



6/18/01
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United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE : June 18, 2001
TO : HS
Through: Todd A. Stevenson, Acting Secretary *TAS*
FROM : Martha Kosh
SUBJECT: Notice of Additional Hydrocarbon Data
ATTACHED ARE COMMENTS ON THE CP 01-3

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CP 01-3-1	4/12/01	Michelle Lee	Bryn Mawr College C-1408 Bryn Mawr, PA 19010
CP 01-3-2	5/10/01	Heidi McAuliffe Counsel, Govern- ment Affairs	National Paint & Coatings Association, Inc. 1500 Rhode Island Ave, NW Washington, DC 20005
CP 01-3-3	5/11/01	Ann McCulloch Manager	Automotive Chemical Manufacturers Council 1225 New York Ave., NW Suite 300 Washington, DC 20005
CP 01-3-4	6/18/01	Catherine Beckley Assoc General Counsel	The Cosmetic, Toiletry, and Fragrance Association 1101 17 th St, NW, Suite 300 Washington, DC 20036

Hydrocarbon
Comment

SECRETARY
DIVISION
4b

Michelle Lee
Bryn Mawr College
C-1408
Bryn Mawr, PA 19010
April 12, 2001

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

Dear Sir/Madam,

I am writing in response to the notice of data availability that was published in the Federal Register of April 11, 2001, regarding the proposed rule for child-resistant packaging requirements. After reviewing the information regarding the additional purchase of data for cosmetic products from the AAPCC, I express my concern for the lack of information for determining the beauty products that fall under the proposed rule for child-resistant packaging. The CPSC admits that even after the purchase of this additional data for brand name beauty products, it has yet to determine the eligibility for 222 products. I regard this an astonishing number considering that it has only determined that 30 products that qualify under the proposed rule.

From the notice of proposed rulemaking (16 CFR 1700), it is clear that the range of viscosities for each beauty product in a single category can vary significantly from one product to another. This fact demonstrates that identifying *all* criteria-meeting products in each category is vital for striving toward the objective of protecting children from injury from products that contain low-viscosity hydrocarbons. Thus I suggest that the CPSC purchase further information to decipher which of the 222 beauty products fall under the parameters for child-resistant packaging. I believe that it is in the interest of both consumers and the Committee to consider this suggestion seriously. Thank you.

Sincerely,



Michelle Lee

May 10, 2001

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

Re: Notice of Additional Hydrocarbon Data

Dear Sir or Madam:

This letter is submitted in response to the Commission's Notice of Data Availability regarding the brand name-specific data on exposure to possible hydrocarbon-containing cosmetics.

The National Paint & Coatings Association, Inc., (NPCA) is a voluntary, non-profit industry association of over 400 member companies which manufacture consumer paint products, industrial coatings or the raw materials used in their manufacture. NPCA represents approximately 95% 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.

Our review of the staff analysis of the brand name-specific data on exposure to possible hydrocarbon-containing cosmetics indicates that none of the products were aerosols, but rather, were products in liquid form. For instance, there were seven fatalities of children under five years of age following aspiration of products known to contain hydrocarbons. The products involved in these incidences include a home-made cleaning product, motor oil, hair oil, baby oil, and a hair moisturizer product.

We believe that this data further supports the argument that aerosol products, and particularly aerosol paint products, should be exempt from any requirement for child-resistant packaging due to the unique characteristics of the aerosol delivery system. An aerosol can is hermetically sealed and its contents can only be accessed if it is properly actuated. In addition, the product is dispelled in a fine, atomized mist which is virtually impossible to collect. Further discussion of these points can be found in our earlier comments on this rulemaking.



NPCA urges CPSC to exempt aerosol paint from this rulemaking because the AAPCC TESS data does not indicate that aerosol products are involved in pediatric aspiration cases which result in injury.

Respectfully submitted,



Heidi K. McAuliffe
Counsel, Government Affairs



Hydrocarbon
Comments
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Automotive Chemical Manufacturers Council

A Product Line Group of
Motor and Equipment
Manufacturers Association

1225 New York Avenue, NW
Suite 300
Washington, DC 20005
Phone: 202 / 393-MEMA
Fax: 202 / 737-3742

May 11, 2001

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

2001 MAY 11 P 2:09
OFFICE OF THE SECRETARY
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Re: Notice of Additional Hydrocarbon Data

Dear Sir or Madam:

The Automotive Chemical Manufacturers Council (ACMC), a product line group of the Motor & Equipment Manufacturers Association, represents nearly 50 manufacturers of chemical products used in, on, or in connection with, all types of motor vehicles and related service and maintenance equipment. Our members offer the following comments on the proposed regulations regarding child-resistant packaging for hydrocarbon-containing products.

ACMC members support the Consumer Product Safety Commission (CSPC) in its efforts to further promote and protect the health and safety of our nation's children. However, as discussed in our earlier letter of December 14, 2000, on this notice of proposed rulemaking, we do not believe that aerosol products should be included in the proposed regulation, and we believe that the spray rate currently proposed as an indicator for products to be regulated improperly targets automotive-related products, possibly the least likely of all consumer products to be used inside the home and accessed by children. Finally, as the examination of the CSPC data announced in the April 11, 2001 Federal Register notice indicates, the agency is basing its understanding of children's exposure to all household products on cosmetics, products far more likely than automotive products to fall into children's hands. See 66 Fed. Reg. 18738 (listing categories of (miscellaneous nail products; sunscreen and suntan preparations; bubble bath and bath oil; and creams, lotions and makeup).

The data reported in the April 11, 2000 Federal Register notice supports our position on these matters. First, the Federal Register announcement did not make clear that any of the injuries discussed involved aerosols. Those discussed appeared to be in liquid form. Second, the instances of exposure appeared to often involve very young children, who would not often come in contact with automotive aerosols. Commercial and industrial consumers constitute the primary markets for aerosol engine degreasers, carburetor cleaners, aerosol adhesives, and other automotive maintenance and repair products. Children

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never come in contact with the vast majority of these products, because they are not purchased by individuals or brought into the home or garage. The category to be impacted most by this proposal should not be regulated based on data from products with completely different exposure patterns.

If aerosols are to be included in the proposed regulation, the methodology that determines which products will be affected must reflect the realities of aerosol propellant chemistry. The proposed test method measures an aerosol product's total discharge of hydrocarbon, not the amount of liquid that a child could ingest. This proposal does not allow for the dissipation of hydrocarbon propellant, which, due to its chemical structure, cannot be ingested, no matter how close to her mouth a child may spray the product.

Based on the arguments set forward in this letter, and our earlier letter of December 14, 2000, we would urge CSPC not to include aerosol products in its proposed regulation. We do not believe that aerosols pose a threat of aspiration to children, but due to a lack of access, automotive aerosol products would present even less potential for aspiration than other household aerosol products. If CSPC chooses to include aerosols, however, the test method for inclusion must recognize the chemical characteristics of hydrocarbon propulsion in aerosol products that pose no risk of aspiration.

We appreciate the opportunity to comment and look forward to working with CSPC on this issue. If there are any questions, or if additional information is required, please contact me at (202) 393-6362.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann McCulloch". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Ann McCulloch
ACMC Manager

CP01-3-4 Hydrocarbon Comment

C T F A

HAND DELIVERY

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

June 18, 2001

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

Mr. Todd A. Stevenson
Acting Secretary
Office of the Secretary
U. S. Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, MD 20814

2001 JUN 18 10 35 AM
U.S. CONSUMER PRODUCT SAFETY COMMISSION

RE: Household Products Containing Hydrocarbons;
Notice of Data Availability and Request for Comments
66 Fed. Reg. 18738 (April 11, 2001)

Dear Mr. Stevenson:

The Cosmetic, Toiletry, and Fragrance Association (CTFA) appreciates the opportunity to comment on the staff analysis of the additional hydrocarbon exposure incident data on mineral-oil-based cosmetic products. The data was purchased by the agency subsequent to the promulgation of the Notice of Proposed Rulemaking (NPR) to require child-resistant packaging for household products and cosmetic products containing ten percent or more hydrocarbons with a viscosity less than 100 Saybolt Universal Seconds (SUS). The data was deemed necessary by two of the Commissioners who voted to propose the NPR because the staff could not determine from the earlier data it had purchased from the American Association of Poison Control Centers (AAPCC) how many of the ingestion incidents from four general cosmetic categories involved mineral-oil-based cosmetics that would be subject to the rule proposed by the Commission.

Introduction

This is the fifth comment CTFA has submitted for the record expressing our concerns about the scope of the rulemaking since the Advance Notice of Proposed Rulemaking was published in February, 1997. Attached to this CTFA comment are the three reports upon which CTFA's comment is based. Richard Kingston, PharmD, CSPI, Stephen Borron, MD, MS, FACEP, DABMT, and Leo Sioris, PharmD, professors at various universities and principals in Prozar International Poison Center, reviewed the staff analysis of the data and point out their concerns with the utilization of the data. Dr. Suman Wason, a Board Certified Pediatrician and former Director of the Cincinnati Drug & Poison Control Center, provides his perspective on the two incidents involving cosmetic products that fall within the scope of the proposed rule. Edward

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SECURING THE INDUSTRY'S FUTURE SINCE 1894

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J. Heiden, PhD, President of Heiden Associates and former Director of Strategic Planning at the U. S. Consumer Product Safety Commission (CPSC), reports on his assessment of the contribution of mineral-oil-based cosmetic products to the overall levels of fatalities and injuries associated with ingestion and related exposures.

