APPENDIX D

2 MAY 1997

1. TASK NUMBER	2. INVESTIGATOR'S ID	EPIDEMIOLOGIC INVESTIGATION REPORT
970304HCC9033	8938	

3. OFFICE CODE	4 DATE OF ACCIDENT YR MO DAY	5 DATE INITIATED YR MO DAY
830	96 08 30	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.)	8 CITY	9. STATE
Women's Shelter Home 51	Alton	IL

10A FIRST PRODUCT	10B TRADE/BRAND NAME	10C. MODEL NUMBER
Baby Oil 1915	Unk.	Unk

10D. MANUFACTURER NAME AND ADDRESS
Unk.

11A SECOND PRODUCT	11B TRADE/BRAND NAME	11C MODEL NUMBER
N/A		

11D MANUFACTURER NAME AND ADDRESS
N/A

12 AGE OF VICTIM	13. Sex	14 DISPOSITION	15. INJURY DIAGNOSIS
212	Male-1	Expired in Hospital-8	Poisoning-68

16 BODY PART (S) INVOLVED	17 RESPONDENT	18. TYPE OF INVESTIGATION	19. TIME SPENT (OPERATIONAL HOURS)
All Parts Of Body 85	Medical Examiner's Office-3	On-Site-1	8.0

20. ATTACHMENT (S	21. CASE SOURCE	22 SAMPLE COLLECTION NUMBER
Medical Examiner's Report-2	MECAP - 12	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	25 REVIEWED BY	26. REGIONAL OFFICE DIRECTOR
5-19-97	8130	

27. DISTRIBUTION

CPSA 6 (b)(1) Cleared
No Mfrs/PrvtLblrs ID
Products Identified
Excepted by
Firms Notified,
Comments Processed.

CPSC FORM 182 (REVISED 10/93) OMB NO. 3041-0029

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.

IDI 970304HCC9033 - Attachment #1 - 1/6

St. Louis City Medical Examiner

[redacted] 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 Aspnyxia. 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 11/08/9
Records Being Sent From [redacted]

Notes: _____

_____

_____

_____

Investigator: [redacted]

Printed 11/21/96 at 09:34 AM

IDI 97030HHCC9033 - Attachment # 1 - 316

[redacted]

Case No.: 96-2031

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] on 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 autops 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 Shelt for Women.

I next contacted the Division of Family Services, Child Abuse Hotline for Illinois, [redacted] and spoke with [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

St. Louis, MO

CHIO

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 CHIO

Requested by Susan Aitken

HS83

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[1] 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.[2]

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[1] 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

[2] 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.[3]

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)

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[3] 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)

products with a "restricted flow" orifice as defined in 1700.15(d); and (iv) products delivered as a 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

Catherine C. Beckley
Associate General Counsel

cc: Chairman Ann Brown
Commissioner Mary Sheila Gall

Commissioner Thomas Moore

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

E. EDWARD KAVANAUGH
PRESIDENT

November 10, 1999

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

Dear Commissioner Gall,

Once again, CTFA and its members would like to thank you for taking the time to meet with us to discuss the Commission's PPPA rulemaking on low-viscosity hydrocarbons (sometimes called petroleum distillates). In the course of that meeting, you and your staff asked for information on several points. CTFA was able to obtain some information that is responsive to these questions.

1.Are all hydrocarbons the same?

The term "hydrocarbons" can be misleading. Strictly speaking, the term should be applied to any single chemical entity consisting only of carbon and hydrogen. In practice (and for the purposes of the proposed rule-making) the term is used to describe various complex mixtures comprising a number of different chemical entities (each of which compose only carbon and hydrogen). Differences in the composition of "hydrocarbons" have a significant impact on the safety of products containing such complex mixtures.

Mineral oils used in cosmetic products are highly refined mixtures of petroleum hydrocarbons. The refining process eliminates aromatic and other unsaturated compounds which could otherwise lead to an increased risk of toxicity. These are the compounds typically found in significant concentrations in other petroleum derived materials such as kerosene, gasoline, mineral spirits, and mineral seal oils. Aromatic compounds, and in particular polynuclear aromatics, are known for their toxic effects. Mineral oils used in cosmetic applications meet purity tests in the USP/NF (United States Pharmacopeia/National Formulary) as well as FDA regulation 21 CFR 172.878. The tests prescribed in these standards assure the absence of polynuclear aromatic compounds so that these materials can be used in medical and direct food applications.

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202 331 1770 FAX 202 331.1969
http //www ctfa.org

Ingestion of mineral oil without aspiration poses essentially no risk of poisoning as opposed to such low viscosity hydrocarbons as kerosene, lighter fluid and gasoline. Ingestion of the latter poses a risk of poisoning because of their oral toxicity independent of their aspiration risk.

More importantly in the context of the proposed regulation, differences in the chemical and physico-chemical properties (which affect things like viscosity, volatility, surface tension, etc.) of hydrocarbons will result in differences with regard to (1) the relative risk of aspiration, (2) the relative risk of an aspiration leading to some degree of toxicity, (3) the relative degree of toxicity, and (4) the type of toxicity. In this context, mineral oil is very different from other "hydrocarbons."

2. Are mineral oil-containing cosmetic products less likely to be aspirated than other hydrocarbon products?

Clinical evidence suggests this is the case.

During the Public Briefing, AAPCC test data was provided by staff. In spite of its limitations in identifying the specific ingredients in the data, the TESS data clearly shows that aspiration (as opposed to ingestion) of mineral oil is a rare event. Of the 742,042 cases of cosmetic products ingestions reported to TESS, less than 1% (726) had symptoms possibly suggestive of aspiration. Less than 0.01% had evidence suggestive of aspiration pneumonia. (One fatal case was reported and will be discussed in the next section.) Despite the ubiquity[1] of mineral oil-containing cosmetic and personal care products in the home and consequently the opportunity for exposure, there is a general lack of cases of consequence that would suggest that there is any significant degree of aspiration risk from an acute or accidental[2] exposure. There is only one case that the staff cites that could be construed as representing an acute or accidental exposure that resulted in a non-fatal but serious consequence. That single case was reported in the medical literature in 1985 by Dr. Santiago Reyes de la Rocha, et. al. Despite the authors' "publicizing" of this case and their call for the reporting of similar cases, in the 15 years since publication of this isolated incident there has been no confirmation or concurrence from the

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[1] Since 1935, one manufacturer estimates that it has sold over 1 billion units of baby oil. A market research firm recently reported to a major baby oil supplier that 93% of these products are sold to households with no children or children over 3. Only 7% of baby oil was bought by households with children aged 0-3 years old.

[2] The major focus of the PPPA is on preventing acute or accidental exposures. These are one-time exposures as opposed to chronic, every day exposures. Unlike other hydrocarbons, mineral oil aspiration has been shown to be a chronic rather than an acute complication of ingestion and it is typically seen with purposeful administration, such as in the case of EIR 981026HEP9021.

medical community that there is an "unrecognized problem" with acute exposures to these products. Indeed, the authors of this study themselves have not published an article detailing another such incident as a follow-up. Importantly, this case involved product removed from its original container.

The one fatal case reported in the TESS data involving a mineral oil-based cosmetic was where a massive exposure resulted in death. In that very disturbing case, police and other local authorities conducted an investigation into the circumstances surrounding the case. It is also important to note that part of the actual container lid was found in the patient's stomach[3]. There were no subsequent medical reports or publications regarding this case and no suggestions from the medical community that this single event demonstrated an unreasonable aspiration risk associated with mineral oil. The circumstances of this case simply do not suggest an aspiration risk from accidental exposure to mineral oil containing products.

3. If mineral oil is aspirated, is there a significant risk of toxicity?

The risk of toxicity is very low. Anything can and has been aspirated (see attached references). But an aspiration does not automatically result in serious symptoms.

