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6/28/97
CP97-2-19



Amway Corporation, 7575 Fulton Street, East, Ada, Michigan 49355-0001

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

Date: 7/10/97

Subject: Comments on ANPR for Petroleum Distillates

The following comments are submitted on behalf of Amway ® Corporation regarding the Advanced Notice of Proposed Rulemaking for Household Products Containing Petroleum Distillates and other Hydrocarbons published February 26, 1997, 62 Federal Register 8659. Amway ® Corporation is a manufacturer and distributor of a wide variety of quality personal care and home care products sold by thousands of independent distributors throughout the country. Although Amway ® chooses to respond separately to this notice we are supportive of comments made by CSMA (Chemical Specialty Manufacturing Association) and we believe the following key points, consistent with CSMA's input, should be given strong consideration when developing any future regulations affecting household products containing petroleum distillates.

Summary Points

- (1) **Child Resistant Packaging should not be required "across the board" for household products containing petroleum distillates.**
- (2) **Maintain as a scientific basis the need for Child Resistant Packaging for products that have 10% or more by weight petroleum distillates and a viscosity of less than 100 Saybolt universal seconds at 100 F where it is technically feasible, practicable and appropriate to impose such a requirement.**
- (3) **Aerosols should be exempt from a requirement for Child Resistant Packaging.**
- (4) **Exposure data collected from independent sources (Poison Control Centers) does not indicate that CRP's would prevent the occurrences of aspiration pneumonitis because a cross section of the data indicates that it is not occurring. (See Attachment I entitled "Human Experience Data For Petroleum Distillate" pages 1-5, prepared by: Phil Casterton, Sr. Research Scientist Amway ® Corporation)**

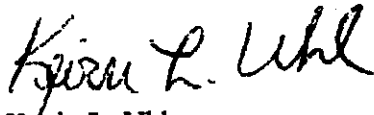
In addition to these summary points, following you will find responses to itemized questions that were asked in the ANPR (Advanced Notice of Proposed Rulemaking).

Responses to Itemized Questions posed in ANPR

- Q. Should a petroleum distillate requirement for child-resistant packaging include aerosol products that contain low-viscosity petroleum distillates?**
- A. Aerosols should be exempt from the requirement of Child Resistant Packaging for the following reasons:**
- (1) the exposure data collected from the Poison Control Center on behalf of products marketed by Amway ® does not indicate that there is a need for CRP for aerosol products.
- (2) toxicological evidence indicates that pressurized aerosols do not present a risk of aspiration pneumonitis from oral or inhalation exposures. Reference CSMA comments for details.
- Q. What is the appropriate viscosity for requiring child resistant packaging of products that contain petroleum distillates?**
- A. Consider Child Resistant Packaging only for those products containing a concentration of 10 % or more by weight of petroleum distillate and having a viscosity of less than 100 Saybolt Universal Seconds (SUS) at 100F.**
- Q. Should restrictive flow be an additional requirement for certain products?**
- A. The use of restrictive flow/orifice is not required for safety purposes, as it will not provide sufficient restriction in liquid products to avoid ingestion in abuse situations. Additionally, in some products the absence of restricted flow/orifice is required for proper product use. For these reasons, restricted flow/orifices should not be mandated.**
- Q. Should a rulemaking for child resistant packaging requirement for petroleum distillates include products that contain other hydrocarbons?**
- A. No. The proposed rulemaking should include only petroleum distillates. Other non-petroleum based hydrocarbons should be considered on a case by case basis as determined to be needed by the Commission.**

Should you require additional information please do not hesitate to contact this department at 616/787-1075.

Sincerely,

A handwritten signature in black ink that reads "Kevin L. Uhl". The signature is written in a cursive style with a large initial 'K'.

Kevin L. Uhl
Research Scientist
Amway © Corporation

ATTACHMENT I.

Human Experience Data For Petroleum Distillate-Containing Amway Products From June, 1992 through March, 1997

Following is a summary of Poison Control Occurrence calls to Amway Corporation on all petroleum distillate-containing Amway products since June, 1992; which is the point in time when Amway began a contractual agreement with the Pittsburgh Poison Center (PPC). The PPC handles, and keeps records on, all poisoning calls related to Amway products in the United States.

The six Tables provided below contain outcome summaries of calls to PPC for each Amway product that contains petroleum distillates and which would be potentially subject to future CPSC regulations pertaining to Child Resistant Closure-requirements. The amount of petroleum distillate in each product is also included. [Note that for some calls, two routes of exposure were reported in the same call. The number of times this happened for each product is provided directly above each Table. Note also that exposures to household pets are additionally captured in the PPC database. The number of times this happened for each product is likewise provided directly above each Table.]

LEGEND FOR OUTCOME DATA

- No Effect:** The patient developed no signs or symptoms related to the exposure.
- Minor :** The patient developed some signs or symptoms as a result of the exposure but they were minimally bothersome and generally resolved rapidly with no residual disability or disfigurement. Example: self limited GI symptoms, drowsiness, skin and eye irritation.
- Moderate:** The patient exhibited symptoms as a result of the exposure which were more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually some form of treatment would have been indicated. Examples: corneal abrasion, high fever, disorientation, GI symptoms causing dehydration.
- Unknown:** Exposures where it was impossible to follow the patient to a known outcome. Could be when a person has provided inaccurate/unreliable follow-up information or who does not return repeated phone messages attempting follow-up.
- Unrelated:** Based on the information presented to the Poison Control Center, the effect reported was not attributable to the alleged exposure.

I. An aerosol furniture polish formulation containing 35% petroleum distillate compounds:

Total Calls = 59

Calls with 2 routes of exposure = 3

Number of calls involving household pets: 1

Route of Exposure	Outcome				
	No Effect	Minor	Moderate	Unknown	Unrelated
Ocular	0	12	0	0	0
Dermal	2	2	0	0	0
Inhalation	2	2	0	0	0
Oral	41	2	0	0	0
Sum	45	18	0	0	0

II. An aerosol automotive cleaning formulation containing 56.4% petroleum distillate compounds:

Total Calls = 14

Calls with 2 routes of exposure = 1

Number of calls involving household pets: 5

Route of Exposure	Outcome				
	No Effect	Minor	Moderate	Unknown	Unrelated
Ocular	1	5	0	0	0
Dermal	1	1	0	0	1
Inhalation	0	0	0	0	0
Oral	3	0	0	0	3
Sum	5	6	0	0	4

III. A liquid car polish formulation containing 30% of a petroleum distillate:

Total Calls = 3

Calls with 2 routes of exposure = 0

Number of calls involving household pets: 0

Route of Exposure	Outcome				
	No Effect	Minor	Moderate	Unknown	Unrelated
Ocular	0	0	0	0	0
Dermal	0	0	0	0	0
Inhalation	0	0	0	0	0
Oral	3	0	0	0	0
Sum	3	0	0	0	0

IV. A liquid automotive cleaning formulation containing 9.0% of a petroleum distillate :

Total Calls = 7

Calls with 2 routes of exposure = 2

Number of calls involving household pets: 0

Route of Exposure	Outcome				
	No Effect	Minor	Moderate	Unknown	Unrelated
Ocular	0	0	0	0	0
Dermal	2	0	0	0	0
Inhalation	0	0	0	0	0
Oral	7	0	0	0	0
Sum	9	0	0	0	0

V. An aerosol pre-wash formulation containing 39.8% petroleum distillate compounds:

Total Calls = 159

Calls with 2 routes of exposure = 12

Number of calls involving household pets: 4

Route of Exposure	Outcome				
	No Effect	Minor	Moderate	Unknown	Unrelated
Ocular	4	50	7	0	0
Dermal	5	8	1	1	1
Inhalation	1	28	2	4	1
Oral	43	14	0	1	0
Sum	53	100	10	6	2

VI. An aerosol all-purpose lubricant formulation containing 89% petroleum distillate compounds:

Total Calls = 22

Calls with 2 routes of exposure = 0

Number of calls involving household pets: 0

Route of Exposure	Outcome				
	No Effect	Minor	Moderate	Unknown	Unrelated
Ocular	1	13	0	0	0
Dermal	0	1	0	0	0
Inhalation	0	1	0	0	1
Oral	5	0	0	0	0
Sum	6	15	0	0	1

Discussion

It is important to note that none of the recorded Poison Center calls involving oral exposure resulted in anything other than a minor effect. This is particularly impressive data when sales data for the same compounds over the same time period is evaluated.

The following Table provides that sales data:

Amway Product	Type of Product	% Petroleum Distillates	Total Domestic Sales; 6/92 through 3/97
furniture polish	Aerosol	35	660,528 Cans
automotive cleaner	Aerosol	58.4	587,084 Cans
car polish	Liquid	30	683,148 Bottles
automotive cleaner	Liquid	9	425,858 Bottles
laundry pre-treatment	Aerosol	39.8	5,065,116 Cans
all-purpose lubricant	Aerosol	89	439,860 Cans
Total "caches" of petroleum distillate-containing products = 7,861,572 cans/bottles			

While selling over 7.5 million cans and bottles of petroleum distillate-containing products over a 4.5 year period, Amway recorded no poisoning-related calls for anything other than minor effects.

The above data shows that these product types are being used responsibly by consumers in the United States and without the use of Child Resistant Closures (CRCs) on the product packaging. This data does not suggest that the addition of CRCs to these product types would prevent occurrences of aspiration pneumonitis because, for this representative cross-section, aspiration pneumonitis is not occurring in our population.

While Amway does not, in general, dispute the aspiration pneumonitis hazard posed by petroleum distillates, a requirement of CRCs for aerosol and automotive products, as typified by our products, does not appear to be necessary.

Prepared By: Phil Casterton
 Title: Senior Research Scientist
 Date: 7/97



Amway Corporation, 7575 Fullon Street, East, Ada, Michigan 49355-0001

Amway Technical/Regulatory Services Fax Number : (616) 787-5625

FAX TRANSMITTAL

TO: Consumer Product Safety Commission

FROM: Kevin L. Uhl

DATE: 7-11-97

SUBJECT: Comments on ANPR for Petroleum Distillates

OF PAGES: 9 including Fax transmittal cover

If any of the above pages are not received, call me at (616) 787- 1075.

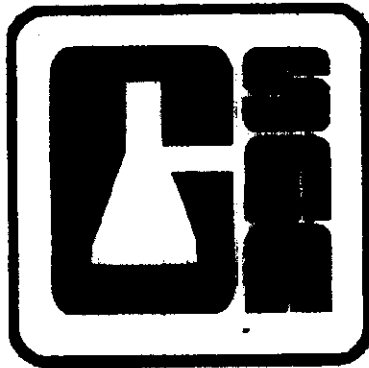
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C 897-2-20 *6000 OK 8/1/97*

**CSMA Comments
on the
ANPR for Household Products
Containing Petroleum Distillates
and other Hydrocarbons**

Submitted July 11, 1997



Founded 1914

1913 Eye St. N.W.
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CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

HAND DELIVERED

July 11, 1997

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

RE: Advance Notice of Proposed Rulemaking for Household Products Containing Petroleum Distillates and other Hydrocarbons, 62 Federal Register 8659.