CTFA is the national trade association for the personal care products industry. Founded in 1894, CTFA has an active membership of approximately 300 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States. CTFA also represents approximately 300 associate companies including manufacturers of raw materials and packaging.

The Staff Analysis Is Incomplete

In December 1999, the Commissioners approved a plan proposed by the staff to purchase 1998 brand-specific data from the AAPCC. The CPSC staff wrote that “[i]dentification of specific brand name cosmetic products would provide more information about the cosmetic products that are being ingested and aspirated by children under five years of age.”¹ However, the staff noted that the brand name identification obtained from the AAPCC does not identify the percent of mineral oil in the product or its viscosity. Therefore, in order to determine whether a cosmetic product involved in an ingestion incident obtained from the AAPCC falls within the scope of the proposed rule, the staff would have to either perform a laboratory analysis or request it from the manufacturer. Cognizant of the burden that testing so many products would place on the CPSC laboratory, CTFA initiated several conversations with CPSC staff regarding the purchase of this data and how CTFA might be of assistance in obtaining formulas from its member companies. It was our understanding that this effort would be a cooperative one. Indeed, Ron Medford of CPSC was quoted as saying that “it will be decided later whether it [the agency] will request product formula information from the manufacturers or do its own analysis of the products.”²

The CPSC staff never responded to any of CTFA’s proposals on ways to assist the staff in determining which of the products involved in an AAPCC ingestion/aspiration incident fell within the scope of this rulemaking. In the March 27, 2001 briefing package setting forth its analysis of the data, the staff said that of the 2,301 products involved in the 31,365 ingestion incidents, it was

¹ CPSC Staff Memorandum dated Feb. 4, 2000, p. 2.

² Bureau of National Affairs, Product Safety & Liability Reporter at p.153, February 21, 2000.

able to identify³ 30 products as falling within the scope of the rule. It was able to eliminate 2,049 products as falling outside the scope of the rule. For 224 products, it was unable to make a determination as to whether these products were inside or outside the scope of the proposed rule. Despite the fact that CTFA stood ready to assist with that determination, the staff proceeded to combine the 224 unknown products with the 30 known products and base their analysis on the combined number.

Consequently, the staff analysis does not provide sufficient specific injury data information on mineral-oil-based cosmetic products that would be subject to the proposed rule to address the concerns raised by the Commission. The incident data reported by the staff are biased by the significantly larger number of unknown products (224/30) versus known products (30/224). This brings the reliability of the entire staff analysis into question.

The Staff Analysis Is Flawed

The principals in the Prozar International Poison Center reviewed both the April 11, 2001 Federal Register notice as well as the March 27, 2001 briefing package. They expressed surprise at several of the data analyses that the staff had performed on the Toxic Exposure Surveillance System (TESS) data, with which they are intimately familiar as they have been contributing members of the AAPCC. They point out again that the data in the TESS database is non-specific and therefore does not lend itself to the detailed assumptions made and the conclusions drawn by the staff in its analysis. This is especially true since there was no attempt to validate any of the individual cases or a representative sample of cases contained in the analysis. It is their opinion that an appropriate use of this data would have been to generate a "hypothesis" and then test and validate the hypothesis before drawing any conclusions.

Another issue that attracted their attention was the inclusion of the medical outcome category of "unknown potentially toxic exposure" in the analysis as representing a "serious" outcome. It has been their experience that there are a wide variety of circumstances in which a poison specialist would utilize this classification. Based on their experience, they do not believe that it is appropriate to use this "unknown" category for regulatory or scientific decision-making.

Prozar also points out that the inherent limitations of the TESS data are so well known that the editors of three major medical journals that publish in the area of clinical toxicology recently

³ The March 27, 2001 Briefing Package does not state how the staff made that determination, i.e., laboratory testing or manufacturers' formulations. It does state that the staff assumed that all baby oil would fall within the scope of the rulemaking because prior testing showed viscosities below 100 SUS, unless it was in a gel or lotion form. Presumably, none of the baby oil incidents that resulted from the ingestion or aspiration of baby oil gels or lotions were included in this analysis.

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explained that they will not accept articles representing retrospective reviews of aggregated TESS data upon which to base toxicological decision making. Other authors have also drawn the same conclusion as cited in Prosar's letter. At most, the TESS data is a useful screening tool and hypothesis generator. In their professional opinion as poison control experts, it should not form the basis for regulatory action.

At best, Prosar concludes that the data demonstrates once again that reported exposure to mineral-oil-based cosmetic products is common and that reported serious outcomes from the ingestion or aspiration of these same products are rare. They urge the Commissioners to grant an exclusion for mineral-oil-based cosmetics as previously requested.

The Staff Conclusion Is Not Valid

CTFA agrees with the staff that the data demonstrates that children can access mineral-oil-based cosmetic products in the home along with thousands of other products. The CTFA disagrees with the staff that the data supports the conclusion that if children can access mineral-oil-based cosmetic products, then serious injury can result. The data, both those derived from CPSC and those derived from other sources, point to the opposite conclusion. Despite widespread exposure to mineral-oil-based cosmetic products, the data demonstrate that these products are involved in very few aspirations that result in serious injury.

The Heiden report reviewed the 1998 data from the National Center for Health Statistics (NCHS), the CPSC death certificate database for 1996-1999, the NEISS injuries in the "Other Poisonings" category for 1997-1999, and the 1998 AAPCC data for four cosmetic categories. It also performed an exposure-adjusted fatality risk comparison with recognized risk prevention standards used by Federal Aviation Administration (FAA) and the Department of Defense (DOD). The Heiden Associates' analysis leads to the conclusion that the level of risk associated with mineral-oil-based cosmetic products is well below that which constitutes a reasonable target for regulatory action under the PPPA.

The data from the National Center for Health Statistics show that there are relatively few (36 out of 62) poisoning fatalities involving children under five that were deemed to be accidental. None (0) of those few poisonings involved products in the NCHS cosmetics category. In contrast, there were 2,500 accidental deaths in 1998 involving children under five from other, non-poisoning causes.

The data from the CPSC Death Certificate File show that there have been two fatalities involving baby oil ingestions by children under five during the period 1996-1999. Suman Wason, M.D., FAAP, has reviewed the CPSC Epidemiologic Investigation Reports on the two fatalities. In Case No. 970902HCC1459, Dr. Wason notes that the cap was taken off the bottle by the mother and the open bottle was placed next to the bed on which the 12-month-old child was placed. Therefore, he concludes that a child-resistant closure would not have prevented this

fatality since the packaging of this baby oil product had nothing whatsoever to do with its availability. In Case No. 000824HEP9008, it is unknown whether the pump dispenser⁴ was on the product at the time of the incident, so Dr. Wason cannot say whether the product was available to the child because of its packaging. Moreover, he states that the facts known about this incident are not conclusory that the incident was accidental. Based on the contents of the CPSC reports and on his own clinical toxicological experience, he concludes that both incidents confirm his own experience that there is a low incidence of serious problems related to mineral-oil-based cosmetic products.

The data from the National Electronic Injury Surveillance System (NEISS) show that from 1997-1999 there were two to three cases annually that involve mineral-oil-based cosmetic products that may fall within the scope of the proposed rule. More cases were reported that involved accidental ingestion by a child under five of alcohol, tobacco or cocaine than of mineral-oil-based cosmetic products that may be covered by the proposed PPPA regulation. Dr. Heiden also noted that the number of cases reported that involved accidental ingestions of products already subject to a PPPA regulation requiring child-resistant closures exceeds those of mineral-oil-based cosmetic products that might be covered by the proposed rule.

The data from the AAPCC show that there were 476 "potential aspirations" of cosmetic products that might fall within the scope of the proposed rule. Of those 476 "potential aspirations," 116 incidents had no respiratory clinical effect, according to the AAPCC data. There were 360 incidents involving some type of respiratory effect. Of those 360 incidents, 356 had respiratory clinical effects that were likely of limited health consequence as evidenced by the small number of moderate or greater outcomes in the data. Two (2) of those 360 incidents had a respiratory clinical effect of some health consequence (hyperventilation, tachypnea, pneumonitis, positive X-Ray findings). Only 2 of those 360 incidents reported a respiratory clinical effect that could be of serious medical concern (bronchospasm). The rarity of serious medical effects from the accidental ingestion of mineral-oil-based cosmetic products explains why these products do not make a discernible impact on either the NCHS fatality data or the NEISS statistics.

Summary

CPSC prides itself on being a "data driven agency." The data that has been compiled by the staff and by the industry on the accidental ingestion of mineral-oil-based cosmetic products support the position of the CTFA that these products should be excluded from the scope of the proposed rule. Despite widespread exposure to mineral-oil-based cosmetic products, the data demonstrate that these products are involved in very few aspirations that result in serious injury.

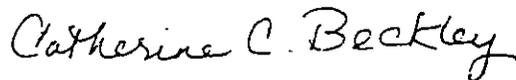
⁴ The pump is not permanently affixed to the glosser container because the pump may clog and must be rinsed out occasionally in order for the consumer to use the entire contents of the bottle.

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The final rule should be restricted to the original focus of the rulemaking, namely automotive and household chemical products subject to the Federal Hazardous Substances Act (FHSA) that contain 10 per cent or more hydrocarbon and have a viscosity less than 100 SUS at 100° F. The data supports the rulemaking for FHSA household products, but does not support it for purposes of Food and Drug Administration (FDA)-regulated cosmetic products. It is unreasonable, unfair, and discriminatory to impose a threshold for regulatory action on cosmetic products that is lower than the statute recognizes to be reasonable.