Mineral oil aspiration produces a different type of pulmonary effect (lipoid pneumonia) than does aspiration of low viscosity hydrocarbons. Lipoid pneumonia is seen not only with mineral oil but with any mineral, animal or vegetable oil; it has been reported in the medical literature with substances such as olive oil, cod liver oil, paraffin oil, and poppy seed oil. In contrast, petroleum distillates with small molecules or carbon chain lengths are, in general, highly volatile and stronger solvents, and as such have a greater tendency to interact with fatty tissues and fluids and cause serious toxicity. The higher molecular weight compounds used in mineral oil do not have the same effect.

Aspiration of mineral oil *can* lead to lipoid pneumonia but this is rare and typically non-fatal. In fact, very few aspirations of mineral oil-based baby oil require medical treatment.

Mineral oils used in cosmetic products have high molecular weight , and average carbon chain lengths of at least C-20. Gasoline and petroleum solvents can have much shorter carbon chain lengths in the range of C-5 to C-15. As a higher molecular weight substance, the mineral oil used in cosmetics has higher viscosity, lower volatility, and higher surface tension. Unlike, hydrocarbons with lower viscosity, higher volatility and lower surface tension, mineral oil is much less likely to reach the lung and, once there, spread along the lung surface. As a result the risk of aspiration when a mineral oil product is ingested is very low.

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[3] 1996 AAPCC Annual Report at 49, Case 89.

4. Is mineral oil so fundamentally different from other hydrocarbons that it should not be considered under the same ruling as low viscosity hydrocarbons?

Yes. The toxicology studies and animal data differentiate mineral oils from other hydrocarbons. The landmark work in this area was done by Horace W. Gerarde, M.D , Ph.D and resulted in an article entitled *Toxicological Studies on Hydrocarbons: The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures*. Gerarde's approach to this issue was to evaluate petroleum distillates for both acute aspiration hazard *and* toxicity. He arrived at the following conclusions:

a) **Risk of aspiration resulting in pneumonia.** Gerarde concluded that any petroleum distillate with an SUS less than 45 posed a high aspiration hazard. Petroleum distillates with an SUS in excess of 59 (including mineral oil) had a low risk of aspiration resulting in pneumonia when ingested.

b) **Toxicity of aspirated petroleum distillate.** By directly instilling various petroleum distillates in the trachea, Gerarde concluded that, when aspirated, the *toxicity* of compounds with viscosities below 45 (e.g gasoline, lighter fluid, kerosene) was greater than for other petroleum distillates products with higher viscosities. For some petroleum distillates with an SUS between 45-59, chemical composition of the petroleum distillate *and* the viscosity dictated the likelihood of injury after aspiration. He further cited the difference between mineral oil and other petroleum distillates stating that:

> "mineral oil and motor oils of comparable viscosity do not cause severe, acute pulmonary edema and hemorrhage characteristic of kerosene and similar low-viscosity hydrocarbon mixtures. The pulmonary effects produced by these hydrocarbons are the "lipoid pneumonia" type of reaction—low-grade, chronic localized tissue reactions which are not fatal."

Dr. Gerarde also reported that "the study with individual hydrocarbons shows that larger molecules are less irritating on direct contact with endothelium than are smaller molecules." This finding helped explain the lack of acute toxicity of mineral oil, a larger molecular compound, on respiratory endothelial tissue.

CPSC's scientists evaluated the Gerarde method to see if it could accurately assess the hazard and toxicity potentials of products capable of being aspirated. CPSC validated[4] the published Gerarde method regarding petroleum distillate evaluation for aspiration hazard and toxicity, concluding that it "showed the best potential for predicting aspiration hazard and toxicity".

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[4]Osterber, RE; Bayard, SP; and Ulsamer, AG, *Appraisal of Existing Methodology in Aspiration Toxicity Testing.* Journal of the AOAC, 59 (3): 516-25, May 1976.

5. What is the appropriate viscosity level to require special packaging for hydrocarbons?

The scientific literature does not support an SUS level of 100 for mineral oil. Several commentators have stated that the greater viscosities of mineral oils make it "unlikely to be aspirated and cause pulmonary complications".

The CPSC 100 SUS minimum acceptable cutoff is understandably designed to incorporate a substantial margin of safety. Although it may be useful as a means of identifying substances which warrant scrutiny, it is important to evaluate *all* relevant factors (including clinical experience) which impact on determination of the actual risk of aspiration from various types of hydrocarbon-containing products. It is certainly unreasonable to apply the standard in specific cases where there is no clear danger from a particular product.

CPSC staff have recommended exemptions for *other* products or specific types of packaging for covered products citing "insufficient evidence" demonstrating an aspiration risk. The evidence demonstrating an unreasonable aspiration risk for mineral oil-containing products appears to be equally insufficient in *this* case.

In conclusion, we hope that you will find this information to be helpful in your consideration of the issues raised by the staff briefing package. The pending rulemaking represents a new approach for the Commission to the PPPA, i.e. regulating by class rather than product by product. By proposing such broad criteria, products that do not pose an aspiration hazard, such as mineral oil-based cosmetic and personal care products, could inadvertently be included simply because of their chemical composition.

Should you have any further questions, please do not hesitate to contact me.

Sincerely,

Catherine C. Beckley

Catherine C. Beckley
Associate General Counsel

Enclosures

Children's Hospital Medical Center

Drug & Poison Information Center

A service of
Children's Hospital Medical Center
University of Cincinnati Medical Center
Hamilton County Alcohol & Drug Addiction Services Board

Programs

Regional Poison Center
Drug Abuse Crisis Service
Drug Information Center

Chemical Dependency/Abuse Prevention & Intervention

Prevention Research Unit (PRU)

Product Consultation Center

Community Pharmacology

P.O. Box 19254
Cincinnati, OH 45219-0254
(513) 558-5111 Hotline
(513) 558-0230 Office
(800) 253-7955 TTY
(513) 558-5301 Fax

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November 10, 1999

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.

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 form 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 asphixial 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,

Suman Wason
Medical Director

PROSA
PRODUCT SAFETY RESOU
1295 Handana Blvd Suit
Saint Paul MN 5
612 917
Fax 612 641
www prosaone

December 2, 1999

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

Dear Commissioner Moore

I very much appreciated the opportunity to meet with you and your staff regarding the proposed rulemaking for hydrocarbons and child resistant closures I just received a copy of the memo from Ronald Medford and Suzanne Barone to the CPSC Commission concerning our recent meeting. It appears that there is still some confusion over what was said and its implications as it pertain to the rule I am particularly troubled by the staff characterization of comments that I have made regarding the establishment of an SUS of 100 as a reasonable cutoff for inclusion of hydrocarbon containing substances for the rule

As I stated in the meeting I have always been supportive of the 100 SUS cutoff as a reasonable "first tier" assessment for hydrocarbon eligibility for inclusion in this rule-making Since this rule covers literally tens of thousands of substances it is unreasonable to expect that the Commission, or any other scientific body, would be able to systematically assess each and every hydrocarbon substance for its inherent ability to pose an aspiration risk Rather, a more appropriate and understandable approach is to establish an "arbitrary" SUS cutoff that would be expected to capture 100 *plus* percent of the substances that could pose an unreasonable risk of aspiration. The staff's approach, by definition, examines only one of several parameters that influence aspiration risk and is expected to capture the vast majority of those substances that do pose an unreasonable risk as well as capture substances that do not. In this scenario I would expect that exceptions would be considered in order to accommodate the limitations of the approach used Mineral oil containing cosmetics should be one of the exceptions to the rule for all of the reasons that we discussed

There also appears to be continued confusion regarding the significance of cases coded in the TESS database as "aspiration" As a practicing clinician who has personally coded tens of thousands of cases in the TESS database I know that in many cases a mere cough results in "aspiration" being coded

It is also troubling that isolated incidents of aspiration continue to be presented as "proof" that an unreasonable risk exists If "aspiration" continues to be the single primary clinical endpoint to justify inclusion in the rule, nothing in the environment could be excluded. As regards lipoid pneumonia, the rule would have to apply to the variety of other substances where lipoid pneumonia has been reported (eg. olive oil, cod liver oil, poppy seed oil etc)

Over the last 24 months, CTFA has sought the counsel of outside practicing experts in the field of medicine, pediatrics, toxicology and poison control on the issue of an exemption for "mineral oil containing cosmetics" for this rulemaking As one of those experts, I have worked with my other colleagues to articulate a view that differs from that of the CPSC staff but one that we believe accurately represents our combined academic, clinical and professional experience that is so specific to this area.

