



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

CPSA 6 (b)(1) Cleared
 3/23/00
 No Mfrs, Prvtl Bldgs or
 Products Identified
 Excepted
 Firms Notified
 Comments Processed

MEMORANDUM

DATE: March 22, 2000

TO : HS

Through: Sadye E. Dunn, Secretary, OS

FROM : Martha A. Kosh, OS

SUBJECT: Proposed Rule on Household Products Containing
 Hydrocarbons, 65 FR 93, January 3, 2000

ATTACHED ARE COMMENTS ON THE CP 00-1

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CP 00-1-1	1/18/00	Roger Tucker Director - Quality & Technology	Coastal UniLube, Inc. 44 North Second St. Suite 1200 Memphis, TN 38103
CP 00-1-2	3/14/00	Dennis Lott Exec. Director of Technical Affairs	Tanning Research Laboratories, Inc. P.O. Box 265111 Daytona Beach, FL 32126
CP 00-1-3	3/17/00	Students (3 classes)	Florida International University University Park Miami, FL 33199
CP 00-1-4	3/20/00	Brigid Klein Regulatory Counsel	Chemical Specialties Manufacturers Assoc. 1913 Eye Street, NW Washington, DC 20006
CP 00-1-5	3/20/00	S.E. Vredenburg	Pennzoil-Quaker State Company 700 Milam, P.O. Box 2967 Houston, TX 77252

Proposed Rule on Household Products Containing Hydrocarbons, 65
FR 93, January 3, 2000

CP 00-1-6	3/20/00	C. Beckley Assoc. General Counsel	The Comestic, Toiletry, & Fragrance Association 1101 17 th St, NW Suite 300 Washington, DC 20036
CP 00-1-7	3/20/00	D. Fanning CAE, Exec. Vice President	The Art & Creative Materials Institute Incorp. 1280 Main St. P.O. Box 479 Hanson, MA 02341



CP00-1-1

Gobh
OK
1/16/00

January 10, 2000
CPSCT OFFICE OF
THE SECRETARY

2000 JAN 18 A 11:05

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

RE: NPR for Hydrocarbons

Coastal Unilube, Inc. is a manufacturer of lubricating oils and car care products, some of which contain petroleum distillates (in the form of mineral spirits). These products currently contain the FHSA-specified labeling for an aspiration hazard (includes the signal word "DANGER", the statement of hazard "Harmful or fatal if swallowed", and the statement "Call physician immediately."). These products are capped with a closure that contains a foil inner seal. After capping, the bottle passes through a machine that seals the foil to the top of the bottle. When the cap is removed, the foil seal remains attached to the bottle opening. While this foil seal does not fit within the definition of "child-proof," it is difficult to open.

These products are intended for "total package use." In other words, when the container is initially opened, the entire contents should be added to the gas tank, and the container should be properly disposed of.

Products of this type would normally be stored in a garage and not inside the house. The majority of this product, when purchased by the consumer at the retail level, is immediately added to the gas tank. A small percentage (we estimate less than 10 percent) of consumers may buy more than one container to keep on their garage shelf for later use.

Coastal Unilube does not feel that a child-proof closure is necessary for these types of products. Several precautions (outlined above) have already been taken. We would, however, be in support of adding a statement to the label such as "Add entire contents to gasoline tank."

Thank you for considering our comments. If you have any questions or would like additional information, please feel free to contact me by phone at (901)522-4104 or by Email at roger.tucker@coastalcorp.com.

Sincerely,

Roger E Tucker
Director - Quality & Technology



TANNING
RESEARCH
LABORATORIES, INC

PO Box 265111
Daytona Beach, FL 32126-5111
(904)677-9559
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CP09-1-2
6-6-00 comment
CPSC/OFFICE OF THE SECRETARY
2000 MAR 14 A 10:29

March 7, 2000

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

NPR for Hydrocarbons

Dear Sir/Madam

Tanning Research Laboratories, Inc (TRLI) is primarily a Suncare OTC Drug and Cosmetic manufacturer. We have reviewed the proposed guidelines for low viscosity hydrocarbon products. Although TRLI has never been apprised of any problem with our products along this line, we certainly are willing to comply with any regulation that promotes consumer safety, and this comment is not intended to argue the regulation merits. We have already initiated a product review, and will immediately begin work on non-compliant products.

Again, we have no problem in working diligently to comply with the regulation. The only concern we have is the time that would be allowed to comply. Suncare is a very seasonal industry. An example of the typical Suncare marketing and sales timing is as follows. For the season 2002, the product line must be decided no later than December 2000. This gives Research and Development time to develop products and do the extensive stability, efficacy, and safety testing needed to allow sales calls and presentations by June/July of 2001. Production for 2002 would then begin as early as August of 2001 with actual shipments starting around November 2001. Any product not sold by May of 2002 would probably be held for sale in the 2003 season. As is obvious, a change can take a long implementation time, and could represent a heavy financial burden if the effective date does not allow adequate industry reaction time. Based on this, it can be seen that two years would be a minimum needed with 3 years being optimum. The recently published FDA OTC Suncare Monograph recognized this and provided similar timing.

We hope that you will give a great deal of consideration to the timing. We in turn plan to take steps as rapidly as possible to comply with this guideline. I welcome any questions concerning this comment.

Sincerely,

Dennis L. Lott
Executive Director of Technical Affairs



6/26/00
3/17/00
CP00-1-3

March 10, 2000

Office of the Secretary
Consumer Product Safety Commission
Washington, D.C.
20207-0001

Re: Docket #Unknown: Consumer Product and Safety
Commissions: Household Products
Containing HYDROCARBONS

To Whom it May Concern:

We the students at Florida International University believe in maintaining the health and well-being of our fellow students as well as that of our community. We belong to a Business course entitled Business and Society. It has been our mission to investigate as well as comment on the proposed rule under the Consumer Product Safety Commission with respect to the issue of Hydrocarbons and the threat they pose to our community as a whole. This issue is one that plays a major role in our lives. We feel it to be our duty as a distinguished university and as a class united to join in the effort of combating the lethal subject of hydrocarbons. As members of such an institution it is and should be our responsibility to gather unite forces and help maintain the environment that belongs to all of us worldwide. It seems as though the population is being affected daily by these hydrocarbons and many are not aware of the problem. Consequently, those who are affected know the dangers but during usage are not focused on the possible harmful threats. For this reason we are in favor of the intent of the proposed rule to safeguard children by placing certain precautions on household items that cause illnesses. We are discouraged by the inconsistencies that are presently existent with respect to the restrictions placed upon various products affecting individuals of all given ages.