CPSC itself acknowledges that child resistant packaging is not child proof.⁵ The test protocols for child resistant packaging recognize that some children can open even child resistant closures (16 C.F.R. 1700.20). Implicit in these statements is the admission that the PPPA cannot prevent every exposure. Unfortunately, it appears that there will always be the intentional poisonings of children under the age of five as well as a small percentage of accidental or unknown poisonings of this same group of children. The child fatality risk from purchase and storage of an individual bottle of baby oil is less than 0.00000001. The FAA and DOD, for purposes of classifying hazards arising from failures in airline or defense systems, products, or parts, have characterized hazards with a probability of less than one in ten million as "remote" and less than one in a billion as "extremely remote." Surely the CPSC will not interpret the PPPA as requiring a standard more stringent than the latter.

Respectfully submitted,



Catherine C. Beckley
Associate General Counsel

Attachments

⁵ CPSC Press Release # 01-105, *40th Observance of National Poison Prevention Week*, March 20, 2000; CPSC Press Release # 91-043, *30th Observance: National Poison Prevention Week Helps Save Children's Lives*, March 14, 1991.

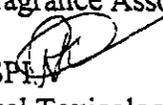


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Memorandum

Date: June 13, 2001

To: Catherine C. Beckley
Associate General Counsel
The Cosmetic, Toiletry, and Fragrance Association

From: Richard Kingston PharmD, CSPT 
Vice President & Senior Clinical Toxicologist
PROSAR International Poison Center
Assistant Professor, Department of Experimental and Clinical Pharmacology,
College of Pharmacy, University of Minnesota

Stephen W. Borron, MD, MS, FACEP, DABMT 
Associate Professor of Emergency Medicine,
George Washington University
Medical Director,
PROSAR International Poison Center
President and Chief Medical Officer,
International Toxicology Consultants, LLC

Leo Sioris PharmD 
Vice President & Senior Clinical Toxicologist
PROSAR International Poison Center
Assistant Professor, Department of Experimental and Clinical Pharmacology,
College of Pharmacy, University of Minnesota

Re: Additional hydrocarbon exposure incident data acquired since the Notice of Proposed Rulemaking

At your request we have reviewed the most recent information from the CPSC regarding: "Additional hydrocarbon exposure incident data acquired since the Notice of Proposed Rulemaking."

In our opinion, these data offer nothing new regarding mineral oil containing cosmetics and the risk of aspiration after unintentional exposure. As with earlier analysis, in a generic sense, the data clearly demonstrate that reported exposure to these products is common and, regardless of circumstance or use pattern, reported serious outcomes are rare.

Given previous discussions regarding the non-specificity of poison center data contained in the TESS (Toxic Exposure Surveillance System) database we were surprised to see

such detailed assumptions made, and conclusions drawn, from such non-specific data. This is of special concern when there was no attempt to validate any of the individual cases or a representative sample of cases contained in the analysis. We were also puzzled by the expansion of the assumptions regarding these data to include a new category of effect known as "potential aspirations." Given our familiarity with how frequently the clinical effect of "cough/choke" is utilized by poison specialists in essentially nontoxic incidents this appears to be an extreme example of reading too much into the aggregated data. We know of no precedence whereby the approach that is outlined in the analysis would meet scientific scrutiny by those familiar with these data and the processes whereby they are collected. If this was intended to be an exercise in generating a "hypothesis", which is an appropriate use of the data, then the hypothesis needs to be tested and validated.

We were also surprised to see the medical outcome category of "unknown potentially toxic exposure" included in the analysis as representing a "serious" outcome. There are a wide variety of circumstances whereby a poison specialist would utilize this classification in a given case including anonymous calls and cases where the caller is uncooperative in providing any information or follow-up. For these reasons this outcome is best described as simply "unknown" and should not be used in regulatory or scientific decision-making.

In the larger picture, when considering the 1998 summary findings of poison center data that related to 4 categories of cosmetics, there were over 31,000 incidents which were ultimately reduced to only 5 cases involving products "in-scope" or, "possibly in-scope", that reportedly included a broad definition of "potential aspiration" *and* a "serious" outcome. In the entire series of cases meeting the description of "potential aspiration" there were only 17 cases with reported outcomes depicted in the analysis as "serious." It's very probable that these small number of incidents fall outside the margin of error for these data.

With such small numbers of incidents distilled down from over 31,000 poison center calls it would seem prudent to investigate the "specificity" of these obvious outliers to determine the accuracy of the coding and confirm assumptions and conclusions that have been drawn regarding their presumed applicability to the rule.

One final comment is noteworthy regarding use of TESS data, which has been so heavily relied upon for this rulemaking. As mentioned in this and previous correspondence, we have been critical of using aggregated TESS data to draw conclusions that support regulatory decisions unless the evidence is both compelling and can be confirmed and/or tested in other scientific venues. At the recent Poison Center Manager's Annual Meeting in Jacksonville Florida, editors from 3 prestigious medical journals that publish work related to the discipline of clinical toxicology participated in a discussion on poison center data. These editors provided insight into their publishing practices that relate to TESS data. They explained their current position regarding their policy of NOT accepting articles representing retrospective reviews of aggregated TESS data upon which to base toxicological decision-making. These authors cited the inherent limitations associated with spontaneous reporting of this nature such as anonymous callers, lack of

physical patient contact/examination to confirm reported clinical effects, inability to confirm that exposure has actually occurred and, inability to confirm dose or product/substance identity. Their reasoning followed much of what has been articulated in previous CTFA comments as well as comments from other groups related to use of these data. It may be of interest to note that other authors have drawn the same conclusion regarding the appropriateness and applicability of these data as they pertain to toxicologic issues.¹ Although these data serve as a useful screening tool and hypothesis generator, their use in forming the basis for regulatory action remains limited. This is especially true if there is no review of the complete text of a representative sample of included cases to determine data accuracy, completeness and applicability to a given set of assumptions.

In conclusion, we would encourage the CPSC Commissioners to grant an exclusion for mineral oil containing cosmetics as previously requested.

¹ Hamilton, R.J. Goldfrank L.R. Poison Center Data and the Pollyanna Phenomenon. *Clinical Toxicology*, 35(1), 21-23 (1997)

Suman Wason, M. D., FAAP
45 Summit Drive
Basking Ridge, NJ 07920

June 18, 2001

Dr. Suzanne Barone
Directorate for Health Sciences
U. S. Consumer Product Safety Commission
Washington, DC 20207

Dear Dr. Barone:

Thank you for allowing me to comment further on the Notice of Proposed Rulemaking (NPR) regarding proposed child-resistant closures (CRC) for "household products" including cosmetic products containing 10% or more hydrocarbons and a viscosity under 100 SUS at 100°F.

I understand that, in the March 27, 2001 Memorandum on Additional hydrocarbon exposure incident data acquired since the Notice of Proposed Rulemaking, the staff of the U. S. Consumer Product Safety Commission (CPSC) have gathered additional data subsequent to my comments to the CPSC in November and December 1999 (see attached).

I write my latest analysis to you as a Board Certified Pediatrician, Medical Toxicologist, and Clinical Pharmacologist. I have had 20 years of clinical experience since my fellowship training in Toxicology. For those 20 years, I was the Director of the Cincinnati Drug & Poison Control Center. During that time, I was affiliated with a tertiary care Emergency Department that served 90,000 pediatric patients each year.

I have had the opportunity to review the staff's March Memorandum to the Commission and the Federal Register notice published April 11, 2001 that makes reference to the March Memorandum. I have the following comments:

1. I agree with the staff analysis' conclusion that one cannot rely on the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS) incident coding. Aspiration, by definition, results in respiratory symptoms. Therefore, working backwards through the TESS incident data and classifying anyone with respiratory symptoms as an "aspiration" is not appropriate.

That is not to say that all respiratory symptoms are indicative of serious health consequences. Many are of little consequence, such as cough/choke and dyspnea (shortness of breath). Others are of moderate consequence. If the symptoms are short term, they are not serious and recovery is quick. Examples of these include

hyperventilation/tachypnea, pneumonitis, and respiratory depression (shallow breathing). Positive X-Ray findings fall in this category because it is possible to have positive X-Ray findings and not suffer any serious health effects and vice versa. Some respiratory effects can indicate serious health consequences. These are the ones that concern the treating physician: bronchospasm, cyanosis, pulmonary edema, and respiratory arrest.

2. Additional Deaths Included in the CPSC Analysis

- a) A 12-month-old female died 45 days after ingesting baby oil. The mother of the child was fixing the hair of the decedent and "put a cap of baby oil on the TV located in the bedroom. She placed the bottle with the cap off in the window sill by the bed." She left the room and later heard the child make an unusual noise. The mother returned to the bedroom and "found the child sitting on the bed with baby oil all over the child's face and the bottle of baby oil on the bed." (See Coroner's Investigative Report included in CPSC Epidemiologic Investigation Report (EIR) (Case No. 970902HCC1459).)

My comments are akin to my comments regarding the 1996 St. Louis ingestion case, in my letter dated November 10, 1999 (attached). Based on my analysis of the clinical course of events, this case, too, represents a probable *massive* ingestion from a bottle of baby oil that was left open. A CR closure would not have made a difference in preventing the fatality, since the cap was not on the bottle.

- b) A 9-month-old female died 6 days after ingesting a hair moisturizer. I have been in touch with Dr. Marcel Casavant, Director of the Columbus Poison Control Center in Columbus, Ohio where the child was treated. Dr. Casavant recalls that the product involved was an oil moisturizer for hair known as a "glosser." The product contained the hydrocarbon paraffin. It is acknowledged in the CPSC EIR (Case No. 000824HEP9008) that "[i]t is unknown what type of closure was on the container, if the closure was on the container at the time of the incident, or how the victim got to or into the product." Without that information, it is impossible to know whether a CR closure would have made a difference in preventing this fatality.