Again, I appreciate your willingness to consider this information.

Sincerely,

Richard Kingston

Richard Kingston PharmD
Senior Clinical Toxicologist
PROSAR International Poison Center
&
Assistant Professor
Dept of Experimental and Clinical Pharmacology
College of Pharmacy
University of Minnesota

Cc: The Honorable Mary Sheila Gall

Attachment D

C T F A

THE COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION

E EDWARD KAVANAUGH
PRESIDENT

January 12, 1999

Suzanne Barone, Ph D
U S Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Dear Dr Barone

Attached is information that The Cosmetic, Toiletry, and Fragrance Association (CTFA) stated in its December 15, 1998 comments would be supplied to the agency after our poison control consultant, Dr Richard Kingston, could review the data of the American Association of Poison Control Centers (AAPCC) on ingestion of cosmetic hydrocarbons

Dr Kingston's findings include an analysis of 1996 and 1997 "baby oil" incident data complied by the AAPCC for CPSC CTFA respectfully requests that Dr Kingston's recommendations to CTFA and findings be added to the record for consideration by the staff and Commissioners in the hydrocarbon rulemaking

I will be out of the country from January 11 through January 20, so if you have any questions regarding the material, please contact CTFA's outside CPSC counsel Mary Martha McNamara at 703-971-8008 If you are unable to reach her in a timely fashion, please contact Tom Donegan, CTFA Vice President-Legal & General Counsel at 202-331-1770

Thank you for considering CTFA's earlier comments and Dr Kingston's report

Sincerely,

Catherine C Beckley

Catherine C Beckley
Associate General Counsel

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January 8, 1999

Catherine C Beckley
Associate General Counsel
The Cosmetic, Toiletry, and Fragrance Association
1101 17th Street, NW, Suite 300
Washington, DC 20036

Dear Ms Beckley,

This correspondence is in response to your request on the part of The Cosmetic, Toiletry, and Fragrance Association (CTFA) and a number of CTFA member companies that I review poison center incident data regarding cosmetic products containing mineral oil, specifically products encompassed by the name "baby oil" in the poison center database I have also been requested to comment on the Consumer Product Safety Commission's intent to expand its coverage of the Poison Prevention Packaging Act (PPPA) to require child resistant closures (special packaging) for mineral oil containing cosmetic products, meeting certain viscosity and percentage concentrations

As you know I am a practicing clinician with the International Poison Center and serve on the faculty of the University of Minnesota I have spent much of the last twenty years in the area of public poison control and have had a special interest in poison prevention packaging and continue to conduct research and speak on the topic It is with this expenence that I provide a response to your request

Much of the debate on the investigation of this issue centers around the concern over the possibility of "aspiration " Generally speaking, aspiration of foreign material into the lung by children or adults with an immature or otherwise compromised gag reflex is a known complication associated with poison exposures by the oral route In the case of ingested solids, vomiting may occur resulting in aspiration of liquid and particulate solid material from gastric contents Because of their physical nature, liquids may be aspirated into the lungs either directly during ingestion or after ingestion in the event of emesis Some low viscosity liquids have been purported to "migrate" to the lungs along mucus membranes In some cases, but not all, a chemical pneumonia occurs as a complication of aspiration. It is also well recognized that volatile liquids are more commonly associated with aspiration and certain of these volatile liquids more frequently cause chemical pneumonia The seventy of the pneumonia is influenced by the physical characteristics as well as the amount of the substance introduced into the lungs.

As a general rule, ingestion of "hydrocarbons" more frequently results in aspiration and chemical pneumonia as compared to other categories of substances This has prompted the CPSC to consider expanding the PPPA by strictly defining the broad class of substances included in the term "hydrocarbons" and apply the special packaging requirements to all substances in this class. When attempting to determine which substances should or should not be included, the question for manufacturers, toxicologists, regulatory officials and others involved in poison prevention efforts is simply stated·

Which "hydrocarbon"-containing household products or substances, when ingested, have been shown to present such an unreasonable level of risk of both aspiration and chemical pneumonia that additional measures of safety are warranted?

In their efforts to answer this question, the Commission has struggled with language and specifications that would establish a large enough safety net whereby all such substances posing an unreasonable risk would be identified

As with any approach that establishes a broad catchment policy, there will be some products, although they meet the general definition and physical characteristics of covered substances, whose specific physical, toxicological, or observed risk characteristics do not meet the intent of the rule making One substance that falls into this category is "mineral oil"-containing cosmetic products

I have commented on this proposed rule in previous correspondence to the Chemical Specialties Manufacturers Association (CSMA) as it regards products manufactured by a number of their members That correspondence has been shared with the Commission In that review of the proposed rule making, I discussed information provided by the Commission and others as it pertained to reported incidents of exposure to a number of hydrocarbon-containing products Mineral oil-containing cosmetics were not included in that review I have subsequently examined exposure-related poison center data specific to the general mineral oil category of "baby oil" in an effort to help the CTFA and its members better understand issues related to reported product exposure incidents

Based on my findings, I have concluded that despite concentrations and SUS ratings in the proposed target range, mineral oil-containing cosmetic products do not pose the same level of aspiration and chemical pneumonia risk as other "hydrocarbons" and, as such, an exemption for this class of hydrocarbon is justified These findings are also supported by experimental studies reported in the medical literature [1] A full discussion of my findings is attached.

Please note that my findings refer to three types of incident data that the Commission has discussed at various times during these deliberations One of those sources of data is the poison center database known as TESS (Toxic Exposure Surveillance System). The TESS database is often utilized as a source of information regarding exposure related inquiries made to poison centers Since TESS data may continue to be used in certain circumstances, a few additional comments are noteworthy

First, the database is exceptionally useful in helping to establish a safety record for products or categories of substances where large numbers of exposures are reported with minor or no adverse consequences Since toxicity and outcome are more likely to be overestimated in this database, lack of significant adverse consequence may help confirm or establish a positive safety record

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[1] Gerarde, HW Toxicological studies on hydrocarbons IX. The aspiration hazard and toxicity of hydrocarbons and hydrocarbon mixtures Archives of Environmental Health, 1963,6 329-341

Second, the use of the database to establish the toxicity of a given substance or category of substances is more difficult, especially if the numbers of significant cases relative to the total category are small It is especially imperative that before considering cases with reported outcomes of significance the "original" case record should be reviewed to assure accurate coding of outcome and appropriate and precise identification of the substance involved where possible Since this is not always possible, the data must be considered in proper context when attempting to draw conclusions for regulatory purposes

As your member companies evaluate the information that has been assembled they may want to compare it with their own surveillance experience so that they may be able to respond to any unanswered questions In my experience, the Commission has always been eager to consider any information a company can provide that would help Commission scientists better understand specific issues of product safety Accordingly, I would encourage both CTFA and its member companies to continue working with Commission staff by exploring any and all methods whereby you can maintain a shared level of comfort related to the safety of these products

If there are any additional questions related to my review of the incident data or if I can be of assistance in any other way during these deliberations please do not hesitate to contact me

Sincerely,

Richard Kingston PharmD
Senior Clinical Toxicologist
The PROSAR International Poison Center
&
Assistant Professor
Department of Clinical and Experimental Pharmacology
College of Pharmacy
University of Minnesota

Attachment Incident Data Findings & Analysis Report

Summary of Incident Data Findings & Analysis

Richard Kingston, Pharm D , CSPI
Vice President & Senior Clinical Toxicologist
PROSAR Product Safety Resources
St Paul, Minnesota