We write with concern about a proposed rule under the Poison Prevention Packaging Act (PPPA), which proposes to require child resistant packaging for certain low-viscosity hydrocarbon products. Such products, even in small amounts, create the risk of chemical pneumonia, pulmonary damage, even death. Therefore it is of utmost importance that clear guidelines and restrictions be defined regarding the packaging of such products. Presently, hydrocarbons are not regulated under the PPPA, and therefore many of these dangerous products are not required to be in child-resistant packaging. These include popular, commonly used products which are easily available to children. Some examples that are not currently required to have child-

resistant packaging are cleaning solvents, automotive chemicals, shoe-care products, and cosmetics.

There are terrible inconsistencies in the current restrictions which, for example, require mineral spirits used as paint solvent to have child-resistant packaging but does not place any restrictions or guidelines on the packaging of products containing even ninety-five percent mineral spirits, like some water repellants. Another inconsistent application of such packaging requirements is that of kerosene; when used as lamp fuel, child-resistant packaging is required, however gun cleaning solvents consisting of more than ninety percent kerosene are not required to have child-resistant packaging. It is crucial that conservative guidelines for threshold levels of hydrocarbons and other hazardous materials be established, and that any product containing dangerous amounts of hydrocarbons be required to have child-resistant packaging. These threshold values must be determined to provide a means of consistent creation and application of laws governing child-resistant packaging. This is why the proposed standard includes all household products as defined by the PPPA, unless exempted, containing ten percent or more hydrocarbons by weight with a viscosity below the defined threshold.

Another serious concern is the inclusion of hydrocarbon-containing aerosol products in these guidelines under the proposed rule. Even though these products are dispensed as mist, dangerous exposure to the product by aspiration is still possible, therefore presenting a clear need for child-resistant packaging. In a time far more concerned with teenagers' use of cocaine, alcohol and tobacco, few parents are aware that some of the most insidious and lethal drugs of all may be lurking in the broom closet, in the cabinet under the kitchen sink or even in the refrigerator. When used correctly, household products such as cleaning fluids and room deodorant sprays or an aerosol can of whipped cream can be killers, contributing to what is known as "sniffing," "bagging," and "huffing."

Congress has named this week as National Inhalants And Poisons Awareness Week. Earlier this month in Pennsylvania, there was a fatal accident in which five teenage girls died and experts say the crash was caused by the driver inhaling Duster II bottle; the bottle was found at the crash site. Traces of the chemical difluoroethane was found in the blood of the sixteen year-old teenage driver.

Just to name a few, difluoroethane, trichloroethylene, toluene, hexane, butane and nitrous oxide are some of the chemicals found in legal products such as aerosol plants, cleaning agents, nail polish, correction fluid, paint

thinner, lighter fluid, glue, gasoline, and hair spray. Even aerosol cans of whipped cream use nitrous oxide as the propellant, which abusers siphon off and inhale. Inhalants not only intoxicate users, causing disorientation, loss of coordination and memory loss, but also cause an array of serious and lasting physical disorders. These named disorders include: permanent brain damage, hearing loss, convulsions, damage to the lungs, bone marrow as well as to the liver and kidneys. Inhalant abuse can also result in death due to cardiac arrest. Sudden sniffing death may occur, even without warning, on the first or hundredth time that a child uses an inhalant. Usually, it comes in the form of a heart attack. Children are more likely to be physically hurt than grown ups due to the fact that they fail to understand the consequences of having inhalants around them.

Furthermore, the PPPA must be expanded to include other dangerous petroleum distillates like hydrocarbons, such as benzene, toluene, xylene, pine oil, and limonene.

At present, hydrocarbons other than petroleum distillates are exempt from child-resistant packaging requirements. However, it is our belief that compounds with the same risk of aspiration should be regulated regardless of their source. First, the term "petroleum distillate" is archaic as it refers to mixtures of hydrocarbons that are distilled from petroleum. This term fails to include the class of toxins recognized as "aromatics" which includes but is not limited to benzene, xylene, and toluene. These aromatics are not considered to be petroleum distillates because their toxicity differs from the aliphatic chemicals. We then recommend that the PPPA expand its definition of products to be included in a child-resistant package to those chemicals that contain hydrogen and carbon. We feel this will make it clear that aromatics as well as other potentially harmful chemicals will be regulated rather than just those that adhere to the term "petroleum distillate." By using the term "petroleum distillate", one will restrict the realm of chemicals that must adhere to the child-resistant packaging to those that are petroleum-derived.

Also, a great advancement or variation of the traditional child-resistant packaging is a restricted flow mechanism which only allows a limited amount of such a product to be dispensed during each attempt. As proposed, one way to avoid all the deaths that hydrocarbons have is by preparing child-resistant packaging that would restrict the flow of hydrocarbons and allow only a certain limited amount of the contents each time the product was used. Just as medicine has a childproof bottle, hydrocarbons should do the same. The items that should have these restraints are those distinct products which include: petroleum distillates and

cleaning solvents, automotive chemicals, shoe-care products, and cosmetics such as nail polish remover.

These items could be put in bottles that could only be open by following directions and have great force exerted upon them. Every time the product is used, only a small amount should be released. This would therefore not allow the consumer to overuse the product unknowingly. Many consumers are not always aware of the fact that only a small amount of the product in question is needed to create the desired effect; this in turn, causes them to use more than the required amount. Another feature that should be included on these products is a label indicating to the consumer that these products should be minimally used because of their viscosity levels. This would let the consumer understand why the product is packaged in the manner that it is.