Dear Madam:

These comments are submitted on behalf of the Chemical Specialties Manufacturers Association (CSMA) regarding the Advance Notice of Proposed Rulemaking for Household Products Containing Petroleum Distillates and other Hydrocarbons published February 26, 1997, 62 Federal Register 8659. CSMA is a voluntary, nonprofit trade association composed of over 400 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. Many of our member companies market consumer products containing petroleum distillates or other hydrocarbons and are, therefore, subject to the provisions of the Poison Prevention Packaging Act (PPPA), 15 U.S.C. § 1471 et. seq., and the regulations promulgated thereunder. Accordingly, CSMA is keenly interested in this ANPR.

I. OVERVIEW

CSMA supports the use of child-resistant packaging when it is technically feasible, practicable and appropriate and necessary "to protect children from serious personal injury." Our members adhere to the packaging and labeling requirements of the PPPA and the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261, and support of objectives of each.

II. SPECIAL PACKAGING

In developing standards for special packaging, the Commission is required to consider the following factors:

1. The reasonableness of such standard;
2. Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness and injury caused by household substances;
3. The manufacturing practices of industries affected by the act; and
4. The nature and use of the household substances. 15 U.S.C. 1472.

Based on the data supplied by CSPC in response to CSMA's Freedom of Information Act request, the data of our member companies and various poison control centers, CSMA cannot support an across-the-board requirement for child-resistant closures for household products containing petroleum distillates. Such a requirement would not be reasonable in light of the data.

Many companies in the chemical specialties industry have embraced the goals of the American Association of Poison Control Centers (AAPCC) and have supported their continued existence through service and consulting contracts. Industry has endorsed POISINDEX (the subscriber system poison centers use for keeping up-to-date with products and product categories) by freely providing product ingredient and toxicity information so that poison centers can accomplish their goals with up-to-date knowledge of marketed products. In addition, CSMA and several of its members were supportive of the creation of the Toxic Exposure Surveillance System (TESS) by AAPCC. TESS was designed to provide both poison centers and industry with very current information for evaluating exposures and chemical product toxicity.

We believe that POISINDEX and TESS data provide a more in-depth analysis of chemical specialty products than National Electronic Industry Surveillance System (NEISS) data. As you know, NEISS represents a very narrow database, that of injuries requiring treatment in a sampling of hospital emergency rooms. The data are not appropriate to evaluate an entire category because they do not include medical outcomes of the overwhelming majority of exposures, those that do not require treatment in a hospital emergency room. The TESS data, on the other hand, provides a statistically significant database for evaluation of a category.

According to the ANPR, CPSC had a contractor conduct 43 in-depth investigations of some of the NEISS incidents. In our review of this analysis we note that none of the

exposures resulted in serious personal illness or injury¹ to children under the age of five. Many of these incidents resulted from leaving the closure off, placing the product in another container, or using a product inconsistent with the label directions and cautions, and therefore use of child-resistant closures would not have prevented the exposures. In at least one of these cases, the product had a child-resistant closure which had not been properly resecured.

The print-out of NEISS data from 1990-1994 provided in response to our FOIA request indicates that the majority of the exposures fall into *category 1 - treated and released or examined and released without treatment*. There were no cases in *category 8 - fatalities*. It is difficult to assess those incidents in *category 3- treated and transferred for hospitalization*, and *category 4 - hospitalized*, without the circumstances surrounding the exposure. Although, it is important to note that in at least the following cases a child-resistant closure would not have prevented the incident:

- 1) pt ingested quellum soap and pine oil mixed together in a glass on top of cabinet (945 Pine Oil, page 1).
- 2) pt ingested pine oil stored in a coke bottle (945 Pine Oil, page 4).

The staff briefing package entitled Child-Resistant-Packaging of Petroleum Distillate-Containing Products states that since 1973 there have been 10 deaths from petroleum distillates involving children under the age of 5. We were provided with in-depth investigation reports on only two of these deaths. In the first case a one year girl died as a result of ingesting an automotive cleaning compound that she found. The second case involves a 19 month-old girl who died after ingesting automotive cleaning fluid she retrieved from a cup on the living room table. Both of these cases are tragic, however, child-resistant closures may not have prevented these incidents. In both cases the child had access to the product. In the first case the product was likely not stored properly, and in the second case the product was in a secondary container.

A review of AAPCC fatalities to children under the age of 6 from 1990 to 1994 reveals 20 deaths listed in the category entitled "Hydrocarbons," see attachment A. It is important to note that 6 of these cases were from products already regulated under the PPPA and packaged with child-resistant closures (lamp oil-4 and charcoal lighter-2). Two were associated with chlorofluorocarbons are therefore not relevant to this discussion. Ten pertain to gasoline and kerosene. The other 2 are from: 1) an unknown hydrocarbon, and 2) fabric protector (mineral spirits). We encourage the Commission to investigate the circumstances of these two cases.

¹The American Association of Poison Control Centers Toxic Exposure Surveillance System) defined "Major effect" as follows: the patient exhibited some symptoms as a result of the Exposure. The symptoms were life-threatening or resulted in significant residual disability or disfigurement.

While CSMA does not support the across-the-board expanded use of child-resistant closures we do think it would be appropriate for CPSC to partner with CSMA, and other interested trade associations, on an education campaign to encourage consumers to read the product label and follow the use directions and cautions. Such an effort seems appropriate based on the exposures in many product categories from children having easy access to products and/or the secondary containers with product (i.e. buckets).

III. ISSUES RAISED IN THE ANPR

1. What, if any, viscosity and/or percentage composition should be used as a threshold for requiring products that containing petroleum distillates to be in child-resistant packaging?

CSMA supports the current threshold, viscosity not less than 100 SUS at 100° F, and a concentration of less than 10% petroleum distillates. Products meeting this criteria should not be required to be packaged with child-resistant closures.

The issue of aspiration hazard and its relationship to the toxicologic and physical properties of hydrocarbon petroleum distillates can be most appropriately evaluated by reviewing the experimental result of a six year period of intensive research by one of the world's most renowned medical toxicologists, Horace W. Gerarde, M.D., Ph.D. The results of these studies were published in the journal of Archives of Environmental Health, Volume 6, p. 35-47, 1963, see Attachment B.

The results of these studies were thoroughly evaluated in 1961 when the U.S. Food and Drug Administration held public hearings on the issue of aspiration toxicity of hydrocarbon petroleum distillate type materials. The experimental findings presented by Dr. Gerarde were considered to be the most definitive evaluation of this issue, and as the major scientific basis for the current regulations which define exemptions for certain products containing hydrocarbon petroleum distillates based on a higher viscosity (not less than 100 SUS at 100° F) and lower concentration (less than 10% by weight). The experimental findings that served as the basis for establishment of the current exemptions are still the most scientifically valid basis upon which the issue of aspiration hazards of hydrocarbon petroleum distillates can be evaluated.

The tendency of a substance to constitute an aspiration hazard depends primarily on its physical properties. The combination of low viscosity/low surface tension and higher concentration levels of the hydrocarbon petroleum distillates increases the aspiration hazards of the substance.

Viscosity is the most important single physical property that determines the aspiration potential of a liquid material. Viscosity also determines the likelihood of entry, the rate of entry and the extent of penetration into the deeper lung structure via the bronchial tree.

In studies of various petroleum distillate based materials ranging in viscosity from 39 to 156 SUS at 100° F, it was established that there is a sharp break in the toxicologic response when the viscosity is greater than 81 SUS at 100° F. The attached two figures, see Attachment B, from the publication of Gerarde depict the sharp break in the dose-response relationship between viscosity and lung response due to aspiration toxicity. These data indicate that there appears to be no unique hazard from aspiration toxicity for hydrocarbon petroleum distillate type of materials with viscosity greater than 81 SUS at 100° F. Therefore, CSMA recommends that the current exemptions, viscosity not less than 100 SUS at 100° F and a concentration of less than 10% petroleum distillates, be retained. Furthermore, CSMA recommends that the Commission consider child-resistant packaging only for those products containing 10% or more petroleum distillates, and which have a viscosity of less than 100 SUS at 100° F, where it is technically feasible, practicable and appropriate to impose such a requirement.

2. Should aerosol products be included in a requirement for the child-resistant packaging of products containing petroleum distillates or other hydrocarbons?

CSMA does not support a requirement for child-resistant packaging on aerosol products containing petroleum distillates. The great weight of the 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 which contained petroleum distillates. 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 activated 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.

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 hydrocarbon petroleum distillates as presenting any unique aspiration hazard.

In addition, the average pressure of an automotive maintenance product in an aerosol form is 60 p.s.i. The majority of the products are of a high stream delivery. If an average child five years of age or younger were to take a can and spray it at his/her face, the pressure

of this stream would most likely stun the child and cause the child to drop the can without an ingestion occurring. Therefore, aerosols should be exempt from a requirement for child-resistant closures.

The CPSC also asked for comment on technical feasibility of child-resistant packaging. As stated in the ANPR, "technical feasibility" means that technology exists to produce packaging that conforms to the standards. Based on the experience of our member companies, technically feasible and practicable technology for child-resistant packaging does not currently exist for all aerosol products. An example of this is aerosol adhesives or lubricants. Although there is a child-resistant valve and actuator currently used for aerosol oven cleaners, this assembly is not technically feasible for aerosol adhesives or lubricants. The chemical composition of adhesives and lubricants (which are mixtures of rubbers and resins) is thicker than the liquids that comprise oven cleaners. In addition, aerosol adhesives and lubricants are much more dependent than are oven cleaners on the proper mixture of product output and spray pattern to provide adequate coverage and final product performance. The child-resistant valve and actuator currently used for aerosol oven cleaners does not allow adequate coverage for aerosol adhesives or lubricants. In addition, it does not allow adequate ultimate bond strength and long-term durability for aerosol adhesives. Therefore, not only is it not necessary for aerosol products containing petroleum distillates to have child-resistant closures, in some cases such a requirement would not be technically feasible.

3. Should PPPA regulation extend only to petroleum distillate or should such regulation also extend to other hydrocarbons, such as benzene, toluene, xylene, turpentine, pine oil, and limonene?

In view of the procedural requirements of the PPPA, we question the appropriateness of regulating multiple substances on the basis of a possible medical effect (aspiration hazard.) No other substance or product category regulated for special packaging includes such a broad range of chemicals and products. Each of the substances, or class of substances, should be evaluated separately for its channels of distribution, use history, health effects resulting from exposure, labeling, packaging, formulation variations, and other mitigating factors.

Pine Oil

Since the 1960's pine oil has been widely utilized in consumer household cleaning products. In these products pine oil functions as a cleaning agent, antimicrobial agent and fragrance. As a cleaning and antimicrobial agent, the typical concentrations range from 5% to 30%. As a fragrance in both cleaning products and EPA-registered disinfectants, the concentration ranges from 0.2% to 1%.