For the purposes of this rulemaking the Commission has relied on three specific types of data to support the expansion of the Poison Prevention Packaging Act requiring Child Resistant Closures (CRCs) for all "hydrocarbon" products meeting certain viscosity and concentration considerations These would include 1) National Electronic Injury Surveillance System (NEISS) data summarizing a four-year period of surveillance, 2) reports of injury made directly to the Commission, and 3) poison center data I will comment on each of these individually

1) National Electronic Injury Surveillance System (NEISS) Data

Although there were no NEISS reports of injury related to mineral oil-containing cosmetics for the time period quoted in the original notice of proposed rule making, it may be useful to comment on this system of surveillance for general perspective Portions of the following comments were included in previous correspondence to the Commission regarding the proposed rulemaking as it affects another consumer product trade association, but are provided here for the benefit of CTFA members that may not have seen those comments

The Commission operates the NEISS data system which collects information from 91 participating hospitals These data represent emergency department visits associated with consumer products A summary of emergency department visits involving products meeting specific criteria was used to estimate the incidence of similar events occurring throughout the U S It is apparent from the report and its descriptors that any pediatric patient presenting to an emergency department with a history of exposure to a consumer product within the defined scope of the project was included in the analysis I have outlined the limitations involved in the interpretation of incidents reported to this system before, but considering the importance they bear repeating The limitations include

It cannot be assumed from these data that all patients in this series were "poisoned" or "injured" just because they presented to an emergency department for evaluation This is best exemplified in the study completed by Anes, et al "Criteria for Hospitalizing Children Who Have Ingested Products Containing Hydrocarbons" appearing in JAMA, Aug 21, 1981, 248 8 In this study, the authors examined the medical records of 950 children who by history had ingested products containing hydrocarbons "Eighty four percent (84%) of these children were asymptomatic at the time of initial evaluation and remained so during a six- to eight-hour period of observation" prior to their discharge from the emergency department

It also cannot be assumed that children "admitted" to the hospital after exposure to petroleum-containing products have experienced serious injury In the same study cited earlier, 150 of the 950 children were "admitted" to the hospital Of these children 71% were asymptomatic and remained so during their hospital stay Pulmonary complications secondary to aspiration occurred in only 7 (0 74%) of the entire series and in each of these cases the child was symptomatic at presentation to the emergency department

"Treatment" of cases of "poisoning" is oftentimes confined to simple observation Unless it is known what specific treatments were performed it is difficult to assign any level of severity to a given case that was "treated" in a medical facility

Without review of the specific medical records related to these emergency department visits, the data series cannot identify which of the patients actually required emergency department evaluation I suspect that the diagnostic classification of "poisoning" was the only one possible given the coding and billing structure utilized in most emergency departments It should be emphasized that cases of suspected "poisoning" are the only cases that I know of where a completely asymptomatic patient, requiring no specific treatment, who experiences no adverse consequences of any type can be assigned to a billing and diagnostic code suggestive of injury It is also noteworthy that the descriptive term "poisoning" can be assigned without any laboratory or other diagnostic confirmation

Despite the limitations of these types of data in assessing product toxicity, the absence of any reported incidents in this database is a positive statement about the safety profile of a given product This is especially true when the product is well represented in the denominator of expected pediatric exposures This would be the case for "baby oil" which is used extensively around children and infants and the opportunity for exposure is vast as it is essentially ubiquitous to their home environment The lack of any reported exposure episodes of consequence in this surveillance system suggests a wide margin of safety

2) Reports of Exposure-Related Injury Made Directly to the Commission

There are 2 incidents of baby oil exposure resulting in significant outcomes that Commission officials have referred to at various times during these deliberations One involves a litigated case where exposure to the product occurred second hand after transfer of the product contents to another container The role of "special packaging" in this instance of product misuse would have had no bearing on this incident Given my 20 years experience in clinical toxicology I have also been suspicious of reports of "poisoning" where the alleged product or substance was in an unlabeled, secondary container Without the ability to verify the authenticity of the reported events through laboratory or other methods of confirmation, there is always some doubt regarding the correct identity of the substance involved

The second case involved the death of a 13-month-old child under mysterious circumstances CPSC investigative reports were sketchy due to lack of information available from those directly involved and refusal on the part of some of those same individuals to pursue necessary details to add clarity to the case Although not included in data released by the Commission, a Poison Center Fatality Report regarding this case was included in the 1996 "Toxic Exposure Surveillance System" (TESS) annual report This report made specific mention of the fact that a radiograph confirmed the presence of the product's lid in the child's stomach When all available facts are considered it is evident that the possibility of child abuse/neglect cannot be ruled out.

These findings diminish the validity of the incident as one supporting the proposed rule making requiring "special packaging" for the product believed to have been involved Had the product cap been lodged in the child's throat, aspiration of stomach contents which likely may have included some of the ingested product, could easily have occurred during respiratory distress Under these circumstances, subsequent CPR with bag ventilation could account for movement of the cap into the stomach Given the extenuating circumstances one cannot reasonably conclude that this exposure represents casual product ingestion resulting in aspiration and death

3) Data from the American Association of Poison Control Centers (AAPCC) "Toxic Exposure Surveillance System" (TESS)

Legal counsel for the CTFA has worked to secure data from the AAPCC regarding "baby oil" related exposures since becoming aware of the Commission's intent to extend the rule making to this class of product

It is my understanding that CTFA requested the exact same data set previously provided to the Commission The data that CTFA has received is an aggregate summary of reported exposure incidents involving the generic category of "baby oil " There are no copies of individual incident reports and none of the aggregate data is broken down into individual case records with tabulation of all associated data fields Although an electronic version of this data was requested, CTFA was informed that the original printed data set provided to both the Commission and the CTFA was all that was requested by the Commission This is unfortunate Although an electronic version of the data would not include original case notes, it would allow matching of data fields for each single incident represented in the database

The information that was provided represents two years of TESS data for the calendar years 1996 and 1997 The generic category of "baby oil" exposures in children less than 5 years of age was included Typically, if a specific brand name product is listed in the "Poisindex" database utilized by poison centers it is assigned a product specific code The product also is matched to an AAPCC "generic code " The product list in Poisindex also contains "general formulation" names with a product specific code An example would be "Baby Oil General Formulation" for which there is

a product specific code as well as "Johnson and Johnson Baby Oil" for which there is a product specific code. Usually each of these product specific codes would be expected to be matched to a generic code for "baby oil" as well and be represented in the database Theoretically, all baby oil products should be generically represented in this report but not identifiable by product name

Data for each year are broken down into two sections One includes all exposure incidents where "baby oil" was involved even if other substances were also involved in the same incident The other includes "baby oil without concomitants" meaning only exposures where "baby oil" was the sole substance is included For the purposes of this summary only "baby oil without concomitants" is discussed

The "medical outcome" category generally describes the intensity of effect and is typically used to delineate severity of a given case The definitions for medical outcome are as follows

No effect The patient developed no signs or symptoms as a result of the exposure

Minor effect The patient developed some signs or symptoms as a result of the exposure but they were minimally bothersome, and generally resolved rapidly with no residual disability or disfigurement A minor effect is often limited to the skin or mucous membranes

Moderate effect The patient exhibited signs or symptoms as a result of the exposure which were more pronounced, more prolonged, or more of a systemic nature than minor symptoms Usually some form of treatment is indicated Symptoms were not life- threatening and the patient has no residual disability or disfigurement.