Many people are not aware of the dangers associated with the products mentioned. We feel that even if some of the products that are mentioned do not meet the desired requirements, a label should be placed on the mentioned products letting the consumer know that their children should *not*, under any circumstance, play with these items.

After severe dealings with the gathered information and the participation of the community in survey, it is safe to conclude that many of our residing individuals show much concern for dangerous substances, but show minimal knowledge on the topic. Not only are parents, in general, concerned with the efforts against hydrocarbon emissions, but also households as a whole have displayed concern as well. It is the lack of information that has terrified the people of the community. Products that one uses on a daily basis can lead to death. Having spoken to people that deal with some of the previously mentioned products on a daily basis, the certain findings were encountered.

A salon was visited and the manicurist voiced her opinion with regards to the hydrocarbon emission in the nail polish remover that she uses as well as the nail polishes themselves. Not surprisingly, she was extremely concerned with the dangers involved. It was as if she had signed her life away having been in the profession so long and having inhaled such an enormous amount of the solutions. She mentioned possible use of masks through out the duty, in an attempt to reduce her inhalation of such life-threatening fumes.

Numerous employees were contacted at a well-known insurance company in reference to the use of correction fluid and its potential dangers. Correction fluid is a very commonly used product in the office environment. Individuals in the

environment use the product and are aware that the product is harmful. However, the concern does not hit home due to the fact that these individuals did not realize the frequent use that they have given the product in question. The employees suggested reduction of the product as a form of prevention. These employees seek safety measures.

Additionally, a gun owner/collector was also contacted for input on the topic at hand. This individual frequently uses gun-cleaning solvents. As he stated, he understands that the product is harmful, but during usage for gun cleaning, he is not attentive to usage procedures. He has inevitably inhaled fumes that have been emitted. He expressed his concern for the issue and stated that he will use precaution with such products. He feels that regulations should be instilled with respect to such products. It was his final say that he does not see it fit that individuals who use such products on a day-to-day basis for care purposes should be at risk for cancerous diseases, he wants changes.

We cannot rely on the fact that people are familiar with potential dangers regarding hydrocarbons, our research has lead us t believe that people are still hungry for the informative figures that provide them with life-saving data. Regardless of whether we are dealing with the percentage of composition to be utilized as a given threshold for the requirements of products meeting child safety restraints or with restricted flow for certain products, one point holds true: safety precautions must take effect so as to prevent deaths. We feel that the mentioned restrictions as far as the flow emitted from products, the percentage of threshold required for child-resistant packaging, aerosol precautions, as well as the inclusion of benzene, toluene, xylene, pine oil, and limonene should be adjusted meet our guidelines in a direct effort to properly handle the various mentioned concerns. We will undoubtedly be in favor of any legal attempt to protect the health of our community, and of our world.

Florida International University
University Park
Miami, Florida 33199
MAN 3701 Business and Society

FACSIMILE COVER SHEET

TO:

Name OFFICE OF THE SECRETARY
Address CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C.
20207-0001

FROM:

Name FLORIDA INTERNATIONAL UNIVERSITY
Location UNIVERSITY PARK
Address MIAMI, FLORIDA 33199
MAN 3701 BUSINESS AND SOCIETY

Total Pages Transmitted 6 (include cover sheet)

Remarks: _____

Sent By _____ Date _____ Time _____

Stevenson, Todd A.

From: Evelin Simpson <esimpson@ci.homestead.fi.us> at INTERNET-MAIL
Sent: Monday, March 20, 2000 3:19 PM
To: Consumer Product Safety Commission <cpsc-os@cpsc.gov> at internet-mail
Cc: Michelle Rodriguez <michybws@aol.com> at internet-mail
Subject: "NPR for Hydrocarbons"

March 20, 2000

Consumer Products Safety Commission
16CFR Part 1700
Household Products Containing Hydrocarbons
Agency Consumer Product Safety Commission

To whom it may concern:

We are a group of students from Florida International University's College of Business and we feel it is our responsibility as informed and concerned citizens to respond to the Consumer Product Safety Commission's Proposed Rule concerning household products containing hydrocarbons. Though some commentaries (CP97-2-6, -15, -19-21) suggest that the number of deaths and incidents are low and therefore child-resistant packaging is not necessary, we feel that just one death is reason enough to protect other children from the hazard. Every time a child is exposed to dangerous chemicals there is the potential for ingestion, aspiration and death.

We feel that there is a need for increased efforts by manufacturers, wholesalers, and retailers to include child-resistant packaging on products like bleach, lighter fluid, and paint thinners. Other products containing petroleum distillates and hydrocarbons such as benzene, toluene, xylene, pine oil and limonene, should also be packaged accordingly before they are sold to the consumer.

As future parents and consumers of products that contain hydrocarbons, we feel that the safety and well being of children must outweigh the increased manufacturing cost, if any, that may result from the requirement of child-resistant packaging. We unanimously agree that the Consumer Product Safety Commission should enact laws such as "Poison Prevention Packaging Act" to protect children from serious illness or injury caused by household products.

Sincerely,
Evelin Simpson
Shamark Davis
Michelle Rodriguez

Naomi Schnog
Carolina Henao
Lizzerett Karpf

Stevenson, Todd A.

6/65
OK 3/17/00
2

From: "E St Hilaire" <sthilair@bellsouth.net> at INTERNET-MAIL
Sent: Thursday, March 16, 2000 9 39 PM
To: cpsc-os@cpsc.gov at internet-mail
Subject: NPR for Hydrocarbons

To Whom It May Concern.

We are a small group of Management majors attending Florida International University in Miami, Florida. This semester, our focus is on studying the role and impact of business in contemporary society. We strongly believe that it is the responsibility of managers, and business people in general, to become involved in improving and protecting our community. There are several parents in our group with young children who found it easy to relate to the Consumer Product Safety Commission's proposed ruling on providing child-resistant packaging on household products containing low-viscosity hydrocarbons.