Products containing pine oil are marketed in two package forms - pourable bottles and trigger sprayers. In pourable products the pine oil functions as a cleaning agent and/or an antimicrobial agent. These products are used either full strength or diluted and are applied

with a cloth, sponge, or mop. In trigger sprayer products, pine oil typically functions as a fragrance at a very low concentration, usually less than 1%. There is no evidence that the low concentration of pine oil in these trigger sprayer products would be an aspiration hazard or present any other toxicological hazard.

According to a study done for one member company, acute aspiration testing conducted with rats on a pine oil-containing product with about 22% pine oil showed no changes in absolute or relative lung weights, macroscopic observations, or histomorphologic lung findings versus a distilled water control. Additionally, the most recent product specific poison center data (1990-1992) on one pine-oil cleaner shows no evidence of aspiration-related effects.

Based on the above information, CSMA does not believe that child-resistant packaging is warranted for household cleaning and disinfecting products solely because of their pine oil content from an aspiration hazard standpoint.

4. Should restricted flow be an additional requirement for certain products?

CSMA is not aware of use patterns of liquid products that necessitate the use of the additional requirement of restricted flow. There are many liquid products on the market without restricted flow, and the child-resistant closures are adequate to protect children.

IV. ADDITIONAL REQUESTS FOR INFORMATION

1. Chemical Properties

Petroleum distillate products are sold in liquid, solid and aerosol form. Formulations of these products are considered confidential business information and are therefore not included in this submission. The level of petroleum distillates in these products range from .1 to 100 percent.

2. Users and Use Patterns

Petroleum distillates are used in formulating several consumer products intended for use in and around the household. These products include the following categories: automotive, cleaning fluids, general purpose cleaners, metal polishes, shoe polishes, and spot removers. In addition to aerosols, CSMA believes that products such as paraffin candles, paste, and waxes should be exempt from a child-resistant packaging requirement since these product forms do not present an aspiration hazard.

3. Current packaging and labeling

CSMA member companies package and label products in accordance with the CPSC requirements under the Poison Prevention Packaging Act and the Federal Hazardous Substances Act.

4. Economic information

A survey of just a few CSMA member companies reveals that between 1992 and 1997 over 400 million units of petroleum distillate/hydrocarbon containing products (including automotive, laundry pre-treaters, furniture polish, air fresheners and EPA products) were sold. These same companies note that there were no exposures greater than moderate and no cases of pneumonitis during this time.

5. Incident information

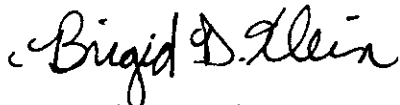
Several CSMA member companies had Dr. Richard Kingston a senior clinical toxicologist with the International Poison Center review proprietary data of products that would be affected by the new rulemaking. Aerosol products containing concentrations of petroleum distillate in excess of 10% by weight were included in the review. Data from company directed product stewardship programs which monitor product exposures in the marketplace were reviewed from these products. The data covered more than 400 million units of product in the marketplace. No incident of exposures resulting in an outcome of moderate or greater was identified. This data supports the premise that aerosol products do not pose the aspiration risk of similar concentrations of ingredients in the liquid form. See Attachment C, comments of Dr. Kingston on the ANPR.

V. CONCLUSION

CSMA appreciates the opportunity to comment on the Advance Notice of Proposed Rulemaking on Household Products Containing Petroleum Distillates and other Hydrocarbons. We trust that the Commission will find this information to be useful. CSMA believes that the current threshold of 100 SUS at 100° F and less than 10% concentration of petroleum distillate should be retained, and that the Commission consider child-resistant packaging only for those products containing 10% or more petroleum distillates, and which have a viscosity of less than 100 SUS at 100° F, where is it is technically feasible, practicable and appropriate to impose such a requirement. Aerosols should be exempt from a child-resistant closure requirement since they do not present an aspiration hazard. We also believe that petroleum distillates and the other hydrocarbons noted in the ANPR should be evaluated separately. In addition, CSMA would like to explore working with the Commission on an education

campaign to educate consumers on proper storage and use of consumer products under the jurisdiction of the CPSC. As always, we look forward to continuing to work with the Commission on this issue as well as other issues of importance.

Sincerely,

A handwritten signature in cursive script that reads "Brigid D. Klein".

Brigid D. Klein
Regulatory Counsel

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

**Summary of Fatalities/Children under the age of 6
AAPCC/TESS "Hydrocarbons" Category**

Year	Substance	Child's Age	Route of Exposure
1990	Charcoal lighter fluid	2 years	Ing/Inh/Ocular
1990	Kerosene	13 mos.	Ing/Inh
1990	Lamp oil (mineral oil 58%/vegetable oil 40%/ perfume oil 2%)	12 mos.	Ing/Inh
1990	Lamp oil (kerosene)	2 years	Ing/Inh
1991	Charcoal lighter fluid	17 mos.	Ing/Inh
1991	Fabric protector (mineral spirits)	3 years	Ing/Inh
1991	Gasoline	15 mos.	Ing/Inh
1991	Gasoline	2 years	Ing/Inh
1991	Kerosene	11 mos.	Ing/Inh
1991	Kerosene	11 mos.	Ing/Inh
1991	Kerosene	2 years	Ing/Inh
1991	Lamp oil (liquid paraffin)	11 mos.	Ing/Inh
1992	Kerosene	13 mos.	Ing/Inh
1993	Gasoline	15 mos.	Aspir/Ing
1993	Gasoline	18 mos.	Aspir/Ing
1993	Unknown hydrocarbon	15 mos.	Aspir/Ing
1994	Chlorofluorocarbon	3 years	Inhalation
1994	Chlorofluorocarbon	4 years	Inhalation
1994	Kerosene lamp oil	14 mos.	Asp/Ing
1994	Kerosene	3 years	Asp/Ing

Toxicological Studies on Hydrocarbons

IX. The Aspiration Hazard and Toxicity of Hydrocarbons and Hydrocarbon Mixtures

HORACE W. GERARDE, M.D.,

Ph.D.

LINDEN, N.J.

Arch. Environ. Health
Vol 6, 35-47, 1963

The accidental ingestion of petroleum distillates is an important cause of poisoning in children in the United States (Carithers, 1955). The principal pathological finding in clinical kerosene intoxication is a chemical pneumonitis which may be complicated by a bacterial pneumonia (Waring, 1933; Lesser et al., 1943; Daeschner et al., 1957). Death results in 4%-10% of the reported cases (Blattner, 1951).

Presented at the 27th Annual Meeting of the Industrial Hygiene Foundation, Pittsburgh, Oct. 24-25, 1962.

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Although there is some disagreement among those conducting animal experiments and clinicians regarding the pathogenesis of the pneumonitis following kerosene ingestion, the preponderance of evidence indicates that the toxicity is due to aspiration and spread of the liquid in the lung rather than to absorption through the gastrointestinal tract. For kerosene the ratio oral LD₅₀/intra-tracheal LD₅₀ is 140/1, which gives some idea of the relative magnitude of the toxicity by these 2 routes (Gerarde, 1959).

The tendency of a substance to constitute an aspiration hazard to the lung depends primarily on its physical properties. The combination of 2 physical properties, low viscosity and low surface tension, increases the aspiration hazard of light hydrocarbons.

Accidental aspiration of liquids from the mouth into the lungs is an acute incident

which occurs in a few seconds—the time required to take a breath. The volume of liquid aspirated is self-limiting. As soon as liquid enters the lung, normal physiological reactions occur which oppose further entry of liquid. These responses are: (1) momentary reflex cessation of breathing, and (2) the expulsive mechanism of coughing.

Clinically, the individual accidentally aspirating poison receives a single dose; usually aspirating once. In an anesthetized or unconscious individual, aspiration may occur more than once because of the temporary absence of normal physiological mechanisms.

Viscosity is the most important single physical property determining the aspiration tendency of a liquid. It determines the likelihood of entry and the rate and extent of penetration into deeper lung structures via the bronchial tree.

Based on studies in our laboratory over the past 6 years, it has been possible to relate aspiration tendency, lung injury, mortality, viscosity, and surface tension for a large number of individual hydrocarbons and hydrocarbon mixtures. Initially, liquid was injected directly into the trachea of anesthetized experimental animals. As work progressed, it was found that an anesthetized rat could be induced to aspirate liquid placed in the mouth. It is well known in clinical medicine that it is hazardous to put liquids into the mouth of an unconscious patient because of the danger of aspiration in the absence of the swallowing reflex. The procedure used in our laboratory is based on this fact. The method eliminates the surgical procedures involved in direct tracheal instillation. Furthermore, it simulates more closely conditions which prevail during clinical aspiration of poison, because it measures aspiration hazard as well as aspiration toxicity. The procedure described has its own built-in safety factor, since each dosing consists of several potential aspirations of the material in contrast to the single aspiration (or at most 2 aspirations), that take place in human aspiration accidents.

Although individual hydrocarbons are used in industry and commerce, the hydrocarbons

that figuratively and literally "turn the wheels" of industry are complex mixtures which may contain hundreds of hydrocarbons belonging to the 3 major classes, aliphatic, alicyclic, and aromatic. The most familiar are lighter fluid, gasoline, kerosene, jet fuels, petroleum ether, Stoddard Solvent, home-heating oil, diesel fuel, mineral oil, motor oil, and rubber. Broadly speaking these mixtures can be grouped into 3 classes, fuels and solvents, lubricants, and polymers. These materials vary in their chemical composition, vapor pressure, and viscosity, all of which influence the aspiration hazard and toxicity. The fuels and solvents in general have a higher vapor pressure and lower viscosity than lubricants. Although paints, adhesives, and protective coatings may contain as much as 30%-40% of hydrocarbon solvents, the viscosity of the finished preparation will be high due to the dissolved or suspended materials. The hydrocarbon solvent could be *n*-hexane, benzene, or kerosene which is readily aspirated in the normal liquid state but as a component blended into a viscous preparation may be almost impossible to aspirate.

This report summarizes our laboratory aspiration studies with a number of liquid aliphatic, alicyclic, and aromatic hydrocarbons, hydrocarbon mixtures, and hydrocarbon aerosols.

Materials and Methods

Hydrocarbons and Hydrocarbon Mixtures.—Individual hydrocarbons were purchased from commercial suppliers or supplied by chemical research laboratories in the petroleum industry. Kerosene was purchased from a local filling station.

Kinematic viscosity determinations were converted to Saybolt Seconds Universal (SSU) at 100 F (American Society for Testing Materials, 1957). Surface tension was measured with a du Nouy tensiometer and recorded in dynes per centimeter at 77 F.

Dosing Procedure.—Male albino rats of Wistar strain weighing from 200-300 gm. were used unless otherwise indicated. The rats were anesthetized to the point of apnea in a covered wide mouth jar (capacity 1 gallon) containing about 1 inch of wood shavings moistened with approximately 1 ounce of anhydrous diethyl ether. The animal was removed from the jar and placed on its back or side on the

table top. The mouth was held open and the tongue pulled forward (Fig. 1). With the animal's head elevated, 0.2 ml. of the test material was delivered into the mouth with a Becton-Dickinson one-half milliliter syringe. This dose is a "mouthful" for the rat and is the maximal quantity that can be placed into the rat's mouth without danger of spilling. As breathing resumed and became regular, the nostrils were closed with the fingers at the end of the expiration phase in the breathing cycle. This was repeated until the liquid had been aspirated or the animal showed signs of regaining consciousness, usually preceded by return of the swallowing reflex.