Major effect The patient exhibited signs or symptoms as a result of the exposure which were life-threatening or resulted in significant residual disability or disfigurement

Death The patient died as a result of the exposure or as a direct complication of the exposure Only those deaths which are probably or undoubtedly related to the exposure are coded here

Not followed, judged as nontoxic exposure No follow-up calls were made to determine the patient's outcome because the substance implicated was nontoxic, the amount implicated was insignificant, or the route of exposure was unlikely to result in a clinical effect

Not followed, minimal clinical effects possible (field added to database in 1992) No follow-up calls were made to determine the patient's outcome because the

exposure was likely to result in only minimal toxicity of a trivial nature (The patient is expected to experience no more than a minor effect)

Unable to follow, judged as a potentially toxic exposure The patient was lost to follow-up, refused follow-up, or was not followed but the exposure was significant and may have resulted in a moderate, major, or fatal outcome

Unrelated effect The exposure was probably not responsible for the effect

1996 DATA

In 1996, out of 2,155,952 exposure related inquires made to poison centers nationwide, 1,136 involved baby oil The vast majority of exposures involved ingestion (91 73%), although other routes of exposure such as dermal (4 68%), and ocular (2 59%) were also reported (See 1996 TESS RPT 11) All but one were listed as "Acute" exposures One was listed as an "Acute-on-Chronic" exposure In 98 4% of the cases the medical outcome was of a minor, unrelated or nontoxic nature (*see* Attachment TESS RPT 22) Six (6) cases (0 53%) were coded as a "moderate" outcome but in only one of the six were there respiratory effects listed Four (4) of the moderate cases listed a duration of 24 hours, one (1) a duration of less than 3 days, and in one (1) the duration was unknown In the one moderate outcome case with respiratory effects it is unknown the duration of those effects as opposed to other reported effects in the same case There was one death reported The single death case appears to be the one known to the Commission and discussed in section 2 above

There were 5 incidents where aspiration was coded along with ingestion (*see* Attachment TESS RPT 72 pp 1-2) In these 5 cases the outcomes were listed as follows (2) minor effect, (2) not followed no more than minor effects possible, and (1) death

1997 DATA

In 1997, out of 2,192,088 exposure related inquiries made to poison centers nationwide, 1,337 involved baby oil The vast majority of exposures involved ingestion (92 05%), although other routes of exposure such as dermal (4 40%), and ocular (2 77%) were also reported (See 1997 TESS RPT 11) All but two were listed as "Acute" exposures One was listed as "Acute-on-Chronic" and one "Chronic" In 99 2% of the cases the medical outcome was of a minor, unrelated or nontoxic nature (*see* Attachment TESS RPT 22) Three (3) cases (0 22%) were coded as a "moderate" with 2 of the 3 listing "cough/choke" as the only respiratory effect For each of these 2 cases the duration of effect was <2hours and <8hours, respectively There was one case with a medical outcome coded as "major" with respiratory and neurological symptoms in duration of >week and <month This case was not coded as an aspiration

but rather as an "ingestion" so it is unknown if it was one of the "Acute-on-Chronic" or - "Chronic" exposure cases

There were six (6) cases in which aspiration was coded along with ingestion (see Attachment TESS RPT 72 pp 1-2) In these cases the outcome was listed as follows (1) no effect, (1) minor effect, (1) not followed, nontoxic, and (3) not followed, no more than minor effects possible

Summary of 1996 and 1997 TESS Data

Out of 2,534 exposure incidents relating to baby oil included in the database, only one of the 11 cases coded as involving an "aspiration" had symptomatology suggestive of hydrocarbon pneumonitis This single case appears to have been the tragic outcome discussed in detail in Section 2 above There were 2 cases where respiratory effects were coded, however, the duration is inconsistent with a diagnosis of "hydrocarbon pneumonia "

In the one case where a "major" outcome with respiratory and neurological effects is reported there is no coding of "aspiration" as having occurred The respiratory effects could have been the result of "Chronic" or "Acute-on-Chronic" ingestion A form of "lipoid" pneumonia has been described with chronic ingestion of mineral oil in certain circumstances It is impossible to determine if this applies here without reviewing the actual case record and corresponding notes as well as the complete data set

Inexplicably, routes of exposure coded as "parenteral" and "bite sting" were also included in the two years of data, likely representative of coding errors within the database which are known to exist at varying frequencies

Conclusion

When considering the available data, the overall general safety profile for "baby oil" is impressive Given the extensive use of the product in and around homes with small children and infants, the number of alleged significant adverse effects is extremely low These actual epidemiological findings support the landmark toxicological work performed by Dr Horace Gerarde[1] in which the lubricant class of hydrocarbons (including mineral oil) did not demonstrate the aspiration toxicity potential observed with other hydrocarbons After studying a wide range of induced hydrocarbon ingestion in unconscious rats, Gerarde concluded

> *"Mineral oil and motor oils of comparable viscosity do not cause severe, acute pulmonary edema and hemorrhage characteristic of kerosene and similar low-viscosity hydrocarbon mixtures "*

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1 Gerarde, HW Toxicological studies on hydrocarbons IX The aspiration hazard and toxicity of hydrocarbons and hydrocarbon mixtures Archives of Environmental Health, 1963 6 329-341

Finally, industry has expressed concern that in the absence of convincing evidence that an aspiration hazard exists, requiring CRCs on baby oil and personal care products with hydrocarbons could create another danger to children That is, much of the baby oil and other personal care products with hydrocarbons sold are used on babies and small children in the bath or on changing tables In the bath or on changing tables, prudent adults must always keep one hand on the child to prevent the child's drowning in the bath or falling off the changing table If parents must use both hands to open a CRC on a baby oil container, the risk of injury during that unattended period of time is considerable It would be tragic if a proposed remedy to a perceived, but unproven, level of toxicity resulted in the emergence of another type of injury This would most certainly be unacceptable to both the Commission and responsible manufacturers

cc Chairman Ann Brown
Commissioner Mary Sheila Gall
Commissioner Thomas Moore

BABY, OIL, EXPOSURES IN CHILDREN < 5 YEARS, WITHOUT CONCOMITANTS, 1996

ROUTE OF EXPOSURE from 01/01/96 to 12/31/96

	Number	Pct
Ingestion	1098	91.73
Inhalation/nasal	5	0.42
Aspiration	5	0.42
Ocular	31	2.59
Dermal	56	4 68
Bite/sting	1	0.08
Parenteral	0	0.00
Other	1	0.08
Unknown	0	0.00
Missing	0	0.00
Invalid	0	0.00
Total	1197	100.00

BABY OIL, EXPOSURES IN CHILDREN < 5 YEARS, WITHOUT CONCOMITANTS, 1996

MEDICAL OUTCOME from 01/01/96 to 12/31/96

	Number	Pct
No effect	320	28 17
Minor effect	75	6 60
Moderate effect	6	0.53
Major effect	0	0.00
Death (direct report)	1	0.09
Death (alternate source)	0	0.00
Not followed, judged as nontoxic exposure	283	24.91
Not followed, minimal clinical effects possible	422	37 15
Unable to follow, potentially toxic exposure	11	0.97
Unrelated effect	18	1.58
Missing	0	0 00
Invalid	0	0.00
Total	1136	100.00

BABY OIL, EXPOSURES IN CHILDREN < 5 YEARS, WITHOUT CONCOMITANTS, 1996

MEDICAL OUTCOME BY ROUTE OF EXPOSURE from 01/01/96 to 12/31/96

Medical Outcome	No effect		Minor effect		Moderate effect		Major effect		Death (direct)		Death (alt)		NF nontoxic	
	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Col %
Ingestion	298	28.63	55	5.28	3	0.29	0	0.00	0	0.00	0	0.00	269	25.84
Inhalation	1	100 00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Aspiration	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ocular	1	3.85	12	46.15	1	3 85	0	0 00	0	0.00	0	0.00	2	7.69
Dermal	0	0.00	1	14.29	0	0.00	0	0.00	0	0 00	0	0.00	2	28.57
Bite/sting	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00
Parenteral	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Other	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00
Unknown	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Multiple Routes														
Ing/Asp	0	0.00	2	40.00	0	0.00	0	0.00	1	20.00	0	0.00	0	0.00
Ing/Asp/Inh	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Inh/Asp/Derm	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00	0	0.00
Ing/Derm	18	39.13	3	6.52	0	0.00	0	0.00	0	0.00	0	0.00	10	21.74
Ing/Inh	0	0 00	0	0.00	1	33.33	0	0.00	0	0.00	0	0.00	0	0 00
Ing/Ocu	0	0.00	1	100.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ing/Inh/Ocu	1	100.00	0	0.00	0	0 00	0	0.00	0	0 00	0	0.00	0	0.00
Ing/Inh/Derm	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00	0	0 00	0	0.00
Inh/Ocu/Derm	0	0.00	1	100.00	0	0 00	0	0 00	0	0 00	0	0.00	0	0.00
Ing/Inh/Ocu/Derm	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00
Inh/Derm	0	0 00	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00	0	0.00
Inh/Ocu	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Ocu/Derm	1	50.00	0	0.00	1	50.00	0	0.00	0	0.00	0	0.00	0	0.00
Other Rte Combs	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Tot Mult Routes	20	33.90	7	11 86	2	3.39	0	0.00	1	1.69	0	0.00	10	16.95
Missing	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Invalid	0	0.00	0	0 00	0	0 00	0	0.00	0	0 00	0	0 00	0	0 00
TOTALS	320	28.17	75	6.60	6	0.53	0	0.00	1	0.09	0	0.00	283	24.91