Our group read and evaluated the proposed ruling in its entirety. We agree with the Commission's observations that pre-composed, non-emulsion liquids found in several cosmetics, health & beauty aids and household items are a dangerous threat to small children. Many of these "safe" items contain at least 10 percent or more hydrocarbons by weight and the viscosities are less than 100 SUS at 100 degrees Fahrenheit, which attribute to copious amounts being ingested by small children as opposed to higher-viscosity products. We also agree and support the Commission's two separate proposed rules for mandatory child-resistant packaging on (1) hazardous substances and (2) drugs and cosmetic products. We applaud the Commission's thoroughness to "cover as many areas as possible" by including automotive products, as well as household cleansers and solvents. It is hoped that this ruling will force open the eyes of our nation's manufacturers on the dangers their products pose to our children. They should be conscious of the need to create, implement and utilize child-resistant packaging for the protection of our children. We fully support the enforcement of this proposed rule and urge the Commission to consider the following comments when finalizing your decision.

First, we would like to present statistical data maintained by the American Association of Poison Control Centers that clearly show that children do gain access to low-viscosity products that contain hydrocarbons. The 1998 Pediatric Exposure for children under 6 years of age shows that there have been thousands of reported cases of unintentional poisonings with children ingesting household cleaning substances, cosmetics and personal care items, automotive fluids and cleaners, and various other hydrocarbon-containing products. Sadly, the outcomes for some of these children have resulted in major physical damage and even death. Therefore, we agree with the Commission's statement, "Each time a child gains access to one of these products that is not in child-resistant packaging, there is a potential for ingestion, aspiration, pneumonitis, and death."

Moreover, we were alarmed to see an upward trend on the cases recorded by the Toxic Exposure Surveillance System for the years 1995-1998. Although it is the parent's responsibility to watch their children, serious illness or injury due to ingestion of non-childproof household products occurs on a daily basis. We believe that there are many more cases that remain unreported due to injury resulting in minor physical damage, yet these often traumatize the child and family.

We decided that our research would not be complete by simply making conclusions regarding these statistics. Clearly, there are experts throughout our nation trained on the dangers of child-poisonings and we

felt their input was vital. We interviewed ER nurses and physicians to get an idea on their thoughts concerning this proposed rule. We spoke with eight registered nurses and two physicians. Most of them agreed with the proposed rule, although four out of the 10 expressed that it is the parent's responsibility to keep the product out of the child's reach. One ER nurse with 6 years experience in the medical field said, "That is a good idea. Many parents do not childproof their homes and I have seen many children in the ER with accidental ingestion because of it. I do not like the idea of rules or laws, but if it saves a life, then it is worth it." Another ER nurse with 10 years of experience said, "I think it is imperative, a necessity, and an obligation to protect children, since in this new age and time some mothers are careless, lack common sense and knowledge in taking care of their children. It is important that someone looks out for these children by protecting them from harmful products."

In all fairness, while most professionals in the medical field interviewed agreed with the terms of the proposed rule, there was some dissension. One ER nurse with 10 years of experience did not agree with the proposed rule and said, "I believe most children would not take sufficient amount of these substances to cause serious injury. They taste awful. Also, it is the parent's responsibility to keep them away from the children. I do not support this law." A physician with 6 years of experience said, "Based on my experience, I do not see it very necessary. Although, it would not hurt to add extra protection for children by making any dangerous household products child-resistant."

The Consumer Product Safety Commission addresses the parental responsibility issue. One commenter (CP97-2-4) indicated that the issue was one of parental responsibility and that the regulation was unnecessary. The Commission's response to this comment was, "The issue of parental responsibility and child-poisoning is not new. The Congressional Committee on Commerce dealt with this issue while drafting the Poison Prevention Packaging Act of 1970. The Committee's report states, 'Parental negligence is not the primary cause of poisonings. There are too many potentially hazardous products in the modern home to hope that all of them can be kept out of the reach of children.'"

Moreover, we urge you to consider applying this proposed rule to products being exported as well as those being produced for use within the United States. The Consumer Product Safety Commission must decide whether its policies should only protect children residing in the U.S. or whether safeguards should be placed to protect children of every nation against possible ingestion of these harmful products that are manufactured within our borders. The U.S. is made up of a diverse group of people from all over the world. Is it not our responsibility to protect what could be family members of U.S. residents and citizens from products that are produced with the U.S.? Can we assume the responsibility of exporting a product that may ultimately lead to the death of a child?

With regard to the financial implications on incorporating such a safeguard for the producers of household products, our research shows the impact would be marginal. The Arts and Creative Material Institute described its members as "tend(ing) to support the proposal." It went on to comment that, "it would not appear to raise major cost obstacles." A study of the financial implication resulted in increases anywhere from one to three percent of packaging costs.

The need to protect our children is our moral obligation. We strongly believe that the benefits of this rulemaking are twofold. First, it serves to protect and prevent children under 5 years of age from serious injury and death from accidental poisonings, and secondly, it creates a consistent regulatory approach to maintaining childproof packaging. Our opinion and analysis are based on both statistical data and our field survey. As concerned parents and as business people, it is our responsibility to protect our children and we urge the Commission

to follow through with this proposed rule

Sincerely,

Cynthia Esquivel
Mariangela Garcia
Mercedes Lee Yee
Jose Roquett
Edith St-Hilaire

Stevenson, Todd A.

6/26/02
OK
10/11/02
[Signature]

From: "LIZZIE" <ldytiger@prodigy.net> at INTERNET-MAIL
Sent: Monday, March 20, 2000 7:24 PM
To: <cpssc-os@cpssc.gov> at internet-mail
Cc: "AGNES APONTE" <AAPONT02@FIU.EDU> at internet-mail, "FIDEL MIRANDA" <ET_@hotmail.com> at internet-mail, "Pamela Cabrera" <pamcabrera@worldnet.att.net> at internet-mail, "VY NGUYEN" <VNGUYE01@FIU.EDU> at internet-mail
Subject: re NPR FOR HYDROCARBONS



FileItem.txt

March 20, 2000

CONSUMER PRODUCT SAFETY COMMISSION

4330 East-West Highway

Bethesda, Maryland 20814

In Re: NPR for Hydrocarbons

To Whom It May Concern:

Below is a response to a proposed rulemaking stating that certain products containing hydrocarbons should be subject to a rule under the Poison Prevention Packaging Act ("PPPA"), that would require child-resistant packaging of the same in order to protect children from the potential effects of aspiration of these products into the lungs, with consequences ranging from pneumonia to death. The following response comes on behalf of a group of five students at Florida International University whom after careful consideration of the proposed ruling on products containing hydrocarbons wish to voice our opinion, which is based on research and our own perception of what can truly harm children, regarding hydrocarbon containing products and respective packaging of the same. The five students' names involved in this project are as follow: Agnes Aponte, Fidel Miranda, Lizbeth Ramon, Pamela C. Cabrera, and Vy Nguyen.