For aerosol dosing, rats, anesthetized in the same manner as for liquid dosing, were placed on a platform 8-10 inches above the table-top level so that the aerosol spray could be directed horizontally into

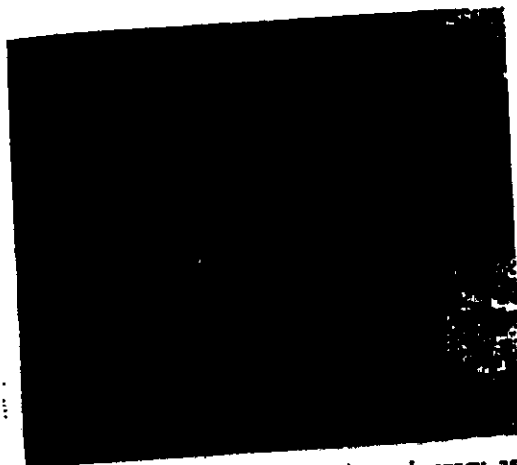


Fig. 1.—Procedure for inducing pulmonary aspiration in rats.

the mouth. The mouth was held open and the tongue pulled forward as shown in Figure 2. A Universal Aerosol Spray Kit, (Nutritional Biochemicals Corporation, Cleveland) was modified to fit a small polyethylene container (Unopette reservoir) so that a known volume of hydrocarbon could be dosed (Fig. 3). The liquid placed in the reservoir is completely aerosolized. The dose used (1.0 ml.) required 2-3 seconds to deliver.

After dosing, the animals were observed for a minimum of 4 hours at intervals ranging from 5 minutes to a maximum of 30 minutes, depending on response. Lungs were removed and weighed as soon after death as possible. Twenty-four hours after dosing the survivors were killed under ether anesthesia by exsanguination from the abdominal aorta. The lungs, dissected free from the heart, trachea, and mediastinal structures, were blotted on a paper towel and weighed to the nearest centigram on a triple beam or torsion laboratory balance.

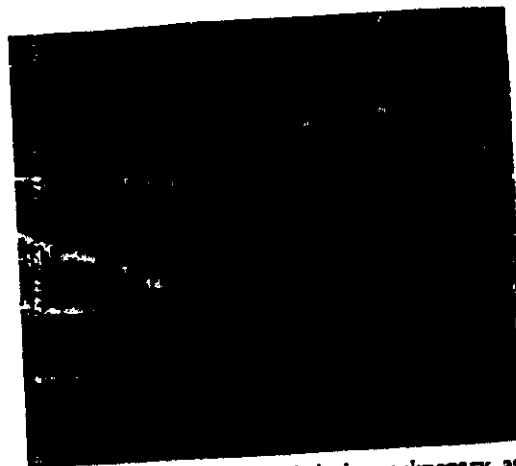


Fig. 2.—Procedure for inducing pulmonary aspiration of aerosols in rats.

Results and Comment

A. Individual Hydrocarbons.—Table 1 summarizes the results obtained with an homologous series of liquid normal paraffin hydrocarbons. Note that *n*-hexadecane (the largest *n*-alkane molecule which is liquid at

Fig. 3.—Modified aerosol spray kit used to deliver measured volume of aerosolized hydrocarbons. Unopette reservoir contains 1.0 ml. of liquid.

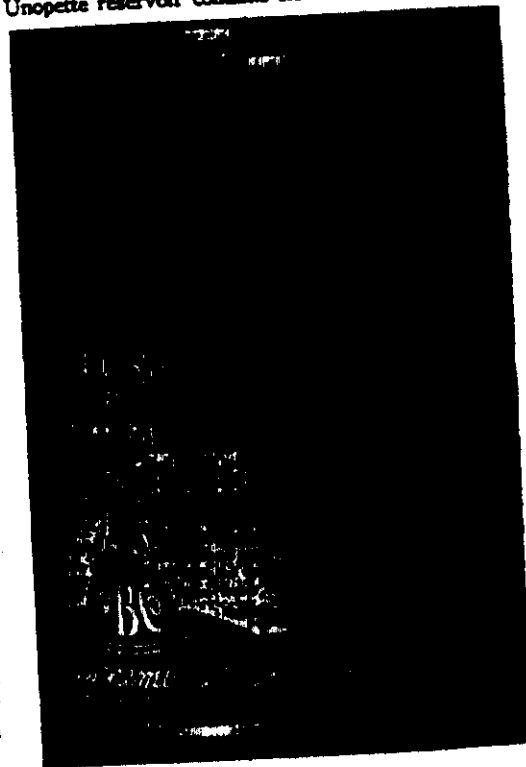


TABLE 1.—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 Ml. of *n*-Paraffin Hydrocarbons (*n*-Alkanes)

Hydrocarbon	Viscosity SSU (100 F)	Mortality (24 Hr.)	Lung Wts. (Gm.) *24 Hr. After Dosing		
			Individual Values	Range	Avg.
<i>n</i> -Hexane	<32	5/5	<u>3.0</u> , <u>3.1</u> , <u>3.1</u> , <u>3.2</u> , <u>3.2</u>	3.0-3.3	3.3
<i>n</i> -Octane		5/5	<u>3.3</u> , <u>3.9</u> , <u>2.7</u> , <u>3.0</u> , <u>2.5</u>	2.5-3.3	2.9
<i>n</i> -Decane		5/5	<u>7.0</u> , <u>4.8</u> , <u>4.8</u> , <u>4.8</u> , <u>3.3</u>	3.3-7.0	4.8
<i>n</i> -Dodecane		5/5	<u>5.5</u> , <u>5.4</u> , <u>5.2</u> , <u>6.1</u> , <u>3.4</u>	3.4-6.1	5.1
<i>n</i> -Tetradecane		33	5/5	<u>5.6</u> , <u>3.7</u> , <u>5.4</u> , <u>4.5</u> , <u>5.9</u>	4.5-5.7
<i>n</i> -Hexadecane	36	1/5	<u>2.9</u> , <u>5.5</u> , <u>4.3</u> , <u>2.3</u> , <u>2.2</u>	2.2-5.5	3.4

* Underscored weights—Animals died in less than 24 hr.
Lung weights of 20 undosed controls: Range 1.1-1.5 gm.
Avg. 1.3 gm.

room temperature) differs markedly from lower homologues in its effects on pulmonary tissues. *n*-Hexadecane is a high boiling (287.5 C), bland, oily hydrocarbon which is less irritating to pulmonary endothelium than the smaller hydrocarbon molecules in this series. There is a sharp "break" in mortality and lung weight between *n*-tetradecane and *n*-hexadecane. These hydrocarbons differ only slightly in viscosity and were readily aspirated. The differences in response must be due to the extent of spread in deeper lung structures and/or differences in effects on capillary and alveolar endothelium. The next higher homologue, *n*-octadecane, is a solid at room temperature so presents no aspiration hazard.

Animals dosed with *n*-hexane and *n*-octane convulse and die in a few seconds after the hydrocarbons enter the lung. Rapid deaths due to *n*-hexane and *n*-octane are attributed to cardiac arrest, respiratory paralysis, and asphyxia rather than to pulmonary edema or hemorrhage. These hydrocarbons are suffi-

ciently volatile at body temperature to fill the lungs with vapor, displacing air. The increase in lung weight is due to transudation from alveolar capillaries into lung spaces. This is not the primary cause of death. With the higher hydrocarbon homologues death occurred much more slowly (in hours rather than seconds) due to progressive pulmonary edema and hemorrhage. The principal clinical signs in these animals were dyspnea, tachypnea, cyanosis, and ultimately a blood-tinged frothy exudation from the nose. Note the marked increase in lung weights in the C₁₀ to C₁₄ dosed animals. The heaviest lungs were found in animals which survived longest after dosing. Grossly and microscopically these lungs were typical "liver-like lungs" (Figs. 4, 5) described previously in kerosene-dosed animals (Gerarde, 1959).

The results obtained with an homologous series of liquid *n*-alkenes (*n*-olefins) are summarized in Table 2. *n*-Pentene is not included in the table, because its volatility is so great at body temperature that the liquid



Fig. 4.—Gross appearance of rat heart and lungs after pulmonary aspiration of 0.2 ml. of kerosene (right and left; center, normal).

TABLE 2.—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 ml. of *n*-Alkenes (*n*-Olefins)

Hydrocarbon	Viscosity SSC (100 F)	Mortality (24 hr.)	Lung Wts. (Gm.) * 24 Hrs. After Dosing		
			Individual Values	Range	Avg.
1-Hexene	<32	3/5	2.8, 2.0, 2.4, 1.8, 2.4	1.6-3.4	2.3
1-Octene		5/5	2.8, 2.8, 3.2, 3.0, 4.0	2.6-4.0	3.1
1-Decene		5/5	4.7, 4.8, 4.7, 3.9, 3.4	3.4-4.9	4.3
1-Dodecene		4/4	5.1, 5.5, 4.1, 4.9	4.1-5.5	4.9
1-Tetradecene		5/5	3.7, 4.2, 4.7, 4.2, 4.8	3.7-4.8	4.3
1-Hexadecene	35	0/5	3.7, 2.8, 4.0, 3.8, 3.4	2.8-4.0	3.9
1-Octadecene	38	1/5	3.3, 2.1, 3.6, 3.0, 2.0	2.1-4.5	3.4
2-Nonadecene	40	0/5	2.8, 2.9, 2.7, 2.8, 2.7	2.6-2.9	2.7

* Underscored weights—Animals died in less than 24 hr.
Lung weights of 20 undosed controls: Range 1.1-1.5 gm.
Avg. 1.3 gm.

evaporated, when placed in the mouth, making testing impossible. As with *n*-alkanes, death occurred rapidly after aspiration of the smaller olefin molecules. 1-Hexene was difficult to dose because of its volatility. Two animals survived because the hydrocarbon "boiled" out of the mouth before it was aspirated. Central nervous system effects (convulsions) were observed in the 1-hexene-dosed rats. Again there was a sharp break in mortality between C₁₄ and C₁₆ (1-tetradecene and 1-hexadecene). The difference in lung weight was not so great as with the corresponding *n*-alkanes.

All the *n*-alkene hydrocarbons (except 1-hexene) were readily aspirated so that differences found in the lungs of animals dosed were due to extent of penetration into deep lung structures and/or endothelial toxicity rather than to differences in the amount of hydrocarbon entering the trachea. Pathologically, the lungs presented the same picture described for the *n*-alkanes.