BABY OIL, EXPOSURES IN CHILDREN < 5 YEARS, WITHOUT CONCOMITANTS, 1996

MEDICAL OUTCOME BY ROUTE OF EXPOSURE from 01/01/96 to 12/31/96

Medical Outcome	NF minimal		NF pot toxic		Unrelated Eff		Missing		Invalid		Total	
	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Col %
Ingestion	391	37.56	9	0.86	16	1.54	0	0 00	0	0 00	1041	91.64
Inhalation	0	0.00	0	0 00	0	0 00	0	0.00	0	0 00	1	0.09
Aspiration	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ocular	9	34.62	0	0.00	1	3.85	0	0.00	0	0 00	26	2.29
Dermal	3	42.86	0	0 00	1	14.29	0	0.00	0	0.00	7	0.62
Bite/sting	1	100.00	0	0.00	0	0.00	0	0.00	0	0.00	1	0.09
Parenteral	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00	0	0.00
Other	0	0.00	1	100.00	0	0 00	0	0.00	0	0 00	1	0.09
Unknown	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Multiple Routes												
Ing/Asp	2	40.00	0	0.00	0	0.00	0	0.00	0	0.00	5	0.44
Ing/Asp/Inh	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Asp/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ing/Derm	14	30.43	1	2.17	0	0 00	0	0.00	0	0.00	46	4.05
Ing/Inh	2	66.67	0	0.00	0	0.00	0	0.00	0	0 00	3	0.26
Ing/Ocu	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	0.09
Ing/Inh/Ocu	0	0 00	0	0 00	0	0 00	0	0.00	0	0 00	1	0.09
Ing/Inh/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00
Inh/Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	1	0.09
Ing/Inh/Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Ocu	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	2	0.18
Other Rte Combs	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Tot Mult Routes	18	30.51	1	1.69	0	0.00	0	0.00	0	0.00	59	5.19
Missing	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Invalid	0	0 00	0	0 00	0	0.00	0	0 00	0	0.00	0	0.00
TOTALS	422	37.15	11	0.97	18	1.58	0	0.00	0	0.00	1136	100.00

BABY OIL, EXPOSURES IN CHILDREN UNDER 5 YEARS, WITHOUT CONCOMITANTS, 1997

ROUTE OF EXPOSURE from 01/01/97 to 12/31/97

	Number	Pct
Ingestion	1296	92.05
Inhalation/nasal	2	0.14
Aspiration	6	0.43
Ocular	39	2.77
Dermal	62	4.40
Bite/sting	0	0.00
Parenteral	1	0 07
Other	1	0 07
Unknown	1	0.07
Missing	0	0.00
Invalid	0	0.00
Total	1408	100.00

BABY OIL, EXPOSURES IN CHILDREN UNDER 5 YEARS, WITHOUT CONCOMITANTS, 1997

MEDICAL OUTCOME from 01/01/97 to 12/31/97

	Number	Pct
No effect	369	27 60
Minor effect	80	5 98
Moderate effect	3	0 22
Major effect	1	0.07
Death (direct report)	0	0 00
Death (alternate source)	0	0 00
Not followed, judged as nontoxic exposure	356	26.63
Not followed, minimal clinical effects possible	496	37.10
Unable to follow, potentially toxic exposure	7	0.52
Unrelated effect	25	1.87
Missing	0	0.00
Invalid	0	0.00
Total	1337	100 00

BABY OIL, EXPOSURES IN CHILDREN UNDER 5 YEARS, WITHOUT CONCOMITANTS, 1997

MEDICAL OUTCOME BY ROUTE OF EXPOSURE from 01/01/97 to 12/31/97

Medical Outcome	No effect		Minor effect		Moderate effect		Major effect		Death (direct)		Death (alt)		NF nontoxic	
	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Col %
Ingestion	337	27.35	62	5.03	3	0.24	1	0.08	0	0.00	0	0.00	342	27.76
Inhalation	1	50.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00
Aspiration	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ocular	8	32.00	10	40.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00
Dermal	1	14.29	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	4	57.14
Bite/sting	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Parenteral	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Other	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00
Unknown	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Multiple Routes														
Ing/Asp	1	16 67	1	16.67	0	0.00	0	0.00	0	0 00	0	0.00	1	16 67
Ing/Asp/Inh	0	0.00	0	0.00	0	0 00	0	0 00	0	0 00	0	0.00	0	0.00
Inh/Asp/Derm	0	0.00	0	0 00	0	0 00	0	0 00	0	0.00	0	0.00	0	0 00
Ing/Derm	16	33.33	1	2.08	0	0.00	0	0.00	0	0.00	0	0 00	8	16.67
Ing/Inh	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ing/Ocu	4	57.14	1	14.29	0	0.00	0	0.00	0	0.00	0	0.00	1	14.29
Ing/Inh/Ocu	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00
Ing/Inh/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Inh/Ocu/Derm	0	0 00	1	100.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ing/Inh/Ocu/Derm	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00	0	0.00	0	0.00
Inh/Derm	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00	0	0.00	0	0.00
Inh/Ocu	0	0 00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00
Inh/Ocu/Derm	0	0 00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ocu/Derm	1	16.67	4	66.67	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Other Rte Combs	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Tot Mult Routes	22	31.43	8	11.43	0	0.00	0	0.00	0	0.00	0	0.00	10	14.29
Missing	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00	0	0 00
Invalid	0	0.00	0	0.00	0	0 00	0	0 00	0	0 00	0	0 00	0	0.00
TOTALS	369	27.60	80	5.98	3	0.22	1	0.07	0	0.00	0	0.00	356	26.63