My other concerns with this report are (1) the ability of a 9-month-old baby to climb off an adult-size bed, walk unaided to another room, and climb up to access the product that was "on the sink or in a cabinet," according to CPSC; and (2) the ability of a 9-month-old baby to mechanically/physically be able to release a pump valve or unscrew a pump dispenser closure or suck on the valve hole to access the mist product in a sufficient quantity to cause the serious outcome. A 9-month-old infant would be highly unlikely to have motor skills to perform all of these activities.

Dr. Suzanne Barone
June 18, 2001
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Although this product would be within the scope of the current NPR, and would require a CRC, the circumstances of this case are not conclusory regarding whether the ingestion was accidental. Furthermore, the child's caretaker was felt to be incoherent at the time of this incident, according to the social worker's written report included in the EIR. There apparently was some suspicion of child abuse because a recommendation for a "high risk referral" was made due to the "social situation (supervision issues)," according to the same report.

Net, I believe that the additional data cited in the Memorandum to the Commission confirm my experience that there is a low incidence of serious problems related to mineral-oil-based cosmetic products. The staff analysis focuses on two cases from a database of 31,365. I do not believe that these two cases, described above, like the St. Louis ingestion I previously discussed, could have been prevented by a CRC.

Sincerely,

A handwritten signature in cursive script that reads "Suman Wason".

Suman Wason, M.D., FAAP



Attachment

November 10, 1999

Drug & Poison
Information Center

The Honorable Mary Sheila Gall
Commissioner
U. S. Consumer Product Safety Commission
Washington, DC 20207

Dear Commissioner Gall,

I speak to you as a Board Certified Pediatrician, Medical Toxicologist and Clinical Pharmacologist. I have had 19 years of clinical experience since my fellowship training in Toxicology. For these 19 years I have been the Director of the Cincinnati Drug & Poison Control Center which last year answered 180,000 calls. I am also affiliated with a tertiary care Emergency Department that serves 90,000 pediatric patients each year.

Let me give you a brief overview of lung problems related to hydrocarbons ("HC"). For this discussion I will limit myself to straight chains hydrocarbons (SCH), excluding the aromatic hydrocarbons which are known to be inherently more toxic. The SCH hydrocarbons produce their toxicity when they accidentally get into a human's lung. As illustrated many years ago by Gerarde's experiments, SCH produce two distinct problems based on the viscosity of the hydrocarbon.

The less viscous HC are likely to get into the lung. Due to their physical properties, they "creep" along mucosal surfaces and produce a significant pneumonia due to their irritant effects. Children exhibit shortness of breath, hypoxemia and significant changes on chest X-rays. These can sometimes have a fatal outcome. Also, the TESS data will attest to the fact that these HC produce many many encounters with Poison Centers and Hospitals each year.

The second problem is related to more viscous HC. When they get into the lung, they produce a more localized inflammatory process in the lungs which results in a less devastating problem. Typically mineral oil aspirations have been reported in humans taking it for constipation on a long-term basis. Most cases have occurred in patients with neurologic impairment who perhaps may also have some abnormalities with their swallowing mechanism. These pneumonias are localized and the diagnosis can only be confirmed by demonstrating fat laden lung macrophages.

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In my experience, I have seen hundreds of children with a HC pneumonitis secondary to low viscosity products, gasoline, furniture polish, etc. Most recover but I am aware of at least a single fatality due to low viscosity HC. I have probably seen 3 or 4 cases of lipoid pneumonia secondary to chronic usage of mineral oil. There were no fatalities. In fact, I tried to get one of these cases published but was unable to do so because I believe the journal editors felt that there was nothing new in my case report. In my case, the diagnosis was confirmed by a lung biopsy.

Of course, you have seen correspondence from Dr. Rick Kingston of the PROSAR International Poison Center and University of Minnesota reporting that the TESS and NEISS data confirm the relative proportions with which these two types of problems are encountered.

The first case, presented by Dr. Santiago Reyes de la Rocha, presents a picture of a diffuse pneumonia (which is not the classic presentation of a lipoid pneumonia) which as the authors note was not diagnostically confirmed with a lung biopsy. They surmise that the exposure and subsequent events suggest strongly that the baby oil was responsible. Indeed, one could present a fairly compelling case that this was a severe atypical (i.e. viral) pneumonia in which the circumstances of the baby oil were secondary. Nonetheless, in the 15 years since, neither the authors nor others have reported such cases in the medical literature. Also, the report states that the child had access to an OPEN bottle. One of my concerns is that if a safety closure is deemed by the caretaker to be difficult to open, many more open bottles may present themselves to children.

The second case of the 3-month-old from Columbus is not relevant to our discussion today. The child was actually given the baby oil by mouth as a feed. The resultant large amount probably caused the problem. This is a situation which would not have been avoided by a safely enclosure.

The third case of the thirteen month old from St. Louis is an unfortunate case where the child seems to literally have choked on baby oil. I do not believe that the baby oil per se caused the death. Any viscous liquid, perhaps even soap or shampoo could cause an asphyxial death if a large amount was forced into the oropharynx and then the lungs, as probably happened in this case.

In summary, I would like you to consider these points as you make your final decision.

Gerarde's studies have remained valid to date. Most medical professionals will agree that there are two types of pathology reported after HC, viz. the acute diffuse chemical pneumonitis due to low viscosity HC and the chronic lipoid pneumonia associated with high viscosity HC.

Of the three reported cases, only one is suggestive of mineral oil toxicity that is likely to be prevented if safety enclosures are instituted. This case does have some limitations that do not fit with a classic mineral oil aspiration.

The numbers of cases of mineral oil ingestion resulting in morbidity, the numerator if you will, remains low despite the large denominator reported to NEISS, TESS and the two major manufacturers of baby oil products.

I urge you not to "throw out the baby with the bath water".

Thank You.

Sincerely,

A handwritten signature in cursive script that reads "Suman Wason".

Suman Wason, M.D.
Medical Director



Drug & Poison
Information Center

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Children's Hospital Medical Center
University of Cincinnati Medical Center
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December 1, 1999.

The Honorable Thomas Moore
Commissioner
U.S. Consumer Product Safety Commission
Washington, DC 20207

Dear Commissioner Moore:

Thank you very much for giving me the opportunity to discuss the pending rulemaking on hydrocarbons. Subsequent to our meeting, I reviewed the letter from Ronald Medford and Suzanne Barone to the CPSC Commission regarding the correspondence from CTFA and myself as well as comments that we made at our meeting with you. It appears that the staff misunderstood several of the points that we made and I would like to clarify those for you.

1. The staff states that our argument hinged on the fact that mineral oil does not cause toxicity following absorption from the GI tract. This is not true. My comments focused on aspiration hazards of mineral oil and other less viscous hydrocarbons. My conclusions were that despite aspiration, mineral oil behaves differently from other straight chain hydrocarbons, vis-à-vis lung toxicity. In other words, even in the rare instances in which mineral oil is aspirated, it does not result in serious lung injury as is seen with less viscous hydrocarbons. In most cases, lipoid pneumonia resolves naturally unlike the case with less viscous hydrocarbons in which serious pneumonia with resultant hypoxia can occur.
2. I also stated that in my 19 years of experience as pediatrician and Director of a large Poison Control Center, I had seen hundreds of cases of low viscosity straight chain hydrocarbons aspirations, e.g. mineral spirits, lighter fluid, etc., but had not encountered a single case of accidental ingestion of mineral oil resulting in pneumonia. The TESS data do attest to mineral oil exposure, but I did not feel they supported mineral oil toxicity. These terms are not synonymous. Exposure cannot be equated to toxicity or harm.
3. With regards to the Poison Prevention Packaging Act, my whole point is that mineral oil does not "present a risk of serious injury or serious illness...." This is because aspiration of mineral oil is very rare and normally results from chronic administration and not accidental ingestion. Only in a few very extreme cases has mineral oil aspiration caused serious illness. These serious cases do not appear to be accidental ingestions and therefore should not be relevant to the issue of the need for special packaging.
4. Mineral oil is not chemically different from other hydrocarbons. However, its physical properties (viscosity) make it less of an aspiration hazard. Mineral oil's longer chain length and larger molecule make it less likely to be aspirated than other hydrocarbons. Similarly, if aspirated into the lung, these properties do not allow it to spread and irritate the lungs, as do shorter chain hydrocarbons.
5. The staff state that I disregarded the incident involving the 3-month-old who was fed mineral oil in a baby bottle. I did, in fact, discuss the case and suggested that

the resultant large ingestion resulted in the aspiration problem and noted that child resistant packaging would not have prevented this unfortunate outcome.

6. I did not question the circumstances of the case of the 13-month-old from St. Louis but suggested that the proximate cause of death was probably choking due to the large amount of fluid that entered the child's mouth (and later, the lungs).
7. Finally, Dr. Reyes de la Rocha did, in fact, himself discuss the limitations of his case in his publication. He noted that fat laden macrophages were not seen in bronchial brushing specimens. He notes that "in our patient, the diagnosis was not confirmed by histological examination, but the history, clinical course, and roentgenographic pattern was indicative of lipoid pneumonia."

My bottom line to the Commission was that the physical properties of mineral oil make it much less of an aspiration risk than other hydrocarbons. Given the relative lack of cases of accidental aspirations with significant medical outcomes, I urged the CPSC not to be dissuaded by two or three rare and unusual cases of toxicity of a ubiquitous consumer product that has been available without child resistant packaging for nearly 70 years.