With *n*-alkynes and *n*-alkadiynes, as shown in Table 3, death due to respiratory failure, cardiac arrest, and asphyxia from displacement of air by hydrocarbon vapor occurred minutes after dosing. In general, the acetylenic hydrocarbons are more volatile than the corresponding olefinic or paraffinic homologues. The relatively low lung weights in these animals are due to rapid death after dosing. The lungs were not grossly edematous or hemorrhagic. The high volatility of these hydrocarbons at body temperature made dosing difficult. The tendency of the liquid to "boil" out of the mouth accounts for the 2 survivors in the 1-hexyne dosed group.

A number of individual cycloparaffins and cycloolefins were also studied (Table 4). The absence of mortality and the normal lung weights in animals dosed with cyclopentene are due to the high vapor pressure of this hydrocarbon, precluding aspiration. This cannot explain the results obtained with the

Fig. 5.—Microscopic appearance of rat lungs after aspiration of 0.2 ml. of kerosene. Left normal; reduced about 12% from mag. $\times 430$.

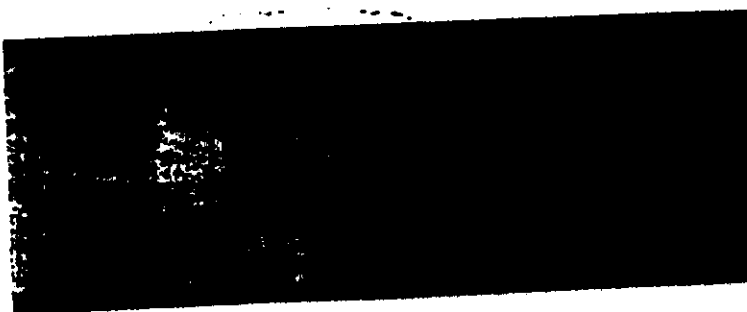


TABLE 3.—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 Ml. of *n*-Alkynes and *n*-Alkadiynes

Hydrocarbon	Mortality (24 Hr.)	Lung Wts. (Gm.) * 24 Hrs. After Dosing		
		Individual Values	Range	Avg.
1-Hexyne	3/3	2.0, 2.4, 2.3, 2.4, 1.8	1.8-2.8	2.2
1-Octyne	3/3	2.0, 2.4, 2.4, 2.4, 2.7	2.4-3.0	2.6
1-Decyne	3/3	2.3, 2.8, 3.0, 2.9, 3.0	2.9-3.3	2.9
1,6-Heptadiyne	4/4	1.8, 1.4, 2.0, 2.1, 1.4	1.4-2.1	1.8
1,7-Octadiyne	3/3	1.1, 2.4, 1.2, 2.1, 2.3	1.1-2.4	1.9
1,8-Nonadiyne	4/3	2.3, 2.7, 2.0, 1.6, 1.3	1.3-2.7	1.9

* Underscored weights—Animals died in less than 24 hr.
Lung weights of 20 undosed controls Range 1.1-1.8 gm.
Avg. 1.3 gm.

cyclooctadienes and cyclooctatetraene, since these were not observed to "boil" out of the mouth during dosing. These hydrocarbons are unstable and undergo oxidation to aldehydes, alcohols, or other oxidized intermediates which presumably do not possess the toxicity for endothelium characteristic of hydrocarbons.

Table 5 presents results obtained with benzene and an homologous series of alkyl derivatives of benzene. Note that with the lower homologues death occurred in minutes due to cardiac arrest and/or respiratory paralysis rather than to pulmonary edema.

TABLE 4.—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 Ml. of Alicyclic Hydrocarbons

Hydrocarbon	Mortality (24 Hours)	Lung Weights (Gm.)
Cycloparaffins		
Cyclopentane	1/3	2.0, 1.5, 1.3
Cyclohexane	2/3	1.4, 2.7, 2.2
Cycloheptane	2/3	2.4, 1.8, 2.5
Cyclooctane	2/3	2.7, 2.4, 2.4
Methylcyclopentane	2/3	2.4, 2.7, 2.8
Methylcyclohexane	3/3	2.2, 2.8, 2.2
Vinylcyclohexane	3/3	2.3, 2.7, 2.8
<i>n</i> -Butylcyclohexane	3/3	2.9, 4.0, 4.0
Phenylcyclohexane	2/3	3.4, 3.0, 4.0
Cycloolefins		
Cyclopentene	0/3	1.2, 1.3, 1.3
Cyclohexene	1/3	1.5, 2.0, 2.2
Cycloheptene	3/3	2.7, 2.4, 2.3
4-Methylcyclohexene-1	2/3	2.4, 2.2, 2.4
1,3-Cyclooctadiene	2/3	2.5, 2.2, 1.9
1,5-Cyclooctadiene	0/3	2.3, 2.1, 1.3
Cyclooctatetraene	0/3	1.8, 1.4, 1.3

One of the 3 animals dosed with *n*-hexylbenzene died 18 minutes after dosing and had a lung weight of 7.5 gm. Sufficient time had elapsed before death to allow extensive infiltration of fluid and blood into the alveoli. The animals dosed with 1-phenyldodecane were killed one hour after dosing. Their lung weights indicated that minimal fluid infiltration had taken place after dosing. The lungs showed little gross evidence of hemorrhage. It appears that lengthening of the alkyl side chain tends to diminish the toxicity for the endothelium of alkyl derivatives of benzene.

All individual hydrocarbons of the 3 principal classes studied had a low viscosity (below 40 SSU at 100°F) and were readily aspirated with the exception of those with a high vapor pressure (C_6 , C_8 , C_7) which

TABLE 5.—Mortality and Lung Weights of Male Albino Rats (250-350 Gm.) 24 Hours After Aspiration of 0.25 Ml. of Aromatic Hydrocarbons

Hydrocarbon	Observations *	Lung Wts. (Gm.)
Benzene	Died instantly, cardiac arrest, breathing continued a few sec.	2.2, 2.4, 2.4
Toluene	Died instantly, cardiac arrest.	2.0, 2.2, 2.2
Ethylbenzene	Died instantly.	2.4, 2.2, 2.9
<i>n</i> -Propylbenzene	Died in a few sec.	2.2, 2.0, 2.7
<i>n</i> -Butylbenzene	Died instantly.	3.7, 2.3, 2.6
<i>n</i> -Hexylbenzene	Died in 1-3 min.	4.4, 3.7
	Died in 18 min.	7.5
1-Phenyldodecane	Killed in 1 hr.	2.0, 2.0, 1.8

* 3 animals dosed per chemical.

evaporated rapidly at the temperature of the oral cavity. In general, it appears that all lower molecular weight hydrocarbons, on entry into the lung, are absorbed rapidly causing central nervous system stimulation, cardiac arrest, respiratory paralysis, and asphyxia due to rapid displacement of air. This causes death in minutes. The larger molecules in an homologous series are slower acting; although they are probably absorbed from the lung into the blood stream, they do not cause marked evidence of systemic intoxication. Direct contact of these hydrocarbons with endothelium causes increased permeability resulting in the passage of plasma and blood into the alveoli which may be sufficiently extensive to cause death. A large, bland molecule such as *n*-hexadecane is a slow-acting endothelial irritant of low potency.

A systematic study of the effects of individual hydrocarbons makes it possible to predict and anticipate the effects that may be elicited by mixtures of hydrocarbons of known chemical composition.

B. *Hydrocarbon Mixtures*.—The effect of a hydrocarbon mixture is illustrated in Table 6. The preparations in the third group in this table (protective coatings and adhesives) were so viscous that they coated the inner surfaces of the mouths of rats dosed and could not be aspirated. Attempts were made to promote aspiration of these viscous materials by keeping the nostrils of the animal closed to the point of asphyxia. These materials pooled slowly over the tracheal opening and sealed the airway but were not aspirated into the lung. It is apparent that preparations such as asphalts, roof cements, paints, lotions, emulsions, or gels may contain high concentrations of petroleum distillates but present little or no hazard of chemical pneumonitis, because their viscosity precludes aspiration (Gerarde, 1961).

No apologies are made for the small number of animals used to study the aspiration hazard of the viscous materials shown in Table 6. The answer could have been obtained with half as many animals with equally conclusive and reliable results. Many more animals were used to establish the safe viscosity "cut off" point in the "gray-area"—the transition zone between fuels and solvents and light lubricants. The heavier lubricants such as motor oils were similar to mineral oil causing a "lipoid pneumonia" rather than an acute chemical pneumonitis characteristic of kerosene.

The Relationship Between Viscosity and Aspiration Hazard: Five blends of kerosene-lubricating oil were used to study the influence of viscosity on aspiration toxicity. These blends contained from 20%-50% kerosene and ranged in viscosity from 385 to 58 SSU at 100 F. The surface tension of these mixtures was also determined, since this was considered an important variable. The kerosene without diluent was used as a control (Table 7).

TABLE 6.—Aspiration Toxicity of 0.2 ML of Hydrocarbon-Containing Mixtures* (Male Albino Rats, 300-400 Gm.)

Name of Mixture	Mortality (24 Hr.)
Fuels & Solvents	
Lighter fluid	2/2 †
Gasoline	2/2 †
Oil of turpentine	2/2 †
Dry cleaning solvent	1/2
Kerosene	3/3
Diesel oil	2/2
Home heating fuel oil	1/2
Lubricants	
Multigrade motor oil (SAE 10W-30)	1/3
High detergency type additive motor oil	1/3
Handy oil #1	0/3
Mineral oil	0/3
Automatic transmission fluid	0/3
Straight mineral crankcase oil without additives	0/3
Multigrade motor oil	0/3
Protective Coatings & Adhesives	
Exterior primer paint (mineral spirits: 18.7%)	0/2
Enamel (aliphatic hydrocarbons: 32.7%)	0/2
Alkyd enamel (mineral spirits: 28.6%)	0/2
Polybutadiene, liquid	0/2

* Arranged in approximate order of increasing viscosity.

† Death instantaneous.

TABLE 7.—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 Ml. of Kerosene-Lubricating Oil Blends

% Kerosene	Viscosity SSU (100 F)	Surface Tension (Dynes/Cm)	Mortality (24 Hr.)	Lung Wts. (Gm.) * 24 Hr. After Dosing		
				Individual Values	Range	Avg.
100	32	28.1	5/10	6.0, 2.5, 4.1, 6.0, 2.7 2.3, 4.4, 3.1, 4.8, 5.3	2.5-6.0	4.2
50	58	30.5	0/10	1.6, 1.4, 1.9, 1.5, 1.3 1.7, 1.2, 1.3, 1.3, 1.4	1.2-1.9	1.7
43	81		0/10	1.6, 1.4, 1.9, 1.6, 1.3 1.7, 1.2, 1.3, 1.3, 1.4	1.3-1.9	1.5
35	122	31.6	0/10	1.3, 1.5, 1.3, 1.7, 1.4 1.4, 1.1, 1.2, 1.3, 1.5	1.1-1.7	1.4
28	197		0/10	1.3, 1.7, 1.4, 1.3, 1.6 1.3, 1.6, 1.3, 1.1, 1.7	1.1-1.7	1.4
20	385	32.0	0/10	1.7, 1.4, 1.5, 1.4, 1.4 1.5, 2.4, 4.0, 1.4, 1.3	1.3-4.0	1.8

* Underdosed weights—Animals died in less than 24 hr.
Lung weights of 20 undosed controls: Range 1.1-1.6 gm.
Avg. 1.3 gm.