First we would like to fill you in some of the research we conducted in order to come to a conclusion as to what the proposed rulemaking on hydrocarbons should be all about and most important of all, our position regarding the proposed rule.

RESEARCH ON PNEUMONIA MORTALITY

INVOLVING HYDROCARBONS

The Center for Disease Control reported the death mortality rate associated with pneumonia to be 86, 449. According to the database on household interviews of the civilian noninstitutionalized population, hydrocarbons account for 1568 exposures, 1563 unintentional, 1

intentional, 271 treated in a health care facility, 825 no effects,, 250 minor effects, 17 moderate effects, 2 major effects and 0 deaths. This data pertains to the 1998 Pediatric Exposures for children under the age of 6

Other figures are as follow:

A. Ethylene Glycol 603 exposures, 801 unintentional, 1 intentional, 305 treated in health care facility, 411 no effect, 40 minor effect, 16 moderate effect, 2 major effect, and 0 deaths.

B. Spot removers: 126,602 exposures, 126,284 unintentional, 49 intentional, 94 adverse reaction, 12,131 treated at health care facility, 42,962 no effect, 25,221 minor effect, 1,325 moderate effect, 55 major effect, 0 deaths.

Spot removers include the following chemicals: Anionic/nonionic, glycol, perchloroethylene, other halogenated hydrocarbon, Isopropanol, starch/fabric finishes/ toilet bowl cleaner, acid, alkali, cationic, Ethanol.

C. Cosmetics/personal care products: 157,550 exposures, 157,086 unintentional, 66 intentional, 291 adverse reaction, 7,013 treated health care facility, no effect 49,582, minor effect 19,946, moderate effect 687, major effect 28, and 1 death.

Cosmetics/personal care products include the following: bath oil,, bubble bath, creams, lotions, make up, dental care products, false teeth cleaning, toothpaste with fluoride, toothpaste without fluoride, deodorants, depilatories, douches, eye products, hair products, coloring agents, rinses, conditioners, relaxers, shampoos, sprays, lipsticks, mouthwash, nail products, polish, polish removers, and perfume soaps suntan/sunscreen products.

TOXIC POISON

SURVEILLANCE SYSTEMS (TESS)

As stated in the TESS system, deaths associated with the exposure of hydrocarbons for the year of 1998 were four. Nonetheless there were 26,018 total exposures to children under the age of 6. Products such as benzene, carbon tetrachloride, diesel fuel, flourochlorocarbons, gasoline, halogenated hydrocarbons, kerosene, lighter fluids,, mineral spirits and toluene were associated with pediatric exposures to hydrocarbons in 1998. While the death rate associated with hydrocarbons was not significantly high, one death alone is reason for concern, given the fact that every life is special and valuable. Please refer to the CPSC publication #383 regarding Poison Lookout Checklist. In this document, the CPSC indicates to consumers that harmful products should be in their original containers, high and out of the reach of children, and have proper child resistant closures. Some products like baby oil do not have these so called child resistant closures. However, the CPSC recommends that these products be contained in child resistant packaging in order to protect children under the age of five from poisoning. Sadly enough, while CPSC publication #383 is accessible to the public, there is not enough awareness about these issues to encourage concerned citizens to inform themselves as to the dangers associated with hydrocarbons, therefore taking necessary actions to find suitable solutions to these emerging problems

BASED ON THE ABOVE RESEARCH WE

RECOMMEND THE FOLLOWING

That all products containing hydrocarbons, regardless of the percentage of hydrocarbons present, or the viscosity of the same, be properly labeled warning of the dangers associated with hydrocarbons

That child resistant packaging be required for all products containing more than 10% by weight of hydrocarbons or petroleum distillates and less than 100 Saybolt Universal Seconds (SUS) at 100 deg F

That proper identification be shown when purchasing any of the above mentioned products to ensure that children under 18 years of age are not purchasing these products.

LDYTIGER@PRODIGY.NET
LRAMON01@FIU.EDU

CP00-1-4

Founded 1914



CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

OFFICE OF THE SECRETARY
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Hand Delivered

March 20, 2000

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

RE: Proposed Rule on Household Products Containing Hydrocarbons,
65 Federal Register 93, January 3, 2000.

Dear Sir or Madam

These comments are submitted on behalf of the Chemical Specialties Manufacturers Association (CSMA) regarding the Proposed Rule on Household Products Containing Hydrocarbons, 65 Federal Register 93. CSMA is a voluntary, nonprofit trade association composed of several hundred companies engaged in the manufacture, formulation, distribution, and sale of non-agricultural pesticides, antimicrobials, detergents and cleaning compounds, industrial and automotive specialty chemicals and polishes and floor maintenance products for household, institutional and industrial uses

Overview

CSMA submitted extensive comments in response to the Advance Notice of Proposed Rulemaking (ANPR) for Household Products Containing Petroleum Distillates and other Hydrocarbons, 62 Federal Register 8659. We are pleased that many of our suggestions are reflected in the proposed rule. However, there are several areas of the proposed rule that need to be addressed. These include the scope of the proposed rule, single use products, and the effective date.

Scope of the Proposed Regulation

Aerosols

In comments on the ANPR, CSMA suggested that aerosol products be exempt from the proposed rule. Under the proposed rule, aerosols that spray in a stream would be covered while those that spray in a mist would be exempt. CSMA continues to believe that all aerosols should be exempt regardless of the spray pattern.