Sincerely,



Suman Wason, MD, FAAP

cc: The Honorable Mary Sheila Gall

**An Analysis of the Proposed Extension of the PPPA
to Mineral-Oil-Based Cosmetic Products**

Prepared for The Cosmetic, Toiletry, and Fragrance Association

Prepared by Heiden Associates, Inc.

June 18, 2001

Introduction

The U.S. Consumer Product Safety Commission (CPSC) has proposed a rule to extend the requirements of the Poison Prevention Packaging Act (PPPA) to “household products” containing hydrocarbons, a definition that at present includes four categories of mineral-oil-based cosmetic products manufactured by The Cosmetic, Toiletry, and Fragrance Association’s (CTFA) member companies. Under the proposed rule products in each of these four groups—bath oil/bubble bath, creams/lotions/make-up products, miscellaneous nail products (specifically, quick dry nail products), and sunscreen/suntan oil products¹—that contain more than ten percent hydrocarbons and have viscosity of 100 SUS or less would be required to have child-resistant closures.

Determining the likely impact of this proposed regulation is complicated by the lack of access by the public, including the CTFA, to the brand-specific poison control center data used by CPSC. Brand-specific data is critical because that is the only way to determine which of the products reported to have been involved with ingestion incidents fall within the scope of the proposed rule.

However, we were able to obtain and analyze data from a number of sources that can be used to assess the likely efficacy of the proposed regulation in averting aspiration-related incidents involving these categories of products. In addition to the non-brand-specific American Association of Poison Control Centers (AAPCC) data furnished to us by the CTFA, extensive data on accidental ingestion, aspiration and inhalation exposures (hereafter, “ingestion and related exposures”) resulting in fatalities and in injuries requiring emergency-room treatment are available from the National Center of Health Statistics (NCHS) and the CPSC’s National Electronic Injury Surveillance System (NEISS), respectively. From these data we were able to develop a comprehensive assessment of the contribution of mineral-oil-based cosmetic products to the overall levels of fatalities and injuries associated with ingestion and related exposures.

Highlights of Results

Our review of these data indicates that extending the requirements of the PPPA to mineral-oil-based cosmetic products will have, at best, a negligible impact on the number of serious incidents involving ingestion and related exposures by children under five years old. First, there are simply not a lot of accidental poisoning fatalities in the NCHS data involving children under five. Of those relatively few accidental poisoning fatalities, none involve cosmetic products. Second, while there are a great number of emergency-room-treated injuries in the NEISS database involving ingestion and related exposures associated with a large number of

¹Incidents involving baby oil are variably reported in either the bath oil/bubble bath or creams/lotions/make-up products categories in the American Association of Poison Control Centers (AAPCC) data.

products and activities by children under five years old, only a few one-hundredths of one percent of these injuries are associated with mineral-oil-based cosmetic products. More specifically:

1. According to NCHS data for the latest data-available year 1998, children under five were involved in 36 *accidental* ingestion, aspiration and inhalation fatalities.² None of these 36 accidental fatalities involved products in the NCHS cosmetics category. Including mineral-oil-based cosmetic products in the proposed PPPA regulation will not have any discernible impact on these fatalities.
2. Child poisonings—whether accidental, intentional, or undetermined—accounted for only 62 of the 18,392 (0.3 percent) of all ingestion and related exposure fatalities in 1998. In contrast, there were more than 2,500 accidental deaths in 1998 involving children under five from other, non-poisoning causes. Motor vehicle accidents, drowning, suffocation and residential fires were the most common causes of accidental deaths in this age group.
3. According to a second source of fatality data, the CPSC death certificate file, there are 77 separate product codes that have been associated with an average of one or more accidental deaths to children under five during 1996-1999, the four most recent data-available years. During this four-year period, there has been either zero or one fatality involving baby oil that may have been averted by the proposed PPPA regulation³ and none involving any other mineral-oil-based cosmetic products that would be subject to the proposed PPPA regulation.⁴ Thus, these products do not represent even a negligible share of the product-associated child fatalities tracked by CPSC in its own fatality database.
4. The number of incidents associated with mineral-oil-based cosmetic products that would be affected by the proposed PPPA regulation is especially small when considered in the

²There were also 17 ingestion and related exposure fatalities that were classified as homicides and another nine which could not be classified as accidental or intentional, suggesting that they were associated with questionable circumstances.

³Two fatalities associated with baby oil have been reported in CPSC in-depth investigations (IDIs) during this four-year interval. In one of these cases (IDI number 970902HCC1459), the cap had been removed prior to exposure, and therefore would not have been averted by PPPA-compliant packaging. The other incident (IDI number 970304HCC9033) took place under circumstances that the CPSC acknowledges are questionable and may not, in fact, actually represent an accidental ingestion scenario at all. To ensure that our comparisons are made on the most conservative basis, we have not excluded this incident from our analysis.

⁴There has, however, been one fatality reported in a 2000 CPSC IDI (000824HEP9008) associated with a hair oil product that is covered by the proposed regulation. However, there is an indication that questionable circumstances were involved. Because NCHS or NEISS data for the year 2000 are not available, we have not included this incident in our estimates or discussion.

context of the overall level of product sales and use. Illustratively, there has been between zero and one potentially avertable product-associated fatality (see above) per 176 million bottles of baby oil in use during the period from 1996 to 1999. Even under the conservative assumption of one avertable fatality, this level of exposure-adjusted risk is more than seventeen times rarer than hazards that the Federal Aviation Administration (FAA) and the Department of Defense (DOD) have characterized in safety standards documents as “remote”. If the number of potentially avertable fatalities was in fact zero (as is likely to be the case), then the hazard associated with baby oil would be classified as “extremely remote” by FAA/DOD standards.

5. We were able to identify only two to three injuries annually to children under five that involve mineral-oil-based cosmetic products included in the scope of the proposed PPPA regulation in the CPSC’s NEISS database comments for data-available years 1997 through 1999. Moreover, the number of cases reported that involved accidental ingestions of products already subject to a PPPA regulation requiring child resistant closures exceeded those of mineral-oil-based cosmetic products that might be covered by the proposed PPPA rule.⁵
6. Many of the specific products that are associated with large numbers of child injuries from ingestion and related exposures have been the subject of previous PPPA rule-making proceedings. These products include aspirin substitutes, antihistamines, and preparations containing iron salts. There are also several products with very high annual estimates of under-five child injuries from ingestion and related exposures that are not typically sold in child-resistant packaging, including general purpose cleaners, gasoline, swimming pool chemicals and pine oil cleaners/disinfectants.
7. The 1998 AAPCC data utilized by CPSC shows that there were 360 “potential aspirations” of products in the four product categories analyzed which involved some type of respiratory effect, but the vast majority of these respiratory effects were almost always limited to “cough/choke”. Only 9 of 360 incidents involved other, possibly more serious, respiratory effects.
8. Moreover, while CPSC did not release the brand-specific AAPCC data, the staff analysis indicates that very few of the products contained in the four categories reviewed were

⁵Because cosmetic products are regulated principally by the Food and Drug Administration (FDA), emergency-room-treated injuries involving these products (and others not regulated by the CPSC) are only recorded in CPSC’s NEISS database if they involve ingestions or related exposures by children under five. It is not always possible to tell from the information provided whether a particular incident involved any mineral-oil-based cosmetic products. Our analysis was therefore limited to cases in which a specific product could be identified from the case description available.

actually mineral-oil-based cosmetic products that would be covered by the proposed PPPA regulation. In fact, 89 percent of the products involved (2,049 out of 2,301 products) would not be covered by the proposed regulation.

In summary, our analysis shows that mineral-oil-based cosmetic products do not account for a significant number of incidents recorded in either the NCHS fatality or NEISS injury databases. Including mineral-oil-based cosmetic products in the scope of the proposed PPPA regulation will have no discernible impact on fatalities or emergency-room-treated injuries involving ingestion or related exposures by children under five.

In the remaining sections of this report, we provide more detail on the data sources we reviewed as part of our analysis. For each source—the NCHS, NEISS and AAPCC—we present estimates of the overall universe of ingestion and related exposure incidents involving children under five. We also present specific data on the number of these incidents that were reportedly associated with the mineral-oil-based cosmetic products that are included in the scope of the proposed PPPA regulation. In addition, we present an illustrative comparison of fatality risk for one product, baby oil, with general hazard standards recognized by two major federal agencies (FAA and DOD) for critical use products.

Child Fatalities from Ingestion and Related Exposures in the NCHS Fatality Data

The National Center for Health Statistics (NCHS) maintains and reports comprehensive, detailed data on mortality for all causes of death. Death certificates are coded using the 9th International Classification of Diseases framework, which provides an approximately 100-page listing of codes for describing the proximate cause of each fatality. CPSC relies on these data to estimate the number of child poisonings reported annually as part of its National Poison Prevention Week briefing package. These data were also used by the Commission to determine the effectiveness, in terms of averted fatalities, of prior PPPA rulemaking activities.

For this project we conducted a detailed review of comprehensive death certificate data available from NCHS for 1998, the most recent data-available year. A summary of these data is provided in Exhibit 1 (attached).

As Exhibit 1 indicates, there were no 1998 NCHS-reported fatalities sustained by children under five (the target population under the PPPA) in the Center's "cosmetics" product category. In fact, accidental child poisoning fatalities from all sources of exposure were comparatively rare: only 0.3 percent (62 of 18,392) of all U.S. poisoning fatalities in 1998 involved children under the age of five. Moreover, 26 of these 62 incidents involving children under five resulted from either intentional poisonings, i.e. "homicides", (17 cases) or incidents for which it could not be determined whether the ingestion and related exposure was accidental

or intentional (9 cases).