The relationship between mortality and viscosity is shown in Figure 6 and between lung weight and viscosity in Figure 7. It is striking to find that a mixture with a viscosity of 58 SSU at 100 F containing 50% kerosene is readily aspirated into the lungs but produces minimal pulmonary irritation. There is no doubt that the 0.2 ml. of the mixture dosed was aspirated quantitatively. This is also true for the other blends, although it became increasingly difficult to in-

duce aspiration as viscosity increased. The animal's nostrils had to be pinched shut for the more viscous blends, causing asphyxia and cyanosis in some animals, the degree depending on the time required to induce aspiration.

On gross inspection, the lungs showed minimal injury confirmed by essentially normal lung weights.

Speculating on the mechanism of action of the lubricating oil blended with kerosene, the

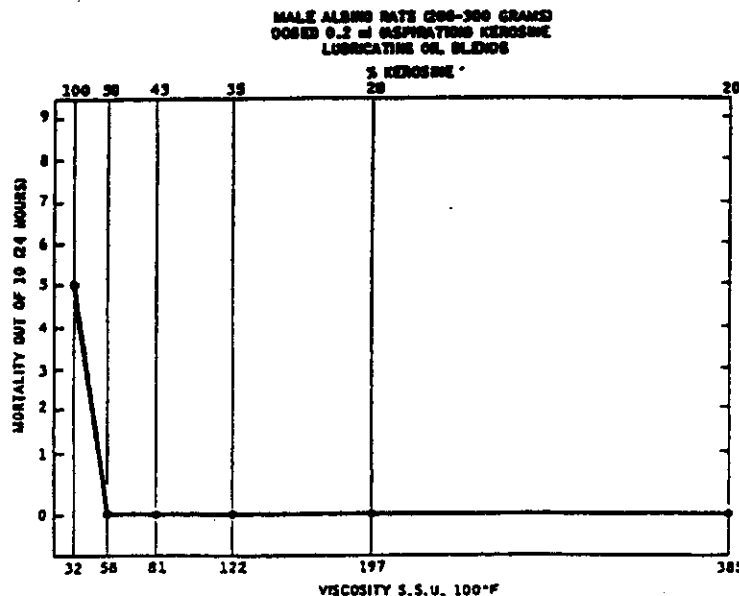


Fig. 6.—The relationship of viscosity to mortality in rats dosed with kerosene-lubricating oil blends.

MALE ALBINO RATS (200-300 GRAMS)
 0.2 ML ASPIRATION KEROSENE
 LUBRICATING OIL BLENDS

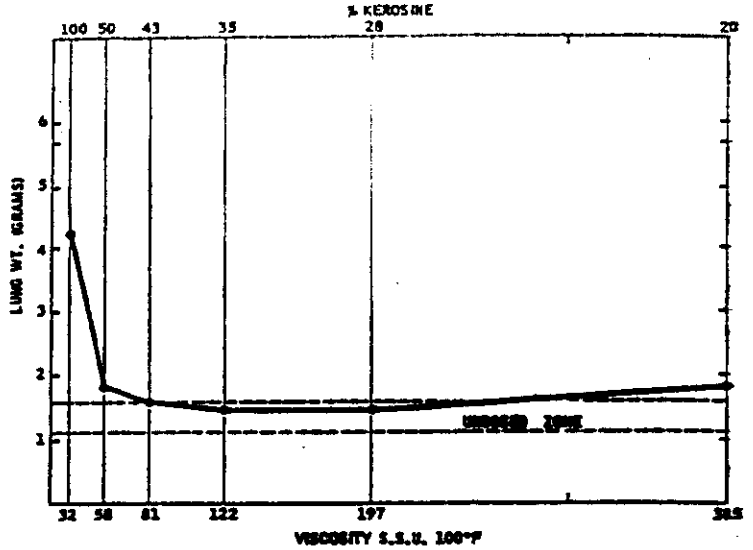


Fig. 7.—Lung weights of rats 24 hours after dosing with kerosene-lubricating oil blends of varying viscosity.

surface tension of the 50% kerosene-blend was 30.5 compared with 28.1 dynes per centimeter for the kerosene. The increased surface tension would tend to decrease the spreading tendency. The increased viscosity would also make it more difficult for the blend to penetrate into the bronchioles and alveoli. In addition to physical factors which control spread of liquid, the lubricating oil also diminishes the direct endothelial irritant effect of kerosene, at least by a factor in proportion to its concentration in the blend. If

it is simply a dilution effect, the blend is half as irritating as the undiluted kerosene.

Another experiment similar in design to that just described was carried out to study the relationship between viscosity and aspiration hazard. The samples were straight petroleum products, mixtures of hydrocarbons varying in viscosity from 39 to 156 SSU at 100 F and in surface tension from 31.6 to 33.4 dynes per centimeter. The results, shown in Table 8 and Figures 8 and 9, revealed a sharp drop in mortality and

TABLE 8.—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 ML. of Petroleum Distillates and Petroleum Oils

Viscosity SSU (100 F)	Surface Tension (Dynes/Cm.)	Mortality (24 Hr.)	Lung Wts. (Gm.) * 24 Hr. After Dosing		
			Individual Values	Range	Avg.
39	31.6	8/10	<u>5.2</u> , <u>3.5</u> , <u>2.0</u> , <u>5.2</u> , <u>4.7</u> <u>6.0</u> , <u>3.8</u> , <u>6.0</u> , <u>4.8</u> , <u>3.8</u>	2.0-6.0	4.7
59	32.6	2/10	<u>2.8</u> , <u>3.7</u> , <u>4.0</u> , <u>1.4</u> , <u>3.1</u> <u>4.4</u> , <u>4.2</u> , <u>1.5</u> , <u>1.9</u> , <u>1.9</u>	1.4-4.4	2.9
73	32.8	1/10	<u>3.6</u> , <u>2.0</u> , <u>3.8</u> , <u>1.8</u> , <u>4.1</u> <u>1.8</u> , <u>2.5</u> , <u>2.1</u> , <u>1.8</u> , <u>1.9</u>	1.8-4.1	2.5
83	32.8	0/10	<u>4.3</u> , <u>2.8</u> , <u>1.9</u> , <u>1.5</u> , <u>2.5</u> <u>2.9</u> , <u>1.4</u> , <u>4.3</u> , <u>2.8</u> , <u>1.6</u>	1.4-4.3	2.6
109	33.1	0/10	<u>2.0</u> , <u>1.5</u> , <u>1.6</u> , <u>1.6</u> , <u>1.7</u> <u>2.0</u> , <u>1.6</u> , <u>1.9</u> , <u>1.5</u> , <u>1.5</u>	1.5-2.0	1.7
156	33.4	0/10	<u>1.8</u> , <u>1.1</u> , <u>1.5</u> , <u>1.7</u> , <u>1.7</u> <u>1.2</u> , <u>1.3</u> , <u>1.3</u> , <u>1.1</u> , <u>1.3</u>	1.1-1.8	1.4

* Underscored weights—Animals died in less than 24 hr.

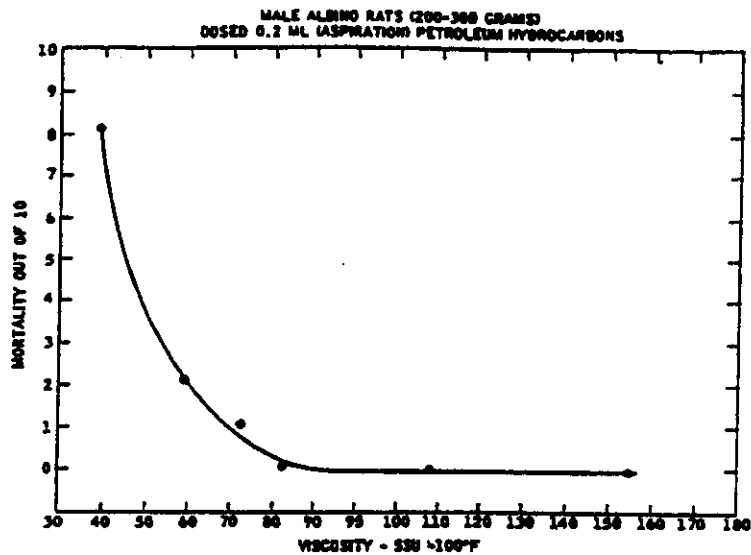


Fig. 8.—Mortality in rats dosed with petroleum hydrocarbons varying in viscosity.

lung weights with an increase in viscosity from 39 to 59 SSU at 100 F. The results are qualitatively similar to data obtained with kerosene-lubricating oil blends. The straight petroleum product or oil with a viscosity of 59 and surface tension of 32.6 was more toxic than the kerosene-lubricating oil blend with a viscosity of 48 and surface tension of 30.5. Since these 2 preparations differed in hydrocarbon composition, it is reasonable to assume that the difference in toxicity is due

to chemical composition rather than to physical factors (viscosity and surface tension) influencing penetration and spread into lung tissue. The straight petroleum product had a higher concentration of small hydrocarbon molecules than the kerosene-lubricating oil blend. The lubricating oil, having a higher boiling point, contains larger hydrocarbon molecules. The study with individual hydrocarbons shows that larger molecules are less irritating on direct contact with endo-

Fig. 9.—Lung weights of rats 24 hours after dosing with petroleum hydrocarbons varying in viscosity.

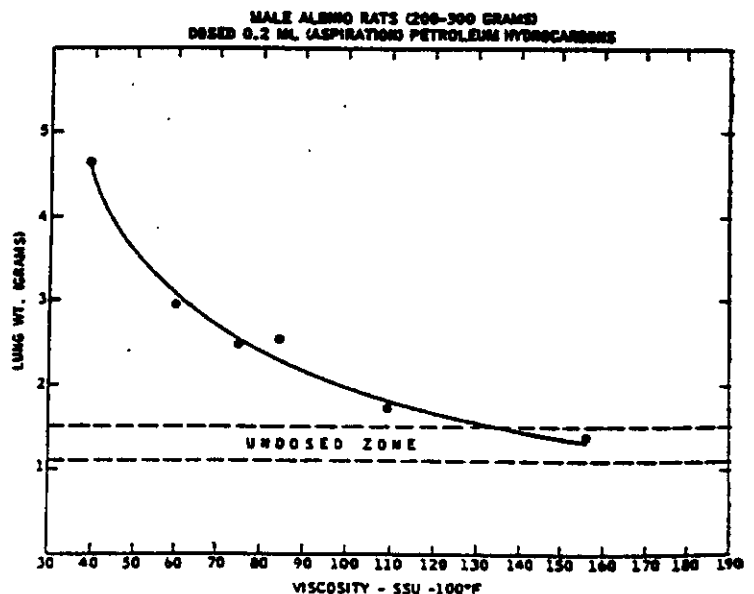


TABLE 9.—Mortality and Lung Weights of 10 Male Albino Rats Dosed with 1.0 ml. of Kerosene Aerosol (Killed 24 Hours After Dosing)

Mortality	Clinical Observations After Dosing	Lung Weights (Gm.) *	Avg.	Gross Pathology
0/10	No evidence of systemic intoxication or pulmonary distress, local irritation around eyes and nose cleared rapidly.	1.18, 1.27, 1.22, 1.04, 1.43 1.28, 1.07, 1.34, 1.42, 1.30	1.28	Lungs normal on inspection

* Lung weights of 20 undosed controls: Range 1.1-1.5 gm.
Avg. 1.3 gm.

thelium than are smaller molecules. Larger molecules are more viscous so viscosity is indirectly a measure of molecular size in a straight petroleum product.