The great weight of data available from poison control centers indicates that pressurized aerosols are extremely unlikely to present a risk of aspiration pneumonitis. One CSMA member company reports that between 1991 and 1996 it sold 302 million units of pressurized aerosols that contained hydrocarbons. Poison control center data for these products indicates that there were no reported cases of aspiration following exposures to this members products during this timeframe.

Animal studies were conducted by Dr. Gerarde to simulate the improbable scenario wherein a child places the nozzle of an aerosol can directly into the mouth and activates the release valve. Using kerosene aerosol as a worst-case type of petroleum distillate, the direct dosing into the mouth of rats with 1 ml of aerosolized kerosene (2-3 seconds delivery time) caused no evidence of pulmonary or systemic toxicity.¹

It was concluded that aerosols containing hydrocarbon petroleum distillates, even when sprayed directly into the mouth, do not present the acute aspiration hazard which may exist with the same hydrocarbon in liquid form. The reason for this difference is that the aerosol droplets sprayed into the mouth tend to collect on the oral tissue surfaces as minute droplets. These minute aerosol droplets do not coalesce to form a pool of liquid which would be the obligatory prerequisite to an aspiration hazard. Based on these experimental findings, there appears to be no basis to consider aerosol type products containing hydrocarbons as presenting any unique aspiration hazard.

In addition, an average child five years of age or younger probably lacks the manual dexterity to direct a spray from an aerosol into his/her mouth. If a child were to take a can and spray it at his/her face, the pressure of this spray would most likely stun the child and cause the child to drop the can without an ingestion occurring. These factors further support the fact that aerosols should be exempt from a requirement for child-resistant closures.

Should CPSC want to divide aerosols covered depending upon spray pattern, such a rule would be difficult to implement for both manufacturers and for CPSC

¹ Gerarde, H W (1963) Toxicological Studies on Hydrocarbons, IX The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures Arch Environ Health, Vol 6, 35-47

Both Manufacturers and CPSC would have to study the spray pattern of aerosol products. It is questionable whether such nuances in the rule will offer extra protection, when all aerosols deliver too small a dose to pose an aspiration hazard.

In the event that CPSC does decide to divide aerosols covered by the rule by spray pattern, the term "stream" needs to be defined. We suggest defining stream as a straight stream having a spray pattern of <2 inches diameter at a distance of 12 inches, anything that is not a stream would be considered a mist.

Trigger Sprayers

We recommend the following changes to the exemption for trigger sprays:

Products in packages in which the only non-child-resistant access to the contents is by a spray device that expels the product solely in a form other than a straight stream. "Straight stream is defined as having a spray pattern of <2inches diameter at a distance of 12 inches

CSMA suggests that senior adult testing should not be required for assessing removability of trigger sprayers, since the child-resistant feature does not impact the usability of the product (i.e., a senior does not need to remove the trigger to use the product.)

Single Use Products

The proposal does not address single-use products. We suggest that the following language be added to the rule:

Any regulated product that is intended and likely to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening.

Effective Date

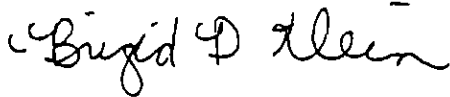
We suggest that the effective date of the rule be at least one year after the proposed rule is issued in final form. We also recommend that the Commission implement a procedure whereby companies that are unable to comply within the time, despite their best efforts, may apply for a temporary enforcement stay as was done with the final rule on Requirements for the Special Packaging of Household Substances, 60 Federal Register 37710.

Conclusion

CSMA appreciates the opportunity to comment on the Proposed Rule on Household Products Containing Hydrocarbons. We assert that aerosols,

regardless of spray pattern, should be exempt from a child-resistant requirement for the reasons noted above. In addition, we suggest that the rule define the term stream, and that single use products also be addressed in the rule. Finally, we request that a process for temporary stay of enforcement be added to the final rule. Please contact me if you have any questions regarding these comments.

Sincerely,



Bridget D. Klein
Regulatory Counsel

cc: Suzanne Barone

PENNZOIL-QUAKER STATE
C O M P A N Y

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CP00-1-5
665
6/20/00

8 Eric Vredenburg
Director
Environmental, Safety, Health & DOT Compliance

March 20, 2000

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

RE: Proposed Rule on Household Products Containing Hydrocarbons,
65 Federal Register 93-104, January 3, 2000

Dear Sir or Madam.

Pennzoil-Quaker State Company (PQS) commends the Consumer Product Safety Commission (CPSC) for their efforts to protect children from unnecessary poisonings from household products containing hydrocarbons, by requiring child-resistant packaging for such products. PQS offers the following comments on the proposal.

Pennzoil-Quaker State Company (PQS) is a leading worldwide automotive consumer products company that markets Pennzoil® and Quaker State® brand motor oils, a complete line of car care products including Axius® auto accessories, Blue Coral® and Classic® waxes and washes, Black Magic® and Westley's® tire and wheel care products, Fix-A-Flat® tire sealants, MEDO® air fresheners, Rain-X® glass treatments, Gumout®, Snap® and The Outlaw® maintenance chemicals and Slick50® engine treatments, and through Jiffy Lube International, Inc. is the world's largest fast lube operator and franchiser. PQS owns and operates a number of facilities including refineries, automotive care product and accessory manufacturing locations, blending and packaging plants, distribution centers, and over 550 fast lube stores nationwide.

PQS supports the comments submitted by the Chemical Specialties Manufacturers Association (CSMA) regarding the Proposed Rule on Household Products Containing Hydrocarbons

General Comments:

PQS submitted comments on the Advance Notice of Proposed Rulemaking (ANPR) for Household Products Containing Petroleum Distillates and other Hydrocarbons, 62 Federal Register 8659 in May 1997. A PQS representative also met with the Commission at that time

We are pleased that many of our suggestions are reflected in the proposed rule. However, we would like to revisit certain issues including the exclusion of aerosol products, coverage of single use products and the effective date

Specific Comments:

1. Exclusion of Aerosol products:

In our 1997 comments on the ANPR, PQS suggested that all aerosol products be exempt from the proposed rule. Under the proposed rule, aerosols that spray in a stream would be covered while those that spray in a mist would be exempt. PQS supports CSMA's position that all aerosols should be exempt regardless of the spray pattern. We feel that existing data on aerosol products do not indicate a risk of aspiration from such exposures. The dose ingested after accidental exposure to an aerosol, whether it is a stream or a spray pattern, is too small to present a risk of aspiration by an individual. It is therefore questionable whether such nuances in the rule will offer extra protection, when all aerosols, not just aerosols that spray in a mist, deliver too small a dose to pose an aspiration hazard.