Of those 36 child ingestion and related exposure fatalities that were determined to be accidental, most involved drugs and medicines (22 cases, some of which may represent exposure to illicit or controlled substances) or gases and vapors (10 cases). Household chemicals of all types—such as methyl alcohol, cleaners, bleaches and automotive chemicals—or other/unspecified products were implicated in only four cases annually.⁶

While children under five were involved in a very small number of accidental ingestion and related exposure fatalities in 1998, and none involving products in the cosmetics category, this age group experienced a large number of accidental deaths from other (non-poisoning) causes, according to the NCHS data. Exhibit 2 (attached) shows that motor vehicle accidents, drowning, suffocation and residential fires were the most common causes of accidental deaths in this age group. All told, in 1998 there were more than 2,500 accidental fatalities from causes other than accidental poisonings involving children under five.

The NCHS data confirm that including mineral-oil-based cosmetic products in the proposed PPPA regulation will have no detectable impact on accidental fatalities involving ingestion and related exposures by children under five. Based on the 1998 data, there are comparatively few of these fatalities, and cosmetic products do not appear to have been implicated in any of them.

Product-Related Fatalities in the CPSC Death Certificate Database Involving Children Under Five

The CPSC also maintains a death certificate database for product-related deaths. While these records are acknowledged to be somewhat incomplete, they can be used to examine the products and activities most often associated with fatalities involving children under five for PPPA purposes. For this analysis, we tabulated the product death certificate data maintained by CPSC for the last four data-available years (1996-1999). The most commonly cited products and activities associated with deaths of children under five are listed on Exhibit 3 (attached). None of these can be identified as cosmetic-related products.

There were 77 specific product codes in the death certificate database that were associated with an average of one or more fatalities annually over the four-year period (1996-1999) examined. By far the largest number of these deaths involved swimming pools (at least 956 of the 3,144 in the database, or 30 percent of the total). There were also at least 49 fatalities

⁶Three of these four cases did not involve mineral-oil-based cosmetic products. In the fourth case, the product was listed as “other/unspecified solid or liquid substance”.

related to drugs or medications, six (6) associated with general purpose household cleaners, and four (4) involving bleach. There were also six (6) fatalities involving ingestion of coins.

In contrast, as we have indicated above, there appear to have been two fatalities associated with mineral-oil-based cosmetic products during this period of time, the two baby oil incidents described in IDI numbers 970902HCC1459 and 970304HCC9033. Furthermore, based on the incident scenarios involved in these cases, neither of these fatalities appeared likely to have been avertable by PPPA-compliant packaging.

Thus, it appears that mineral-oil-based cosmetic products do not account for even a minimal share of the product-related child fatalities in the death certificate database maintained by the CPSC.

Exposure-Adjusted Fatality Risk Compared with Risk Prevention Criteria

Because of the time limitations imposed by CPSC for comments, we were not able to obtain comprehensive data on annual sales of all of the mineral-oil-based cosmetic products that would be affected by the proposed PPPA regulation. However, it is possible to develop an estimate of the *avertable* fatality risk associated with one of these products—baby oil—using information from previous CPSC rule-making activity. Specifically, CPSC has previously estimated that annual sales of baby oil totaled approximately 35 million units. The industry estimate is that each bottle of baby oil remains in use for between 6 and 24 months. Using the midpoint of this range—15 months—there are a total of about 44 million bottles of baby oil in use at any point in time.

Combining this estimate of the number of product units in households at a single point in time with the available fatality data helps to place the level of risk in the context of the amount of aggregate exposure to the product. In this case, there have been two (2) CPSC IDIs for fatalities associated with baby oil during the period from 1996 to 1999. However, the incident scenarios in at least one of these fatalities (IDI number 970902HCC1459) would not have been altered by compliance with the PPPA requirements, since the cap had been removed prior to exposure. The other incident (IDI number 970304HCC9033) took place in 1996 under circumstances that the CPSC acknowledges are questionable and may not, in fact, actually represent an accidental ingestion scenario at all.⁷ This leaves a residual product risk level of between zero and 0.25 fatalities annually. Thus, the child fatality risk from purchase and storage of an individual bottle of baby oil is less than 0.00000001. Alternatively, there are either zero or one product-associated

⁷It is our understanding that the circumstances associated with this second fatality call into question whether the death was the result of accidental self-ingestion of baby oil by the child, so the risk estimate presented here is conservative.

fatality per 176 million bottles of baby oil in use.

This level of exposure-adjusted risk is well below that regarded as an appropriate level for concern even under demanding risk prevention standards. The Federal Aviation Administration and the Department of Defense (FAA/DOD), for purposes of classifying hazards arising from airline or defense system, product, or parts failures, have characterized hazards with a probability of less than one in ten million as “remote”. Thus, even under the most conservative assumptions about possible product involvement, the level of child fatality risk associated with baby oil therefore appears to be more than seventeen times rarer than hazards that the FAA/DOD have characterized in safety standards documents as “remote”. If the number of potentially avertable fatalities was in fact zero (as is likely to be the case), then the hazard associated with baby oil would be classified as “extremely remote” by FAA/DOD standards.

Detailed Review of NEISS Injuries in the “Other Poisonings” Category

A third source of data on accidental ingestion and related exposure hazards involving children under five is available from the National Electronic Injury Surveillance System (NEISS) database of emergency-room-treated (ER) injuries maintained by CPSC. However, the mineral-oil-based cosmetic products that would be included in the proposed PPPA regulation are generally not subject to CPSC jurisdiction, and thus are not tracked in the NEISS data with specific product codes. Consequently, assessing the contribution of these products to the overall number of ER-treated child ingestions of products not included in the NEISS coding system requires detailed review of short one-line descriptions (the “comments” field entries) that are available from CPSC only in hard copy form. We therefore obtained these hard copy listings and reviewed all injury descriptions in this category for the three most recent data-available years (1997 through 1999).

It is not always possible to tell from the NEISS one-line comment information provided which injuries were associated with products that would be affected by the proposed regulation. However, product descriptions are available in most cases. Of those products that are cosmetics within the PPPA and FDA definitions, there were only two to three (2 to 3) cases annually in the entire database that involved mineral-oil-based cosmetic products. In fact, between 1997 and 1999 there appear to have been more cases reported that involved ingestion and related exposure injuries by a child under five of alcohol, tobacco or cocaine (8 cases) than of mineral-oil-based cosmetic products that may be covered by the proposed PPPA regulation. Moreover, as discussed below, the number of cases reported that involved accidental ingestions of products already subject to a PPPA regulation requiring child resistant closures exceeds those of mineral-oil-based cosmetic products that might be covered by the proposed PPPA rule.

Ingestion and Related Exposure Injuries Requiring Emergency-Room Treatment

The NEISS records can also be used to develop annual estimates of the number of ER-treated injuries to children under five that were associated with ingestion of, or related exposure to, any particular product or group of products that are regulated principally by the CPSC. We therefore identified, extracted and analyzed all 1997-1999 NEISS-reported injuries involving ingestion and related exposures by children under five years of age. Exhibit 4 (attached) presents detailed tabulations of the estimated numbers of injuries associated with drugs or medicines, personal use items (a category that includes objects such as coins, combs, and cigarette lighters, but does not incorporate cosmetic products or other FDA-regulated products), and household chemicals, for each NEISS product code associated with an average of 100 or more ER visits annually.

Many of these products have been the subject of previous PPPA rule-making proceedings, including:

	<u>Estimated Number of Injuries, 1997-1999</u>
Aspirin substitutes	24,327
Antihistamines	10,207
Preparations Containing Iron Salts	3,785

On the other hand, it is noteworthy that while many of the drugs and chemicals on this list are subject to PPPA requirements, several products with very high annual estimates of under-five child ingestion or related exposure injuries are not typically sold in child-resistant packaging, including:

	<u>Estimated Number of Injuries, 1997-99</u>
General Purpose Household Cleaners	7,388
Gasoline	5,075
Swimming Pool Chemicals	3,254
Pine Oil Cleaners/Disinfectants	2,788

Thus, the estimated number of ingestion and related exposure injuries associated with products that represent the previous and present targets of PPPA rule-making proceedings appears to be many times greater than the number associated with mineral-oil-based cosmetic products.

Review of AAPCC Data on Incidents Involving Four Categories of Cosmetic Products

Because there are no fatalities and very few ER-treated injuries associated with the mineral-oil-based cosmetic products in NEISS that would be subject to the proposed PPPA

regulation, we examined a fourth source of data—the 1998 AAPCC incident reports obtained by CTFA—to assess the frequency and average severity level of aspirations and ingestions with related respiratory effects involving these potentially regulated products. Our analysis focused on the frequency of respiratory effects associated with products in each of the four relevant AAPCC cosmetic categories reviewed—bath oil/bubble bath, creams/lotions/make-up products, miscellaneous nail products (specifically, quick dry nail products), and sunscreen/suntan oil products, as well as the likelihood that these effects would be serious.

The AAPCC data obtained by the CPSC identified the specific brand name of the product, where available. The CPSC staff review indicated that most of the products in these four groups (2,049 of 2,301 or 89 percent) would not, in fact, be covered by the proposed regulation. For the remainder, CPSC was able to make a determination that 30 products would be covered by the proposed PPPA regulation. The staff lacked sufficient information to make that determination for 222 products but nonetheless combined the 222 unknown products with the 30 known products for purpose of their analysis.

