for hospital to perform postmortem examination.

Livery Service: Remains Not Brought In

Disposition of Remains: Private Burial  
Date Body Released: 09/23/96//11:08 AM to: Family  
Funeral Home: [Redacted] Undertaking Co. (W. Floris.)

Person Notif.: [Redacted]  
Address: 474 [Redacted] St, St. Louis, MO 6311 Phone No.: [Redacted]

Arrangements Made? Yes

Remains Identified By: Visual Identification at the Hospital

Who Made the Identification: [Redacted] H Phone: [Redacted]  
Address: [Redacted] Alton, IL 62202 B Phone: ( ) -

Relationship: Mother. Date/Time: 09/23/96//10:30 AM

ICD Code: (E866.8) Accidental poisoning by other and unspecified solid and liquid substances; Other specified solid or liquid substances

Cause of Death Hierarchy:

Immediate Cause: Complications of Hydrocarbon (mineral oil) pneumonitis

Due to or as a consequence of (b): \_\_\_\_\_

Due to or as a consequence of (c): \_\_\_\_\_

Due to or as a consequence of (d): \_\_\_\_\_

Other Significant Conditions: \_\_\_\_\_

Notification: Mid-America Transplant. Association at 367-6767: No

Notes: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Long-Distance Telephone Calls Log:

Date	Caller Phone #	Name Called	Notes	City Called
__/__/__	( )	_____	_____	_____
__/__/__	( )	_____	_____	_____

St. Louis City Medical Examiner

Main Narrative Report:

[REDACTED] Memorial Hospital, contacted this office at 10:45 a.m., 09/23/96 reporting the death of [REDACTED] b/m 1 year.

[REDACTED] stated that the deceased was originally hospitalized at [REDACTED] Hospital, Alton, Illinois on 08/30/96 and then transferred to [REDACTED] the same day. The deceased had aspirated baby oil while at home and was taken to the hospital at 4:15 p.m., 08/30/96.

[REDACTED] stated that in reading from the original admitting notes the deceased was found lying on the floor covered with baby oil. Near the child was a 13 ounce bottle of baby oil with approximately two (2) ounces remaining. The mother was unable to state how much was last seen in the bottle or when she purchased the bottle of oil. The floor and baby were both covered with the oil, which was on the floor with other diaper creams and clothing.

The infant was placed on an Extracorporeal Membrane Oxygenation until his death this date.

[REDACTED] stated that the child had no other unusual or questionable marks on admission and that doctor's found nothing suspicious during the hospitalization. The family had granted permission for a limited autopsy (heart and lungs) at [REDACTED]

I notified [REDACTED] Chief Medical Examiner of these circumstances and he advised that the hospital could perform the autopsy with this office to sign the death certificate.

I notified [REDACTED] of the same and requested copies of the medical records from [REDACTED] and [REDACTED] Hospital via written requests (see attached copies).

I also requested copies of the autopsy findings.

On contacting the Alton Police Department, [REDACTED], I spoke with [REDACTED] Detective Bureau - Alton PD, who denied that his office was ever made aware of the original incident. [REDACTED] went on to say that the home address shown by the hospital was the Oasis Shelter for Women.

I next contacted the Division of Family Services, Child Abuse Hotline for Illinois, [REDACTED] and spoke with M. [REDACTED]. [REDACTED] later notified me that the [REDACTED] Women Center had filed a report to the State Central Registry on 09/03/96. The report was taken as an "inadequate supervision" and was given the report number of [REDACTED] and was to be handled by [REDACTED] with Madison County.

Otherwise no prior reports were on file for the family and it appeared

Main Narrative Report:

that the deceased was the only child for [REDACTED]

A message was later left at the [REDACTED] Office, [REDACTED] for Mr. [REDACTED] to contact this office.

I later spoke with Admitting at [REDACTED] and advised that the remains were released with this office to sign the death certificate.

[REDACTED] later contacted this office on the afternoon of 09/23/96 and advised that someone would be assigned the investigation but that it would probably be some time in putting together information due to the length of time that has expired.

IDI 970304HCC9033

Attachment #1-416

[REDACTED]  
Medico-Legal Investigator

Supplemental Report:

IDI 970304HCC 9033  
Attachment #1516

On 9/23/96 at 1615 hrs., I received a call from

[REDACTED]  
Child Protective Investigator  
Illinois  
(Division of Family Service)  
[REDACTED]

who was returning a call from [REDACTED]

He said that he had a report on the child, [REDACTED]  
since 8/31/96. It was called in on the hotline.

He said that the mother and child were living in the shelter. The mother told [REDACTED] that she had been changing the child's diaper and put the bottle of baby oil on a TV next to the bed.

The child was on the bed next to the TV.

He said that the mother left the bottle there and the child on the bed; she went downstairs to the kitchen on the 2nd floor.

She told [REDACTED] that the child was awake on the bed when she left him. He said she went down to the kitchen on the 2nd floor. He said that it was well out of sight and sound of the baby.

She told him she was gone for a couple seconds and then came back upstairs.