2. Single use products:

The proposal does not address single-use products. We suggest that the following language be added to the rule:

Any regulated product that is intended to be fully used in a single application must meet the child-resistance and adult-use-effectiveness specifications for only the first opening of the container.

3. Effective Date

We agree with CSMA's suggestion that the effective date of the rule be delayed at least one year after the rule is finalized.

Summary

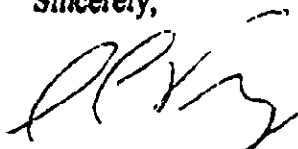
In summary, Pennzoil supports CPSC's efforts to minimize the risk of children being poisoned by low viscosity household products containing hydrocarbons. We recommend that only those products that present a significant risk be required to be packaged in child-resistant packaging. Specifically we recommend that

- All aerosol products be exempted from this rule; and

- Language is added to clarify the coverage of single use products

Should you need additional information please do not hesitate to contact me or Dr Suneeta Mahagaokar at 713-546-8760

Sincerely,



S Eric Vredenburg

Cc. Brigid Klein, Chemical Specialty Manufacturers Association

FILE TX GEN Regulatory, CPSC, TX Petro Association, Doc name Regulatory/cpschohydrocarbonrule300

Hand Delivery

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

March 20, 2000

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

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

Re Notice of Proposed Rulemaking Regarding Household Products Containing Hydrocarbons, 65 Fed Reg 93 (1/3/00)

Dear Dr Barone

The Cosmetic, Toiletry, and Fragrance Association (CTFA) wishes to submit a brief comment on the proposed rule mandating child-resistant closures for certain hydrocarbon-containing products. Since the initial advance notice of proposed rulemaking (ANPR) in February 1997, CTFA has submitted four comments for the public record expressing our concerns about the scope of the rulemaking and related issues (See Attachments A-D)

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

A Review of CTFA's Previous Written Comments

On September 1, 1997, CTFA submitted an extensive comment to respond to the agency's request for very specific information about household products that could potentially be included in the rulemaking. In that spirit of cooperation, CTFA surveyed over 200 representatives about cosmetics that could be affected by the rulemaking and CTFA members supplied detailed information on product categories, ingestion incidents and their outcome for each category, product viscosity and "petroleum distillate" (now hydrocarbon) percentages, aerosols, the use of restricted flow closures, chemical properties of the products highlighted in our member survey, users and use patterns, current packaging and labeling, and economic information about packaging costs (See Attachment A, CTFA Comment to CPSC (9/1/97))

On December 15, 1998, at the request of CPSC staff, CTFA submitted comments on suggested exemptions from the rulemaking. CTFA reiterated the conclusion of our first comment that cosmetics should be excluded based on the lack of injury data and the survey of CTFA members' products. CTFA supported other exclusions for pressurized spray containers expelled as

a mist, pen-like devices distributing the product through an absorbent dispensing tip, impregnated pads used for makeup remover for example, the use of small orifice closures, when appropriate and products delivered as a non-aerosolized mist with a permanently affixed, non-removable cap (*See* Attachment B, CTFA Comment (12/15/98) in response to 11/18/98 meeting with CPSC and affected industries)

As a follow up to CTFA's December 1998 comments, the association submitted an analysis by Dr Richard Kingston of 1996 and 1997 "baby oil" incident data compiled by the American Association of Poison Control Centers (AAPCC) Dr Kingston's report to CTFA concluded "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 " (*See* Attachment C, CTFA submission of Kingston letter to CPSC (Jan 12, 1999))

Finally, CTFA's most recent submission to the agency were letters to the Commissioners in November 1999 as follow up to meetings with the Commissioners and/or Commissioners' staff The purpose of the letters was to expand on some of the points made at those meetings and to supply specific information requested by the Commissioners (*See* Attachment D, CTFA Letter to Commissioners)

The points made in the most recent CTFA letters to the Commissioners include (1) not all hydrocarbons (e g mineral oil vs kerosene) are the same chemically which impacts their effect if ingested, (2) clinical evidence indicates that mineral oil-containing cosmetic products are less likely to be aspirated than other hydrocarbon products and such incidents are rare, (3) the risk of lipoid pneumonia and other adverse effects from aspiration of mineral oil is very low; and (4) based on toxicological studies and animal data, mineral oil is different from other hydrocarbons in terms of risk of aspiration resulting in pneumonia and toxicity of aspirated hydrocarbons Therefore, mineral oil should not be included in a rulemaking with other low viscosity hydrocarbons such as gasoline and lighter fluid ¹

CTFA's Comments on the Current Proposed Rule (1/3/00)

CTFA supports a rulemaking to mandate CRCs for household chemical products such as gasoline, kerosene and mineral seal oil that meet the viscosity and hydrocarbon percentage criteria CTFA, however, thinks that because incidents involving mineral-oil containing cosmetics that require medical attention are so rare, such products should not be included in the proposed hydrocarbon rule or regulated separately

CTFA supports the CPSC's recognition that certain product delivery forms such as aerosol

¹ Suman Wason, M D , Medical Director, Children's Hospital Medical Center Drug & Poison Information Center, Cincinnati, Ohio and Richard Kingston, Pharm D , Senior Clinical Toxicologist, PROSAR International Poison Center and Assistant Professor, College of Pharmacy, University of Minnesota, also submitted letters to the Commissioners stating that, based on their clinical experience, mineral-oil based cosmetics do not pose a risk warranting child-resistant closures (CRCs)

or pump/trigger-actuated sprays emitting a mist do not pose an aspiration danger CTFA interprets the latter exclusion as applicable to pump sprays that have the dispensing unit permanently affixed to the container Such an approach was discussed at a November 1998 meeting with CPSC staff and if such pumps are not excluded, we would urge the Commission to amend the rule's current exclusion language

CTFA supports the exclusion of products "from which the liquid cannot flow freely, including but not limited to makeup removal pads" because such products do not pose an aspiration risk to children.