However, these data are available to the public, including the CTFA, only with the brand information redacted. We cannot therefore determine which *incidents* discussed in the staff briefing package and accompanying reports involved products that would actually be affected by the regulation being considered. It is likely, however, that most of these ingestion and related exposures do not actually involve the mineral-oil-based cosmetic products that would be included in the proposed PPPA regulation.

Nonetheless, we reviewed and tabulated the available data; the results of this analysis are summarized in Exhibits 5 and 6 (attached). Exhibit 5 provides additional detail for an analysis that was presented in the April 11th CPSC Federal Register notice. The 1998 data cited by CPSC on this point appear to be correctly reported—we were able to identify 476 cases that are considered by CPSC to represent “potential aspirations”. Of these, 360 involved some type of respiratory effect.⁸ Exhibit 6, however, shows that these respiratory effects are almost always limited to “cough/choke”. Only nine (9) of the 476 incidents involved other, possibly more serious, respiratory effects such as bronchospasm and dyspnea.

This rarity of serious respiratory effects, combined with the fact that most of the products in these four AAPCC cosmetic categories would not fall within the scope of the proposed PPPA regulation—helps to explain why mineral-oil-based cosmetic products do not make a discernible impact on either the NCHS fatality data or the NEISS injury statistics.

⁸While very few incidents involving these products are coded as aspirations, CPSC also defined incidents with exposure arising from inhalation and ingestion exposures with related respiratory effects as potential aspirations.

Summary and Conclusions

The obvious conclusion of this analysis is that the level of risk associated with mineral-oil-based cosmetic products appears to be well below that which constitutes a reasonable target for regulatory action under the PPPA, in light of the minimal contribution of these products to the overall levels of accidents sustained by children under five. There is, by contrast, a large number of other products and activities that are involved in much more significant shares of these incidents.

In a study of earlier years of the NCHS fatality data presented in this report, the CPSC estimated that the PPPA requirements have led to a 45-percent reduction in aspirin-related fatalities (1.4 fatalities averted annually per million children under five) since the early 1970s. With a 1998 U.S. population of nearly 19 million children in this age range, this translates to an average of 26 or 27 averted fatalities annually since aspirin packaging was subject to the requirements of the PPPA.

By contrast, the NCHS data confirm that including mineral-oil-based cosmetic products in the proposed PPPA regulation will have no detectable impact on accidental fatalities involving ingestion and related exposures by children under five. Based on the 1998 data, there are comparatively few of these fatalities, and cosmetic products do not appear to have been implicated in any of them. This lack of involvement in child fatalities is confirmed by analysis of 1996-1999 death certificate records maintained by the CPSC. Mineral-oil-based cosmetic products do not account for any product-related child fatalities in this database.

Similarly, only a *de minimis* number of ingestion and related exposure injuries to children under five in the 1997-1999 NEISS database involved mineral-oil-based cosmetic products. As we noted above, the number of cases reported that involved accidental ingestions of products already subject to a PPPA regulation requiring child resistant closures far exceeded those of mineral-oil-based cosmetic products that might be covered by the proposed PPPA rule.

Finally, the 1998 AAPCC data we reviewed indicates that while cosmetic products of all types are associated with a number of incidents with respiratory effects, nearly all of these cases involve respiratory effects that are limited to "cough/choke". Moreover, the CPSC staff analysis acknowledges that most of the products contained in these reports fall outside of the scope of the proposed PPPA regulation.

Thus, based on the data we reviewed, we concluded that including mineral-oil-based cosmetic products in the proposed PPPA regulation will have no discernible impact on fatalities or emergency-room-treated injuries involving ingestion and related exposures by children under five. They do not therefore, represent an appropriate target for regulatory action.

Exhibit 1
NCHS Death Certificate Poisonings, 1998

NCHS Death Certificates	Under 5	Total	Percentage Under 5
All Deaths	33,622	2,337,256	1.4%
All Poisonings	62	18,392	0.3%
Accidental/medical	22	9,838	0.2%
Accidental/other	14	963	1.5%
Suicide/homicide	17	5,158	0.3%
Undetermined	9	2,433	0.4%
Accidental/medical (E850-858)			
850 analgesics...	8	3,141	0.3%
851 barbituates	1	16	6.3%
852 other sedatives...	0	8	0.0%
853 tranquilizers	0	107	0.0%
854 other psychotropic...	1	334	0.3%
855 other central nervous sys...	4	1,540	0.3%
856 antibiotics	0	39	0.0%
857 anti-infectives	0	4	0.0%
858 other drugs	8	4,649	0.2%
Accidental/other (E860-869)			
860 alcohol, n.e.c.	1	300	0.3%
861 cleaning/polishing agents...	0	10	0.0%
862 petroleum products...	2	37	5.4%
863 agricultural chemicals...	0	8	0.0%
864 corrosives/caustics, n.e.c.	0	5	0.0%
865 foodstuffs/plants	0	3	0.0%
866 other/unspec solid/liquid	1	54	1.9%
8667 cosmetics	0	1	0.0%
867 pipeline gas	0	15	0.0%
868 utility gas/carbon monoxide	9	444	2.0%
869 other gases/vapors	1	87	1.1%
Suicide (E950-952)			
950 solid/liquid	0	3,346	0.0%
951 gases in domestic use	0	20	0.0%
952 other gases/vapors	0	1,706	0.0%
Homicide (E962)			
9620 drug/medicine	9	41	22.0%
9621 solid/liquid	1	20	5.0%
9622 gas/vapor	7	24	29.2%
9629 unspecified	0	1	0.0%

Exhibit 1
NCHS Death Certificate Poisonings, 1998

NCHS Death Certificates	Under 5	Total	Percentage Under 5
Undetermined whether accidental/inflicted			
9800 analgesics...	4	899	0.4%
9801 barbituates	0	8	0.0%
9802 other sedatives...	2	8	25.0%
9803 tranquilizers	1	171	0.6%
9804 other drugs	2	846	0.2%
9805 unspecified drugs	0	366	0.0%
9806 corrosives/caustics	0	1	0.0%
9807 agricultural chems...	0	4	0.0%
9809 other/unspec solid/liquid	0	48	0.0%
981 gases in domestic use	0	0	xx
982 other gases/vapors	0	82	0.0%

Percent with Age Group

Accidental/medical	35.5%	53.5%
Accidental/other	22.6%	5.2%
Suicide/homicide	27.4%	28.0%
Undetermined	14.5%	13.2%
Total	100.0%	100.0%

Exhibit 2
NCHS Death Certificates, 1998

NCHS Death Certificates	Under 1	1-4	Under 5	Percentage of Total
Drowning				
Recreational	0	13	13	0.5%
Bathtub	34	39	73	2.8%
Other drowning	22	306	328	12.5%
Unspecified	7	138	145	5.5%
Fall	20	45	65	2.5%
Fire/hot object				
Fires in dwellings	39	240	279	10.6%
Other fire/hot object	4	24	28	1.1%
Firearm	0	19	19	0.7%
Machinery	0	18	18	0.7%
Motor Vehicle Traffic				
Occupant	125	330	455	17.3%
Pedestrian	5	186	191	7.3%
Other, unspecified	27	109	136	5.2%
Pedestrian, other	2	106	108	4.1%
Transportation, all other	3	31	34	1.3%
Natural/environmental	15	32	47	1.8%
Accidental poisoning/medical				
Analgesics...	0	8	8	0.3%
Barbituates	0	1	1	0.0%
Other psychotropic...	0	1	1	0.0%
Other central nervous sys...	4	0	4	0.2%
Other drugs	3	5	8	0.3%
Accidental poisoning/other				
Alcohol, n.e.c.	1	0	1	0.0%
Petroleum products...	0	2	2	0.1%
Other/unspec solid/liquid	0	1	1	0.0%
Cosmetics	0	0	0	0.0%
Utility gas/carbon monoxide	1	8	9	0.3%
Other gases/vapors	0	1	1	0.0%
Struck by/against	5	26	31	1.2%
Suffocation				
Food	34	53	87	3.3%
Other object	30	25	55	2.1%
Bed/cradle	184	15	199	7.6%
Plastic bag	6	2	8	0.3%
Other, unspecified	122	57	179	6.8%
Other/undetermined	27	63	90	3.4%
Total	720	1,904	2,624	100.0%

Exhibit 3
CPSC Death Certificates, 1996-1999

Product	Number
Swimming Pools, Not Specified	842
Bathtubs or Showers	282
Beds, Not Specified	240
Mattresses, Not Specified	127
Sofas, Couches, Davenports, Divans...	115
Ceilings And Walls	102
Cribs, Not Specified	80
Pillows	80
General Home or Room Involvement In Fire	59
Built-In Swimming Pools	58
Whirlpools, Hot Tubs or Home Spas	56
Plastic Bags	55
Buckets or Pails	48
Above-Ground Swimming Pools	43
Bedsprings or Bedframes	42
Waterbeds or Water Pillows	37
Window Shades, Venetian Blinds or Indoor...	36
Baby Mattresses or Pads	34
Crib Extender Rails or Youth Bed Rails	32
Blankets, Not Specified	31
Other Drugs or Medications	30
Playpens	24
Bedding, Not Specified	24
Toilets	24
Hot Water	21
Car Seats (For Infants or Children)	16
Tractors, Other or Not Specified	16
Desks, Chests, Bureaus or Buffets	16
Drugs or Medications, Not Specified	15
Bunk Beds	15
Carbon Monoxide Poisoning	15
Clothing, Not Specified	15
All Terrain Vehicles (# Of Wheels Unspecified)	14
Bassinets or Cradles	13
Bedspreads, Throws or Comforters	12
Rope or String	11
Electric Wire or Wiring Systems	11
Toys, Not Elsewhere Classified	11
High Chairs	10
Waste Containers, Trash Baskets...	10
Bicycles And Accessories...	10
Balloons (Toy)	10
Mobile Homes	9