C. *Hydrocarbon Aerosols*.—A limited number of studies were conducted to determine the hazard of direct spraying of hydrocarbon aerosol into the mouth. It is conceivable that a child could accidentally, or a deranged adult could intentionally, put the nozzle of an aerosol can into his mouth and push the button. To simulate these highly improbable conditions, rats were anesthetized and dosed with 1.0 ml. of aerosolized kerosene (Fig. 2). The time required to deliver the 1 ml. of hydrocarbon aerosol was 2-3 seconds. Results are presented in Table 9. Additional experiments with hydrocarbon aerosols in conventional aerosol containers confirmed these findings. It is concluded that

aerosols of hydrocarbons even when sprayed directly into the mouth do not present the acute aspiration hazard which exists with the same hydrocarbon in liquid form. The myriads of minute hydrocarbon droplets in aerosol form collect on the oral tissue surfaces. They do not coalesce to form a pool of liquid which can be aspirated into the trachea. It is possible to deliver a large volume of aerosol directly into the mouth so that a pool will form which can be aspirated.

Lung Weights as Criteria of Injury: Lung weight has been recognized in experimental toxicology as a simple, objective, gross measure of pulmonary injury. Figure 10 is a histogram of weights of lungs removed within 24 hours after dosing 429 male albino rats with 0.2 ml. of the hydrocarbons and hydrocarbon mixtures used in this study. None that died within 24 hours had lung

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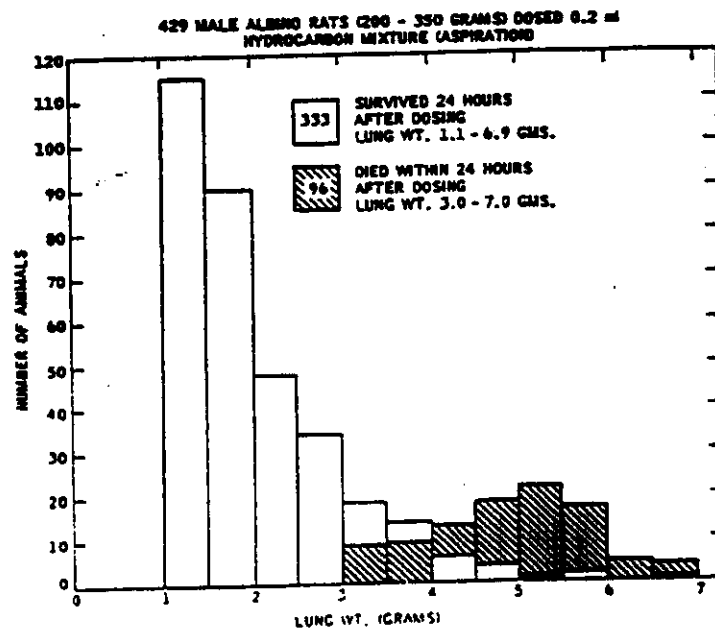


Fig. 10.—Histogram of lung weights of rats succumbing and surviving within 24 hours after aspirating 0.2 ml. of hydrocarbon mixtures.

TABLE 10.—Effect of Increasing Doses of Kerosene Aspirated by Male Albino Rats (200-275 Gm.)*

Dose (ML.)	Mortality (Hr. After Dosing)						18 Days
	1	2	6	24	48	72	
0.05	0/10	0/10	0/10	0/10	0/10	0/10	1/10 †
0.10	0/10	1/10	3/10	4/10	4/10	4/10	4/10
0.15	0/10	2/10	6/10	7/10	8/10	9/10	9/10
0.20	0/10	3/10	7/10	8/10	9/10	9/10	9/10
0.25	4/10	7/10	10/10	10/10	—	—	—

* Sprague-Dawley strain.

† Died on 10th day.

weights under 3 gm., weights ranging from 3 to 7 gm. Most animals surviving 24 hours after dosing had lung weights less than 3 gm., ranging from 1 to 7 gm. Deaths following hydrocarbon aspiration occurred within 24 hours after dosing. This is well recognized in clinical human cases of hydrocarbon aspiration poisoning. It is axiomatic that, if a child lives 24 hours after the aspiration accident, he is out of danger.

Experimental evidence for this is shown in Table 10. At the doses used in our experiments, all but the smallest doses produced deaths within 24 hours after dosing. Indeed, most deaths occurred 6 hours after dosing. These data are the basis for using 24 hour mortality and 24 hour lung weights of surviving animals as criteria of aspiration hazard and toxicity in these experiments. It is concluded that a rat having a lung weight less than 3 gm. 24 hours after dosing has minimal to moderate lung injury compatible with survival. By employing these criteria the test for aspiration hazard can be completed in slightly more than 24 hours. The additional time is that required to dose the animals, killing the survivors, removing and weighing the lungs. The method is useful in evaluating the hazard and toxicity of a large number of hydrocarbons and hydrocarbon mixtures.

Summary

A method has been described for determining the aspiration hazard and toxicity of liquids and aerosols. It has been used to determine the aspiration hazard and toxicity of a number of individual hydrocarbons and

hydrocarbon mixtures. For the *n*-alkanes and *n*-alkenes a sharp decrease in toxicity occurs with the C₁₀ hydrocarbons, *n*-hexadecane, and *n*-hexadecene. Individual low-boiling hydrocarbons of the 3 major classes are highly toxic by this route of administration, causing death by cardiac arrest, respiratory paralysis, and asphyxia. 1-Phenylododecane is less toxic than 1-hexylbenzene. It appears that further lengthening of the chain beyond C₆ tends to diminish the toxicity of these compounds for the endothelium. A limited number of cycloparaffinic, cycloolefinic, and acetylenic hydrocarbons were tested and found to be toxic when aspirated into the lungs. The more volatile, smaller molecules caused death by cardiac arrest, respiratory failure, and asphyxia.

All of the individual hydrocarbons tested have a low viscosity, not exceeding 45 SSU at 100 F, and were readily aspirated. Hydrocarbon mixtures of low viscosity (lighter fluid, gasoline, kerosene) are readily aspirated and highly toxic by this route. Highly viscous materials such as paints, adhesives, asphalts, rubber cement, etc., may contain high concentrations of hydrocarbon solvents and be without hazard by the aspiration route. Mineral oil and motor oils of comparable viscosity do not cause severe, acute pulmonary edema and hemorrhage characteristic of kerosene and similar low-viscosity hydrocarbon mixtures. The pulmonary effects produced by these hydrocarbons are the "lipoid pneumonia" type of reaction—low-grade, chronic localized tissue reactions which are not fatal.

The aspiration toxicity of kerosene was markedly reduced by blending with an equal volume of a lubricant oil. This blend, containing 50% kerosene and having a viscosity of 58 SSU at 100 F, caused no mortality and minimal lung injury based on lung weight. A straight petroleum oil with a viscosity of 59 SSU at 100 F was much less toxic than a petroleum distillate with a viscosity of 39 SSU at 100 F. The record of human experience with petroleum distillate intoxication by accidental ingestion incriminates liquids with viscosities below 45 SSU at 100 F—gasoline, lighter fluid, kerosene, Stoddard Solvent, mineral spirits, etc. (Food and Drug Administration Public Hearing, Washington, D.C., July 13-14, 1961). This confirms the experimental findings with animals in this study. Viscosity is the most important physical property determining the aspiration hazard toxicity of liquid hydrocarbons. The effect of surface tension appears to be overshadowed by viscosity, probably because surface tension varies within a narrow range for most hydrocarbon mixtures.

Mr. W. Herman Barcus, Manager, Research Service, Research & Development Division, Sun Oil Company, prepared the samples of kerosene, lubricating oil blends, and petroleum distillates; Mr. Larry Garland, of the Photographic Department, Esso Research and Engineering Company did the photographs used in this report.

Horace W. Gerarde, M.D., Ph.D., Medical Research Division, Esso Research and Engineering Co., P.O. Box 45, Linden, N.J.

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July 3, 1997

Brigid Klein
Regulatory Counsel
Chemical Specialties Manufacturers Association
1913 Eye St. N.W.
Washington, DC 20006

Dear Ms Klein,

I appreciate the opportunity to advise the CSMA of my opinions regarding the proposed petroleum distillate rulemaking. As you know I am a practicing clinician with the International Poison Center and serve on the faculty of the University of Minnesota. Much of my experience regarding public poison control programs was gained through my affiliation with Minnesota Poison Control for the past twenty years. I have had a special interest in poison prevention packaging and continue to conduct research and speak on the topic.

I believe it is important that all of us in the professional community work together to better understand the issues regarding poison prevention. We must target our limited resources in the most cost effective manner possible to achieve the maximum impact in preventing childhood poisoning. Whatever action is taken either by your member companies or the Agency, must be supported by sound data and scientific merit. It is with this goal in mind that I offer my suggestions regarding this important proposed regulatory action.

For the purposes of this project I have reviewed the information you received from the CPSC through the Freedom of Information Act. These include:

1. The Briefing Package on child-Resistant packaging of Petroleum distillate-Containing Products;
2. 43 Epidemiologic (In-Depth) Investigation Reports;
3. A letter petitioning the Commission to require child-resistant closures on a certain spot remover;
4. NEISS Data from 1990-1994;
5. The Federal Register notice announcing the ANPR; and

 **International Poison Center**

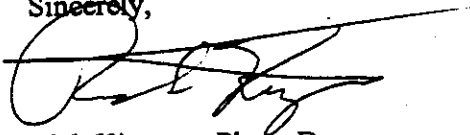
Riverview Office Tower, 8009 - 34th Avenue South, Suite 1050, Minneapolis, MN 55425 USA
612.814.7100 fax: 612.814.7101

6. In-depth Investigation reports from 2 of the 10 deaths noted in Appendix A of the Briefing Package.

I have commented on each section as well as provided an overall assessment of strengths and weaknesses of the information as a whole. I have also reviewed proprietary data supplied to me by a number of CSMA member corporations regarding products they manufacture that would be affected by this rulemaking. I believe this data will help put an additional perspective on the issue.

If you have any questions regarding my comments please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Rick Kingston", written over a horizontal line.