Commissioners' Recent Statements & Additional Cosmetic Incident Data Collection

The NPR proposes that household products containing low-viscosity hydrocarbons should have child-resistant closures if they meet certain criteria Because such a broad range of "household products" is covered by the rulemaking, several categories of cosmetic products are affected as well Those cosmetics have been included because they contain the ingredient mineral oil, which is a low-viscosity hydrocarbon CTFA previously presented arguments explaining why mineral-oil based cosmetics should be excluded from a rulemaking that equates aspiration risks associated with mineral oil with those of hydrocarbons such as kerosene and gasoline

The recent Statements of Commissioners Mary Sheila Gall and Thomas Moore² demonstrate there is some concern within the agency about the wide scope of this rule Although the Commission voted 3-0 to publish a proposed rule for public comment, two Commissioners voiced reservations about the completeness of the staff's briefing package that serves as the legal basis for a rulemaking

In her Statement, Commissioner Gall said that

[T]here 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

Gall Statement at 1-2 (12/3/99)

Commissioner Gall explained there was a "paucity of incident data contained in the staff briefing package" presented as the basis for the broad proposed hydrocarbon rule that includes all household products meeting viscosity levels below 100 SUS at 100° F and 10 percent or more hydrocarbon by weight (Gall Statement at 1) Therefore, the Commissioner directed the staff to collect specific incident data on cosmetics before a final rule is issued

² CTFA has attached for inclusion in the record, the Commissioners' Statements that are cited in a footnote in the January 3, 2000 Federal Register notice, but are not quoted in that public notice (See Attachment E, Commissioners Gall and Moore Statements at December 3, 1999 Public Meeting)

Commissioner Thomas Moore also expressed in his Statement his concerns about the impact of a broad rule on the data collected

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?

Moore Statement at 1 (12/3/99)

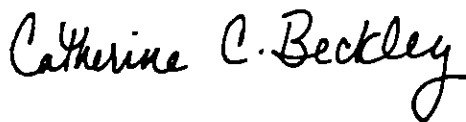
Accordingly, Commissioner Moore urged "that staff actively seek out all available information relevant to the inclusion and the exclusion of products within the scope of this rule"(emphasis added). Moore Statement at 2

Next Steps

On February 15, 2000, the Commission approved the staff plan that the agency purchase 1998 incident data from the AAPCC for specific brands of mineral-oil based cosmetics, not just generic cosmetic product categories. Any AAPCC data being reviewed would include four categories of cosmetics: creams/lotions/make-up, miscellaneous nail products, bath oil/bubble bath and suntan/sunscreen products. (See Attachment F, Memorandum to Commission from R Medford and S Barone (2/4/00))

CTFA currently does not know how the 1998 data for the four cosmetic categories and the specific brands will be presented to the affected publics or if the Commission has even received the data yet. Given that two Commissioners requested that this data be collected because of incomplete incident information in the existing rulemaking record, it is clear the critical role this data will play in determining the scope of the final rule. CTFA requests the opportunity to review and comment on the AAPCC data when it becomes available. It is critical for the agency to comply with the Administrative Procedures Act and provide for another round of public comment and hearing on this significant piece of evidence.

Respectfully submitted,



Catherine C Beckley
Associate General Counsel

Attachments



CPSC/CDR REGULATORY SECRETARY
FACILE

SEP 01 1997 2 17

THE COSMETIC TOILETRY, AND FRAGRANCE ASSOCIATION

September 1, 1997

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

E. EDWARD KAVANAUGH
PRESIDENT

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

Dear Dr. Barone

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

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

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

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SECURING THE INDUSTRY'S FUTURE SINCE 1894

Introduction

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

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

Summary of Survey Findings

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

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

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

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

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

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

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

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

Ingestion Incidents

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

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

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

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

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

Results of Industry Information Survey

Part 1: General Issues to be Considered During Rulemaking

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

1 Viscosity & Percent Composition

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

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

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

2. Other Hydrocarbons

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

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

3. Aerosols

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

4 Restricted Flow

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

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

Part II Additional Requests for Information

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

A. Product Category: Baby Oil

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

Chemical Properties of Products with Petroleum Distillates

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

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

Users and Use Patterns

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

Current Packaging and Labeling

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

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

Economic Information

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

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

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

Incident Information

Table 1 - Incident Information - Baby Oil

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

Explanation of Table 1

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

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

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

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

B. Product Category: BATH OIL

Chemical Properties of Products with Petroleum Distillates

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

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

Users and Use Patterns

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

Current Packaging and Labeling

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

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

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

Economic Information

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

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

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

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

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

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

Explanation of Table 2

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

C. Product Category: Eyemakeup RemoverChemical Properties of Products with Petroleum Distillates

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

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

Users and Use Patterns

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

Current Packaging and Labeling

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

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

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

Economic Information

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

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

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

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

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

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

Explanation of Table 3

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

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

Chemical Properties of Products with Petroleum Distillates

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

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

Users and Use Patterns

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

Current Packaging and Labeling

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

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

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

Economic Information

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

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

Incident Information

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

E. Product Category: Massage Oil

Chemical Properties of Products with Petroleum Distillates

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

Users and Use Patterns

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

Current Packaging and Labeling

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

Economic Information

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

Incident Information

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

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

Chemical Properties of Products with Petroleum Distillates

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

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

Users and Use Patterns

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

Current Packaging and Labeling

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

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

Economic Information

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

Incident Information

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

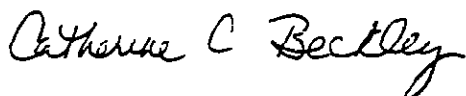
Conclusion:

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

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

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

Respectfully submitted,



Catherine C. Beckley
Assistant General Counsel

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