BABY OIL, EXPOSURES IN CHILDREN UNDER 5 YEARS, WITHOUT CONCOMITANTS, 1997

MEDICAL OUTCOME BY ROUTE OF EXPOSURE from 01/01/97 to 12/31/97

Medical Outcome	NF minimal		NF pot toxic		Unrelated Eff		Missing		Invalid		Total	
	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Row %	Number	Col %
Ingestion	462	37 50	5	0.41	20	1 62	0	0.00	0	0 00	1232	92.15
Inhalation	0	0 00	1	50.00	0	0.00	0	0.00	0	0.00	2	0.15
Aspiration	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00
Ocular	6	24.00	1	4.00	0	0.00	0	0.00	0	0.00	25	1.87
Dermal	2	28.57	0	0.00	0	0.00	0	0.00	0	0 00	7	0.52
Bite/sting	*0*	*0.00*	*0*	*0.00*	*0*	*0.00*	*0*	*0.00*	*0*	*0.00*	*0*	*0.00*
Parenteral	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00	0	0.00
Other	1	100.00	0	0.00	0	0.00	0	0.00	0	0 00	1	0.07
Unknown	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00
Multiple Routes												
Ing/Asp	3	50.00	0	0.00	0	0.00	0	0.00	0	0.00	6	0.45
Ing/Asp/Inh	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00
Inh/Asp/Derm	*0*	*0.00*	*0*	*0.00*	0	0.00	0	0.00	0	0 00	0	0.00
Ing/Derm	18	37.50	0	0.00	5	10.42	0	0.00	0	0 00	48	3.59
Ing/Inh	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0 00
Ing/Ocu	1	14.29	0	0.00	0	0.00	0	0.00	0	0 00	7	0.52
Ing/Inh/Ocu	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Ing/Inh/Derm	0	0.00	0	0.00	0	0 00	0	0 00	0	0.00	0	0.00
Inh/Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	1	0.07
Ing/Inh/Ocu/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Derm	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Ocu	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Inh/Ocu/Derm	0	0.00	0	0.00	0	0 00	0	0.00	0	0.00	0	0.00
Ocu/Derm	1	16.67	0	0.00	0	0.00	0	0.00	0	0.00	6	0.45
Other Rte Combs	2	100.00	0	0.00	0	0.00	0	0.00	0	0.00	2	0.15
Tot Mult Routes	25	35.71	0	0.00	5	7.14	0	0.00	0	0.00	70	5.24
Missing	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00
Invalid	0	0.00	0	0.00	0	0.00	0	0.00	0	0 00	0	0.00
TOTALS	496	37.10	7	0.52	25	1.87	0	0.00	0	0.00	1337	100.00

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D C. 20207

STATEMENT OF THE HONORABLE MARY SHEILA GALL ON PUBLICATION OF A NOTICE OF PROPOSED RULEMAKING TO REQUIRE SPECIAL PACKAGING FOR LOW-VISCOSITY HYDROCARBONS

December 3, 1999

Today, I voted to publish for public comment notice of a proposed rule (NPR) to require special packaging for low-viscosity hydrocarbons My vote to go forward with this proceeding was conditional upon the Commission directing the staff to develop a detailed plan to capture incident data for mineral oil based hydrocarbon products. Such information must be collected and analyzed in order to supplement the paucity of incident data contained in the staff briefing package.

On February 18, 1997, I voted in support of an advance notice of proposed rulemaking (ANPR) to determine whether child resistant closures should be required for certain household products containing petroleum distillates. I believed that the evidence presented to the Commission, at that time, was sufficient to proceed at that preliminary rulemaking stage. To publish an NPR, however, requires more precise information and a greater level of certainty that a rule may be necessary to address an alleged hazard.

Included in the published ANPR, was a request for public commentary on the appropriate scope of this proposed rule. As a consequence, staff eliminated certain products and certain types of packaging, but decided to expand the general scope of the rule to incorporate a broad class of low-viscosity household products containing a certain threshold of hydrocarbons. After reviewing the staff briefing package, as well as the staff's responses to a series of follow-up questions and comments, I was left unsatisfied that the information at our disposal justifies the inclusion of all product classes currently encompassed in the proposed rule.

Specifically, I agreed that we possessed sufficient information – including incident data – to support going forward with respect to that class of hydrocarbons regulated under the Federal Hazardous Substances Act (FHSA) This includes a number of automotive and household products that seem to pose a clear risk of serious personal injury or illness.

On the other hand, there simply was inadequate data available to support going forward with respect to those mineral oil based hydrocarbons regulated under the Federal Food, Drug and Cosmetic Act (FDCA) This would include such common household

products as baby oil and sun tan lotion. Indeed, this appears to be considerable disagreement as to the toxicity and potential hazards posed by such products

There is no need to provide an elaborate analysis of the statutory requirements under the Poison Prevention Packaging Act (PPPA) at this point. It should be noted, however, that the PPPA does require that the Commission consider incident data "concerning childhood accidental ingestions, illness and injury caused by household substances" Based upon my review of the available incident data involving such mineral oil based products, I concluded that additional information is needed before this Commission can make any final determination on this rule.

At our meeting today, the Commission did direct the staff to collect and analyze incident data involving these products My vote to proceed forward was couched in considerable reservation. None the less, I feel it is prudent, at this stage of the rulemaking process, to remain open to the possibility that there may be justification to include these products within the scope of the rule The propriety of doing so will be determined by the information gathered during this NPR stage

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D C 20207

STATEMENT OF COMMISSION THOMAS H. MOORE
ON THE PROPOSED RULE TO REQUIRE CHILD-RESISTANT PACKAGING
FOR LOW-VISCOSITY HYDROCARBONS
December 3, 1999

Today, I have voted to issue the proposed rule to require child-resistant packaging for low-viscosity liquid hydrocarbons I have done so because I believe that the information that has been provided by our staff sufficiently supports their recommendation to issue the proposed rule I think that the Commission staff has done an excellent job of determining what properties of a product lead to an aspiration hazard and thereafter defining parameters under which products would be regarded as hazardous because of their potential for aspiration However, I also believe that there may be some unresolved issues concerning the inclusiveness of the scope of the regulation as defined by staff

To issue a final rule under the PPPA, this Commission must make certain findings First and foremost, we must find that there are potentially serious consequences to the availability of a substance to children, that the availability must be by reason of its packaging, and that special packaging is required to protect children from the serious consequences of that substances' availability Additionally, the Commission must find that that child-resistant packaging is technically feasible, practicable, and appropriate for products that fall within the scope of the regulation.

The substances of concern in this rulemaking are liquid products that contain more than 10% hydrocarbons by weight and have a viscosity of less than 100 SUS at 100° F There is substantial evidence that, if ingested by children, many products within these parameters pose serious aspiration risks Without question, staff's recommendation would impact many different classes of products that currently do not require child-resistant packaging The sweep of staff's recommendation is much broader than anything we've previously contemplated covering under the PPPA This therefore raises the relevant question of whether the Commission should or even could have detailed injury data information on every product that may be covered by this regulation?

I hardly think that it is necessary to have detailed injury data information on every specific product that may fall within the scope of the proposed rule However, I do think that we should have enough specific injury data information on the classes of products that may fall within the scope of this rulemaking such that we can reasonably conclude that if a product falls within the recommended criteria for regulating, then there clearly exists the potential for serious consequences for children

Therefore, along with my vote to issue the proposed rule, I strongly recommend that staff actively seek out, during the period of time provide by this step, all available information relevant to the inclusion and the exclusion of products within the scope of this rule It is extremely important that this Commission have for its examination all of the available information from every reasonable source before going into the final stages of this rulemaking

As I have indicated, I think that staff, based upon the information available to the Commission, has done an excellent job of recommending reasonable parameters for regulating and I have voted to issue those parameters as a proposed regulation An enormous amount of time was spent gathering data and communicating with the regulated community before the scope of the proposal was settled upon Accordingly, the participation by the regulated community in setting these proposed parameters must be acknowledged for its importance Whether by comments, meetings with staff, or meetings with this Commissioner, the input received from industry representatives and others has been invaluable I am hoping that such participation will continue as we move forward with this rule

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: FEB - 4 2000

TO : The Commission
Sayde E. Dunn, Secretary

THROUGH: Michael S. Solender, General Counsel MSS
Pamela Gilbert, Executive Director PG

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

SUBJECT : Plan for obtaining additional information about mineral oil-based cosmetics.

This memorandum presents an option to obtain additional information about mineral oil-based cosmetics

BACKGROUND

At the Commission meeting on December 3, 1999, Commissioner Gall requested that the staff develop a plan for the collection of additional information on mineral oil-based cosmetic ingestion incidents. This plan is to be forwarded to the Commission for their review and consideration.

In the briefing package dated August 10, 1999, the staff recommended that the Commission propose child-resistant packaging requirements for household chemical and cosmetic products that contain 10 percent or more hydrocarbons and have a viscosity under 100 SUS at 100°F. The staff presented ingestion data from general cosmetic categories that may contain low viscosity hydrocarbons collected by the American Association of Poison Control Centers' (AAPCC) Toxic Exposure Surveillance System (TESS). The categories included creams/lotions/make-up, miscellaneous nail products, bath oil/bubble bath, and suntan/sunscreen products. The data presented were from the years 1995 through 1997. A total of 74,042 ingestion incidents from these product categories were recorded. The staff also noted that 114 of the cases were coded as aspirations.