She found the child on the floor on his back. The bottle of baby oil was beside him and there was a puddle of baby oil on the baby and floor.

It was a 16 oz. bottle of baby oil and was a new bottle according to the mother.

The baby was taken to [REDACTED] Hospital in Alton, IL.

He said that the hospital estimated that the baby swallowed 10 to 14 oz. of the baby oil and aspirated it into his lungs.

He was taken to [REDACTED] where some experimental procedures were taken to try to save the child.

[REDACTED]  
St. Louis City Medical Examiner

Case No.: 96-2031

Supplemental Report:

*IDI 970304 HCC 9033*  
*Attachment #1-616*

He said that the bottle of baby oil was a flip top type of bottle and that the child could have opened it himself.

He said that the mother has a history of drug use and neglect. He indicated that he believed the mother was "on the run" from the Division of Family Services in MO (St. Louis City.)

He said that the DFS in MO indicated she had other neglect charges at different times. As he understands it, one child is with a relative; one child is in custody of the MO DFS at a relatives and other children that she has had have been given away to other people.

He said that he will be calling the Alton PD back but that there would most likely be some type of neglect charges being filed against the mother in the case.

His report is [REDACTED] and he said he will forward his hotline report to this office.

He said that the deceased was believed to have been born in MO.

I contacted [REDACTED] Hospital and the child had not been born there.

I contacted Regional Hospital and the clerk said that the baby had been born there. She said she would send the birth record over after receiving a fax authorization from our office.

I then faxed her a copy of a request.

No further.

[REDACTED]  
Medico-Legal Investigator

St. Louis, MO

CH10

ACCIDENT INVESTIGATION REQUEST FORM 324a

DOCUMENT NUMBER X96C0820A

DATE OF INCIDENT 04 August 1996

CATID CHNN01

FOLLOW-UP REQUESTED

HAZARD ANALYSIS (x)  
SEC.15 ( )

TYPE OF FOLLOW-UP

TELEPHONE ( )  
ON-SITE (x )

HEADQUARTERS CONTACT Susan Aitken (301) 504-0477 X1195

ASSIGNMENT MESSAGE

Use attached telephone questionnaire for hydrocarbon poisonings. If a CR closure was involved, and there is an indication of container failure, collect sample and forward to Chuck Wilbur, HSPS, for evaluation. If treated at emergency room, determine type of treatment. If fatal, collect medical records and all official documentation.

Person to contact

Task Number 970304HCC9033

Date 04 Mar 1997

Assigned to CH10

Requested by Susan Aitken

TK-32

S-05

Medical Examiner and Coroner Alert Project (MECAP)

St. Louis City Medical Examiner's Office

1300 Clark

St. Louis, Mo. 63103

Phone: 622-4971 Fax: 622-4933

X96C0820

M.E. Case Number: 96-2031 Age: 1 Sex: B Race: M

Date of incident: 8/30/96 Date of death: 9/23/96

Accident Involves: Aspiration of baby oil 1915

Circumstances: One year old child left alone in floor with diapers, cream, and bottle of baby oil. Mother returned after several minutes to discover the child covered with baby oil. The death was attributed to pneumonia secondary to hydrocarbon ingestion.

Submitted by:

[Redacted signature]

Investigator

ISSUE 13 -

For:

[Redacted signature]

Chief Medical Examiner

DEC 26 1996

CPSA 6 (b) *1/2/98*  
No Mfrs/Prvt/bks or  
Product Identified  
Excepted by *MPA*  
Firms Notified,  
Comments Processed.

*CP 11-5-98*

**C T F A**  
THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION  
1101 17TH ST, N.W., SUITE 300 WASHINGTON, D.C. 20036-4702

December 15, 1998

Suzanne Barone, Ph.D.  
Directorate of Epidemiology and Health Sciences  
U.S. Consumer Product Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

Dear Dr. Barone:

The following comments are submitted on behalf of interested members of The Cosmetic, Toiletry, and Fragrance Association<sup>1</sup> at the request of the agency at a November 18 public meeting with affected industries to discuss household products containing petroleum distillates/hydrocarbons and child-resistant packaging.

### I. Cosmetics Should be Excluded from the Hydrocarbon Rulemaking

CTFA strongly believes that cosmetic products should not be subject to this rulemaking based on a thorough survey of companies' product incidents. Our 1997 comments to CPSC demonstrated that the companies that manufacture these products rarely encounter ingestions, much less aspirations. (See CTFA Comments to CPSC on ANPR regarding Petroleum Distillates (September 1, 1997)) These CTFA member companies work with the top Poison Control Centers in the country, publicize their consumer information 800 number and take extensive measures to ensure that their products are safe on an on-going basis.<sup>2</sup>

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<sup>1</sup> CTFA, founded in 1894, is the national trade association for the personal care products industry. CTFA members consist of approximately 275 active member companies that manufacture or distribute the vast majority of cosmetic products in the United States. CTFA also represents approximately 275 associate members that provide goods and services such as ingredients and packaging to the cosmetics industry.