Exhibit 3
CPSC Death Certificates, 1996-1999

<i>Product</i>	<i>Number</i>
Wading Pools	9
Containers, Not Specified	8
Tables (Excl. Baby Changing Tables...	8
Windows or Window Glass, Not Specified	8
Other Bedding	7
Slides or Sliding Boards	7
Baby Strollers	6
Portable Baby Swings (For Home Use)	6
General Purpose Household Cleaners	6
Chairs, Not Specified	6
Other Chairs	6
Nonbaby Mattresses	6
Floors or Flooring Materials	6
Coins	6
Clothing Accessories	6
Ranges, Not Specified	5
Portable Cribs	5
Cribs	5
Plastic Products, Not Specified	5
Draperies, Curtains, Shower Curtains	5
Furniture, Not Specified	5
Drapery or Curtain Rods, Hooks or Rings	5
Nonelectric Blankets	5
Heaters or Heating Systems, Not Specified	4
Bleaches (Noncosmetic)	4
Paper Products	4
Aspirin Substitutes	4
Sheets or Pillowcases	4
Stairs or Steps	4
Recliner Chairs, Not Specified	4
Nails, Screws, Carpet Tacks or Thumbtack	4
Day Wear	4
Swimming Pool Equipment	4
Tricycles	4

Exhibit 4
NEISS Injuries by Product, 1997-1999

Product	1997		1998		1999		Total		Percentage Hospitalized
	Hospitalized	Total	Hospitalized	Total	Hospitalized	Total	Hospitalized	Total	
Coins	2,861	21,841	3,353	24,972	3,334	25,875	9,549	72,688	13.1%
Tablet or Capsule Drugs	2,189	17,936	3,481	15,096	2,550	14,242	8,221	47,275	17.4%
< 5 Poisonings - No Other Code	683	10,336	522	12,581	786	14,088	1,992	37,005	5.4%
Other Drugs or Medications	826	8,297	1,031	9,042	1,175	8,186	3,032	25,525	11.9%
Aspirin Substitutes	397	9,153	427	8,433	90	6,742	913	24,327	3.8%
Bleaches (Noncosmetic)	453	6,807	270	6,568	23	5,226	746	18,601	4.0%
Liquid Drugs	131	4,479	406	5,542	330	5,292	867	15,313	5.7%
Jewelry	99	3,648	226	4,374	258	4,350	583	12,372	4.7%
Antihistamines	649	3,541	132	3,429	104	3,236	886	10,207	8.7%
Drugs or Medications, Not Specified	186	2,298	132	2,938	170	3,758	488	8,995	5.4%
Chemicals, Not Elsewhere Classified	133	2,005	19	3,498	82	2,439	233	7,941	2.9%
General Purpose Household Cleaners	180	2,698	165	1,964	16	2,726	361	7,388	4.9%
Liniments or Rubbing Compounds	100	2,355	6	2,583	18	1,684	124	6,622	1.9%
Gasoline	207	1,981	389	2,121	133	972	730	5,075	14.4%
Preparations Containing Iron Salts	246	2,163	105	845	151	777	502	3,785	13.3%
Aspirin or Aspirin Compounds	163	1,490	51	1,010	77	1,243	290	3,742	7.8%
Swimming Pool Chemicals	66	1,059	19	1,588	0	608	86	3,254	2.6%
Desk Supplies	32	730	0	1,553	29	912	60	3,194	1.9%
Cigarettes, Cigars, Pipes or Tobacco	0	739	68	1,452	103	936	171	3,128	5.5%
Lamp Oils	271	1,433	329	826	195	714	795	2,973	26.7%
Paints, Varnishes or Shellacs	108	1,544	37	961	89	430	234	2,935	8.0%
Pine Oil Cleaning And Disinfectant...	6	878	31	1,305	94	605	132	2,788	4.7%
Ammonia, Household	108	970	86	875	0	715	194	2,559	7.6%
Paint or Varnish Thinners	87	682	19	664	68	724	174	2,070	8.4%
Personal Protection Devices	0	1,131	0	597	0	139	0	1,867	0.0%
Hair Curlers, Curling Irons, Clips...	108	682	19	381	35	741	161	1,805	8.9%
Laundry Soaps or Detergents	26	777	0	392	0	395	26	1,565	1.6%
Keys, Key Rings or Key Chains	153	590	0	236	11	716	164	1,542	10.7%
Adhesives	0	527	0	726	0	286	0	1,539	0.0%
Lighter Fluids	13	670	75	502	23	345	110	1,517	7.3%
Kerosene	75	475	172	706	11	209	258	1,390	18.6%

Exhibit 4
NEISS Injuries by Product, 1997-1999

Product	1997		1998		1999		Total		Percentage	
	Hospitalized	Total								
Automotive Chemicals	44	661	0	381	5	294	49	1,336	3.7%	3.7%
Acids	0	1,021	0	224	0	79	0	1,324	0.0%	0.0%
Drain Cleaners	47	434	385	635	41	244	474	1,313	36.1%	36.1%
Soaps (Excl. Laundry Soaps or Detergents)	0	335	0	502	0	433	0	1,271	0.0%	0.0%
Toilet Bowl Products	0	302	66	331	0	335	66	967	6.8%	6.8%
Liquid Room Deodorizers or Fresheners	0	302	0	282	0	278	0	862	0.0%	0.0%
Furniture Polishes or Waxes	150	415	81	178	5	207	236	801	29.5%	29.5%
Lubricants	0	159	6	100	0	529	6	789	0.8%	0.8%
Oven Cleaners	6	462	19	282	0	18	25	762	3.3%	3.3%
Abrasive Cleaners	19	231	0	303	0	189	19	723	2.7%	2.7%
Room Deodorizers or Fresheners, Not Spec.	0	70	0	163	0	467	0	700	0.0%	0.0%
Spot Removers or Cleaning Fluids	0	306	0	249	0	131	0	686	0.0%	0.0%
Windshield Wiper Fluids	0	267	84	214	18	194	102	675	15.1%	15.1%
Detergents, Not Specified	0	244	0	344	0	5	0	593	0.0%	0.0%
Antifreeze	0	91	0	249	0	179	0	519	0.0%	0.0%
Automotive Waxes, Polishes or Cleaners	0	155	0	179	0	172	0	506	0.0%	0.0%
Fuel Oils, Not Specified	71	209	6	25	0	260	77	494	15.6%	15.6%
Dishwashing Liquid	0	120	0	240	0	94	0	455	0.0%	0.0%
Veterinary Medicines	0	141	44	189	0	77	44	407	10.8%	10.8%
Fertilizers And Other Chemicals For Outdoor...	0	94	0	152	0	149	0	396	0.0%	0.0%
Methyl Alcohol (Solvent)	0	116	66	158	0	121	66	394	16.8%	16.8%
School Laboratory Chemicals	0	93	0	217	0	68	0	378	0.0%	0.0%
Metal Polishes, Tarnish Removers...	0	95	0	150	0	89	0	334	0.0%	0.0%
Mouthwashes or Mouth Rinses...	0	6	0	160	0	142	0	308	0.0%	0.0%

Exhibit 5
 Cosmetic Potential Aspirations to Children Under 5, 1998
 (General Unintentional Exposures without Concomitants)
 by Type of Cosmetic and Exposure Route

Exposure Route	Type of Cosmetic				Total
	Bath Oil/ Bubble Bath	Creams/ Lotions/ Makeup	Nail Products/ Misc.	Suntan/ Sunscreen Products	
Aspiration Exposure Specified					
Aspiration & Ingestion with Respiratory Effects	7	5	0	0	12
Aspiration & Ingestion without Respiratory Effects	11	15	5	9	40
Subtotal	18	20	5	9	52
Inhalation/Nasal Exposure Involved					
Nasal Only with Respiratory Effects	5	2	1	1	9
Nasal Only without Respiratory Effects	15	18	14	3	50
Nasal & Ingestion with Respiratory Effects	2	0	0	0	2
Nasal & Ingestion without Respiratory Effects	11	11	2	2	26
Subtotal	33	31	17	6	87
Ingestion Only with Respiratory Effects	196	109	19	13	337
<hr/>					
Total Potential Aspirations	247	160	41	28	476
Total Potential Aspirations with Respiratory Effects	210	116	20	14	360

Source: American Association of Poison Control Centers TESS data.

Exhibit 6
 Cosmetic Potential Aspirations to Children Under 5, 1998
 (General Unintentional Exposures without Concomitants)
 by Respiratory Clinical Effect and Exposure Route

Respiratory Clinical Effect	Exposure Route			Total
	Aspiration Exposure Specified	Inhalation/ Nasal Exposure Involved	Ingestion Only with Respiratory Effects	
None	40	76	0	116
Cough/Choke	11	11	329	351
Dyspnea	1	0	1	2
Bronchospasm	0	0	1	1
Bronchospasm & Cough/Choke	0	0	1	1
Dyspnea & Cough/Choke	0	0	3	3
Hyperventilation/Tachypnea & Pneumonitis & Cough/Choke	0	0	1	1
Hyperventilation/Tachypnea & Positive X-ray Findings	0	0	1	1
Total Potential Aspirations	52	87	337	476

Source: American Association of Poison Control Centers TESS data.