It is not known how many of these incidents involved products that contain low viscosity hydrocarbons that would be subject to the rule recently proposed by the Commission. These data were relied on by the staff to demonstrate that children access cosmetic products that may contain low viscosity hydrocarbons.

CPSA 6 (b)(1) Cleared 2/4/00 No Mfrs/PrvtLblrs be identified by

NOTE: This document has not been reviewed or accepted by the Commission. Date 2/4/00

For this project, the staff purchased TESS data on baby oil ingestions for the years 1996 and 1997 to examine incidents from products that are known to contain low viscosity hydrocarbons. A total of 2,560 ingestions of baby oil were in the database for these two years including a death in 1996 These ingestion cases are a subset of the creams/lotions/make-up category.

POSSIBLE STUDY

As described above, the ingestion incident data that CPSC purchases annually from the AAPCC does not identify specific products or brand names. Identification 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.

The AAPCC collects brand name information when a poisoning occurs. According to Dr. Toby Litovitz, Executive Director of the AAPCC, brand names are identified about 70 percent of the time in the TESS database. This percentage may vary for individual product categories. However, the product is identified generically (i.e. bubble bath or suntan oil) even when the brand name is not known. This additional information would provide more specificity than is currently available. However, it may not be possible to identify only products that would be included in the proposed rule. If a product is only identified as suntan oil, the staff has no way of determining the chemical composition and viscosity of the product.

Even if the additional information identifies the brand name of the product, it will not identify the percent of mineral oil in the product or its viscosity. Therefore, unless the staff has already tested a particular product in the laboratory (currently 23 cosmetic products have been tested), there will be no way to know if the product falls within the definition of the proposed rule. This information could only be obtained by requesting it from the manufacturer or by laboratory analysis. To collect and test the potentially large number of products identified from the data (depending on the number of brand names identified) could place a large burden on the CPSC chemistry laboratory. Any lotions, creams, or other emulsions identified by the study can be eliminated from the data since they are specifically excluded from the proposed rule. In addition, baby oil may be assumed to be in scope, unless it is a gel or lotion, because the viscosities of baby oils measured previously by the staff were all below 100 SUS.

In order to purchase information on specific brand names, the CPSC must obtain special permission from the AAPCC Board of Directors. The rationale for the need to identify the products in the interest of public health must be provided to the Board for their consideration. The CPSC staff has made requests for brand name data twice in the past and was granted permission on both occasions. The estimated cost of buying brand name data for the four cosmetic codes is $3,400 per year for an electronic copy.

CONCLUSION

If the Commission determines that these data are necessary, the staff recommends purchasing 1998 brand name data for the four cosmetic categories. These data should be readily available if permission for the purchase is granted to CPSC by the AAPCC Board of Directors.

C P00-1-7

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March 20, 2000

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

RE: NOTICE OF PROPOSED RULEMAKING (NPR) TO REQUIRE CHILD-RESISTANT PACKAGING FOR HOUSEHOLD PRODUCTS CONTAINING HYDROCARBONS (65 Federal Register 93) (January 13, 2000)

In response to the Notice of Proposed Rulemaking (NPR) on the extension of the Poison Prevention Packaging Act (PPPA) by the Consumer Product Safety Commission (CPSC) to certain products containing hydrocarbons, The Art and Creative Materials Institute, Inc. (ACMI) is pleased to submit the following comments relating to consistency with applicable Federal Hazardous Substance Act (FHSA) requirements. ACMI has no background as to products covered by the Federal Food, Drug and Cosmetic Act requirements. 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 continues to this day. Its program was expanded in 1982 to evaluate and properly label adult art materials.

The NPR explains that the Commission is considering the extension of the PPPA regulations, contained in 16CFR1700.1 through 1700 20, to some additional products containing 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

ACMI urges CPSC, in its consideration of this subject matter, to maintain the specific exemptions for writing and drawing implements contained in 16CFR1500 83 (7), (9), (12) and (38), 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 ehylene 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 forseeable 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 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, MD, 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 NPR. ACMI also agrees with CPSC staff that paint markers should be exempt from these PPPA regulations for the same reasons stated above in reference to exempted ink markers.

ACMI also urges 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.

Extension of PPPA Regulations to Household Products Containing Hydrocarbons

ACMI recommends that the PPPA regulations be extended to household products containing hydrocarbons unless they do not present an aspiration hazard, on the basis of the recommendation of ACMI's Toxicologist. Our recommendation would not include aerosol products that do not form a discrete stream when sprayed, as they would not present an aspiration hazard. Our recommendation does include the retention of the viscosity level of less than 100 SUS at 100° F. and urges that it be applied to all ingredients, including turpentine.

Viscosity and Percentage Composition

ACMI supports the retention of the current viscosity level of less than 100 SUS at 100° F found in FHSA regulations at 16CFR1500.83 (13) and in PPPA regulations at 16CFR1700.14(7) and (15) and the percentage compositions, also found in FHSA and PPPA regulations. This viscosity level was established based on appropriate animal aspiration studies and we do not believe that very limited aspiration incidents would require a change in this level. We would, however, urge that this viscosity criterion be consistently applied to all hydrocarbons where a toxicologic assessment shows an aspiration concern Materials that meet this viscosity criterion and would be a health risk if aspirated include petroleum distillates, hydrocarbons, turpentine and other terpenes, such as *D-Limonene*. The adverse effects from aspiration of these materials can include sudden death, intense lung injury, and a lipoid pneumonia. Although all petroleum distillates, hydrocarbons and terpenes may not have been tested for aspiration risk, there is sufficient evidence of risk of harm from members in each class that meet the viscosity criterion such that extension of concern to all members of each class (meeting the viscosity criterion) is reasonable. Extending the viscosity criterion to all such products, including turpentine to which the viscosity level does not currently apply, would standardize the PPPA regulations and facilitate labeling and packaging of products for those manufacturers who sell the same product in the global market.

Types of Ingredients to be Included

ACMI also supports the extension of PPPA regulations to hydrocarbons and terpenes that present an aspiration risk as listed in the NPR at the percentage compositions contained in the FHSA regulations with the viscosity criterion discussed above. In the case of art materials, this would extend PPPA regulations to any art material containing 10% or more of xylene, toluene, petroleum distillates, and D-Limonene.

Art Materials to be Included in Extended PPPA Regulations

The effect of our recommendation would be to extend PPPA regulations on an ingredient-specific basis, rather than product-specific, which would help to eliminate current gaps in the regulations. In truth, the ingredient presents the hazard, no matter the type of product, provided the viscosity and current packaging allows aspiration of the product In the case of art materials, driers, mediums, ceramic specialty products, ceramic stains and overglazes, and liquid metallic paints with 10% or more hydrocarbons at a viscosity of less than 100 SUS at 100° F would be covered under our recommendation, not just solvents and brush care products which are currently covered Other art materials that would be covered under our recommendation include glass stains and mediums, varnishes, fixatives, some ceramic thickeners, and some ceramic glazes.

Inclusion of Aerosols

ACMI recommends that aerosols containing hydrocarbons and that form a coherent stream be included in the extension of the PPPA regulations. We would support a specific regulatory definition based on scientific testing and study of whether a coherent stream is formed.

Additional Information

While information on the formulations of the art materials in question is confidential and unavailable to ACMI, a very limited survey of members reveals that these products are produced in both liquid and aerosol forms at viscosities varying from 60-150 SUS at 100° F These products are normally used by the serious professional artist or ceramicist in a home or studio The products vary in size from two ounces to one gallon and are packaged in glass or plastic containers. Some ACMI-member manufacturers currently are voluntarily using child-resistant packaging for materials that have DANGER warnings for aspiration hazards but are not currently covered under the PPPA regulations We do not at this time have sufficient cost-related information from members. But, as members tend to support the proposal and have products already in child-resistant packaging, it would not appear to raise major cost obstacles.

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.

Respectfully submitted,

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