<sup>2</sup> CTFA planned to submit an analysis of product category incident data from the American Association of Poison Control Centers (AAPCC) to demonstrate further that cosmetics should be excluded from this rulemaking. However, since late October-early November, the AAPCC did not respond to CTFA's requests for data. This data was obtained by CPSC earlier from the AAPCC, but the agency has not made this data available to the public. Therefore, the fact that essential incident data which the agency is relying on in this investigation was unavailable to CTFA until a few days ago has put us at a significant disadvantage in filing these comments.

Therefore, CTFA proposes that only "hazardous products" as defined by the Federal Hazardous Substances Act (FHSA) be subject to a CRC requirement for hydrocarbons. It was mentioned by CPSC staff at the November 18 public meeting with industry that the purpose of the present investigation into hydrocarbons was to bring internal consistency between the FHSA labeling requirements for products containing hydrocarbons and the Poison Prevention Packaging Act (PPPA) packaging requirements for the same products.<sup>3</sup>

Currently, all applicable products containing 10% by weight of petroleum distillates are considered hazardous and therefore must bear certain warning statements on their packaging under the FHSA. However, only some of these same products are required to have CCS under the PPPA. At this time, the agency seeks to broaden the scope of the PPPA regulation to require all the products that must bear labeling under the FHSA also have child resistant closures.

Cosmetic products are specifically excluded from the jurisdiction of the FHSA. They are not part of the internal inconsistency in the current CPSC regulations that the staff is trying to remedy and should they be a part of this rulemaking. These products are not "hazardous" and do not require the CPSC-mandated warnings under the FHSA.

## II. Other Packaging Exclusions

The purpose of the November 18 meeting was to discuss "exclusions" from any future regulation that would require child-resistant closures (CCS) for household products "containing more than 10% hydrocarbon(s)\* by weight with a viscosity of less than 100 SUS at 100 degrees F." CTFA supports several exclusions suggested by CPSC staff such as "prepackaged, nonemulsion-type liquid products." CTFA also supports an exclusion for "pressurized spray containers that are expelled as a mist" because of the lack of evidence indicating an aspiration risk from such a product delivery system.

CTFA, however, proposes revised draft language relating to the scope of a future proposed rule:

***Prepackaged nonemulsion-type liquid hazardous products as defined by the Federal Hazardous Substances Act containing more than 10% hydrocarbon(s)\* by weight with a viscosity of less than 100 SUS at 100° F, must be packaged in accordance with the provisions of 1700.15(a) and (b), except for the following: (i) those packaged in pressurized spray containers that are expelled as a mist; (ii) pen-like devices distributing the product through an absorbent dispensing tip; (iii) products with a "restricted flow" orifice as defined in 1700.15(d); and (iv) products delivered as a***

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<sup>3</sup> The Advance Notice of Proposed Rulemaking described this "anomaly" as the "[v]arying scope of the Federal Hazardous Substances Act and PPPA regulations." 62 Fed. Reg. 8661 (February 26, 1997).

***non-aerosolized mist with an affixed, non-removable cap.***

In the revised draft language, CTFA thinks that delivery systems that absorb the product such as impregnated pads and absorbent tip pen-like devices should be excluded from any future regulation because they pose no aspiration hazard due to the small amount of product delivered and the fact that they do not permit the free flow of the substance. CTFA also favors an exclusion from any CRC requirement for products that meet the CPSC regulations for "restricted flow" closures.

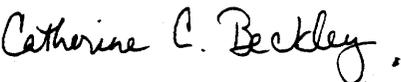
In addition, non-aerosol packages that dispense the contents as a mist should be excluded if equipped with a cap or pump affixed to the rest of the package. The rationale to exclude non-aerosol packages that dispense a mist is similar to the reason to exclude aerosols that dispense a mist -- there is not an aspiration hazard in either case to justify special packaging. Also, the means of dispensing the product for pumps or other permanently affixed caps is similar to the design of an aerosol package which also has a spray mechanism attached to the rest of the package. Therefore, because of the similarities in delivery and package function, non-aerosol packages dispensing a mist with a permanently attached top should be excluded.

In conclusion, CTFA believes a cosmetic exclusion is warranted due to a lack of incident data on aspirations of hydrocarbons by children under 5 years old indicating a need for special packaging. Also, in this comment, CTFA submitted draft regulatory language aimed at addressing the staff's desire to exclude those product delivery systems or packaging components that make aspiration extremely remote.

Since receiving the AAPCC data last week, CTFA is having it reviewed by an outside expert, but it was not possible to do a thorough job in such a short time for purposes of this comment. Therefore, CTFA respectfully requests that we be granted permission to submit an analysis of the data, if appropriate, at a later date before a briefing package is submitted to the Commission.

Thank you for consideration of our comments.

Respectfully submitted,



Catherine C. Beckley  
Associate General Counsel

cc: Chairman Ann Brown  
Commissioner Mary Sheila Gall  
Commissioner Thomas Moore