Rick Kingston PharmD
Senior Clinical Toxicologist

Executive Summary and Conclusions

The CPSC (Agency) has advised of its intent to expand its coverage of the Poison Prevention Packaging Act (PPPA) and require child resistant closures (special packaging) for all products containing petroleum distillate. The PPPA which is administered by the Agency currently requires the use of "special packaging" on certain product categories but does not address petroleum containing products outside of those categories. Many of these unregulated products fall under the FHSA standards for labeling but are not required to be packaged with special packaging. The Agency has proposed a change in requirements for special packaging based on the ability of petroleum containing products to produce aspiration pneumonitis, a form of chemical pneumonia. This respiratory effect has occurred after oral exposure and subsequent aspiration of low viscosity products under certain circumstances. Since 1973 there have been a number of reported "exposures" to unregulated products containing petroleum distillates. There have also been 10 deaths in children less than 5yrs of age where an unregulated petroleum distillate containing product appears to have been involved.

The Agency is also considering the inclusion of non-petroleum derived hydrocarbons. The most prevalent of these products contain Pine Oil. Five deaths involving Pine Oil containing products in children under 5 have been reported to the Agency since 1973. Much of the data relied on for the purposes of this rulemaking pertains to Pine Oil containing product exposures.

In support of its proposed rulemaking position the agency has supplied 43 "Epidemiologic (In-Depth) Investigation Reports", a letter petitioning the Commission to require child-resistant closures on a specific product involved in a childhood poisoning and death, National Electronic Injury Surveillance System data summarizing a four year period of surveillance, In-depth Investigation Reports from 2 of the 10 deaths known to the Agency, and Poison Center Data from the TESS (Toxic Exposure Surveillance System) database. The Agency is also attempting to better define: the role of special packaging for aerosol products, issues related to restricted flow requirements, the inclusion of non-petroleum derived hydrocarbons, and viscosity.

Although a reasonable hypothesis has been generated, data clearly supporting the rulemaking is lacking. It is unknown how many exposures resulting in serious outcomes are due to unregulated petroleum containing products and hospital visit data presented by the agency does not adequately define any level of harm experienced by the patients involved. Hospital data that has been presented involves patients without any clinically significant outcomes and, in and of itself, does not demonstrate that any of the patients were at risk of serious injury. Throughout the years there are certainly patients who have experienced clinically significant exposures to petroleum distillate containing products and some have even died. Unfortunately the data presented here has not identified which *specific* products and *concentration* of ingredients have been involved and under what circumstances these exposures occurred. It is important that the CSMA and others continue to support the Agency's efforts in gathering data to better define the nature of

these exposures.

Based on what we do know of the inherent risk of aspiration demonstrated by certain petroleum distillate containing products I would support the following recommendations:

1. Special packaging requirements for petroleum distillate containing products with a concentration of more than 10%w/v *and* a viscosity rating of 100 SUS or lower should be endorsed.
2. An exemption should be made for petroleum distillate containing aerosol products.
3. Other non-petroleum distillate containing hydrocarbons should be evaluated separately as they may or may not be adequately covered by these criteria.

And,

4. The Agency should endorse and support the education efforts of CSMA and others in the area of responsible use of consumer products.

SPECIFIC REVIEW OF AGENCY DOCUMENTATION

Role of Viscosity and Aspiration Pneumonia

From a clinical perspective, viscosity appears to be the single most significant factor in evaluating the tendency of a petroleum distillate to produce aspiration pneumonia. Animal studies have clearly demonstrated that low viscosity liquids, when introduced into the lungs, are capable of producing aspiration pneumonia. The most comprehensive report delineating this finding is the study by Gerarde, "Toxicological Studies on Hydrocarbons" published in the Archives of Environmental Health, vol 6, pp35-47, 1963. Dr. Gerarde clearly demonstrated the effects of varying concentrations of petroleum distillates and the resulting clinical response and injury in the animal model. Although these studies simulate an artificial exposure created in a laboratory setting the information can be used to help clinicians evaluate the worst case scenario in the event of a human exposure to products containing low viscosity petroleum products. The findings support the Agency's current requirement that certain products containing 10 percent or more by weight of petroleum distillate and having a viscosity of less than 100 SUS (Saybolt Universal Seconds at 100F) be packaged in "special packaging".

Special Packaging for Petroleum Distillate Containing Products in Aerosol Form

Certain petroleum distillate containing products may fall within the viscosity guidelines outlined above, but not pose an aspiration hazard because of packaging characteristics currently in use. This would include products in an aerosol form. Data supporting this premise fall into two categories, animal studies and human epidemiologic analysis. In the first category, the studies performed by Gerarde included exposing animals to aerosolized hydrocarbons in an effort to address the possibility of a petroleum distillate containing aerosol exposure in a child. Even when using 100% aerosolized kerosene, no aspiration hazard could be demonstrated. Dr. Gerard concluded that:

"It is concluded that aerosols of hydrocarbons even when sprayed directly into the mouth do not present the acute aspiration hazard which exists with the same hydrocarbon in liquid form."

In my 20 year experience of managing thousands of pediatric exposure cases in the poison control center environment I cannot recall one case of a petroleum distillate containing aerosol producing an aspiration injury. Additionally, in my review of the human experience which included the cases supplied by the Agency, I could find no data demonstrating that accidental exposure to aerosol packaged versions of petroleum containing products have resulted in aspiration pneumonia. More information regarding human exposure data is contained in the following sections.

Epidemiologic Evaluation of Human Exposures

The Agency has reviewed four areas of data regarding human exposure to petroleum distillate containing products. These include data from the National Electronic Injury Surveillance System (NEISS), Telephone Investigations, Poison Control Center Data, and Investigative Reports regarding two cases involving death. Each of these areas have unique characteristics which must be considered when examining and assessing their impact on the proposed rulemaking. These four areas provide the substance upon which rulemaking must be based.

Although there appears to be reasonable concern on the part of the Agency to further investigate and define the scope of the problem. I have attempted to articulate some of the limitations inherent in evaluating data from these sources. Hopefully this will help identify areas of common ground as well as areas where more specific data would be useful.

1. **NEISS Data:** The Agency operates the NEISS data system which collects information from 91 participating hospitals. This data represents emergency department visits associated with consumer products. A summary of emergency department visits involving products meeting specific criteria was used to estimate the incidence of similar events occurring throughout the US. It is apparent from the report and its descriptors that any pediatric patient presenting to an emergency department with a history of exposure to a consumer product within the defined scope of the project was included in the analysis. Although this appears to be a reasonable approach to better define the scope of the problem there does not appear to be any acknowledgment of the limitations inherent in this type of assessment. Throughout the narrative describing these cases it appears to be assumed that all patients included in the numbers were "poisoned" by the product in question. It also assumes that all patients presenting to an emergency department were in some way "treated". And finally, some may inadvertently assume that an emergency department visit was necessary just because it occurred. When interpreting these data the following limitations must be kept in mind.

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

* It cannot also be assumed that children "admitted" to the hospital after exposure to petroleum containing products have experienced serious injury. In the same study cited earlier, 150 of the 950 children were "admitted" to the hospital. Of these

children 71% were asymptomatic and remained so during their hospital stay. Pulmonary complications secondary to aspiration occurred in only 7 (0.74%) of the entire series and in each of these cases the child was symptomatic at presentation to the emergency department.

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

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

For these reasons, care must be taken when interpreting aggregate data of this nature. Review of the actual medical record or an interview with the attending health professionals would be invaluable in providing a more in-depth evaluation of the incidents depicted in the numbers.

2. **Telephone Investigations:** A subset of data collected through the NEISS system between October 1994 and May 1996 was also used to identify cases to be included in a telephone investigation. During this 15 month period 160 cases were identified and successful interviews were carried out on 85 of the cases. Of the 85 cases interviewed only 43 represented products meeting the criteria of being a pine oil containing product or an unregulated petroleum distillate. Of these cases over 58% were Pine Oil containing products. No medical records were reviewed in any of the cases and all information was based on interviews with lay persons, usually family members or other caregivers. None of the exposures resulted in any significant adverse effects and 97% were released directly from the emergency department. The remaining cases were admitted for observation and discharged the following day. These data appear to support the premise that the vast majority of exposures of this nature do not result in any significant clinical effects. In the majority of cases presented here even the need for hospital evaluation was questionable. It is interesting to note that in a number of cases patients received activated charcoal which is not routinely recommended for petroleum containing exposures where aspiration is a concern. Review of the medical records would have helped add clarity to the data. It is also of interest to note that the exact product, and thus the exact concentration and composition of ingredients, could not be identified in the majority of incidents. It is also of interest that the majority of exposures occurring in these

cases were the result of behaviors that would be unaffected by special packaging.

3. **Poison Center Data:** The agency has cited data reported in the American Association of Poison Control Centers (AAPCC) Toxic Exposure Surveillance System (TESS) database. The following background information on the American Association of Poison Control Centers and the TESS system may be useful.

The American Association of Poison Control Centers (AAPCC) is a non-profit professional trade association that sponsors the TESS (Toxic Exposure Surveillance System) reporting system. Member poison centers provide rapid, emergency information and triage to callers who suspect or know that someone may have come in contact with a substance in a manner that the caller believes may adversely affect that individual's health. There is no preregistration, payment or any other requirement of the callers who use the service and calls may be made anonymously. Calls or reports to the center are voluntary and there are no local or national requirements that any given incident must be reported. Data collection is important but secondary to the service function of patient triage. In the triage capacity, center personnel are required to make an immediate assessment of the need for medical treatment and determine whether it can safely be administered at the site of the exposure or if referral to a health care facility is warranted.

There does not have to be an actual case of poisoning for an individual to contact a poison center. An individual need only perceive that a poisoning related threat may exist. The poison center specialist assesses the incident and determines the most appropriate method to mitigate injury if injury is likely. This may include advising the caller on appropriate treatment options or referring a patient to a local healthcare facility for further medical evaluation. It is usually the practice of poison specialists to consider a worst case scenario regarding the incident in question. This may result in the misrepresentation of the incident as a "poisoning" even if no exposure has occurred or may lead one to assume that effects reported with the exposure are causally related to the alleged exposure.

There are a number of apparent misconceptions as to what various subsets of the data represent. Some researchers have attempted to use the number of patients seen in or referred to a health care facility (HCF) to assign a given level of risk to cases reported in the database. Care must be taken in doing so for a number of reasons. First, there are a variety of reasons why exposed individuals present to a HCF on their own, or are referred into a HCF by a poison center. Many of these reasons are not based on medical need to be seen by a physician. Poor or incomplete information resulting in a Specialist in Poison Information's (SPI) inability to completely assess an exposure incident may result in HCF referral as a precaution. The TESS system was not designed to capture how a SPI may perceive the likelihood, or risk of injury occurring before any toxicity is noted. Regarding asymptomatic patients already in a HCF when the poison center was contacted, there is no way of determining if the patient was ever at risk of injury regardless of any treatment rendered. This is also true for patients that later present to a HCF after first contacting a poison center. For these

reasons there are significant limitations in using this parameter to determine the degree of hazard associated with any substance.

Another parameter often misinterpreted is the category of cases "admitted for medical care." Again there is no estimate, implied or otherwise, regarding a given patient's risk of injury after an exposure, based on admission to the hospital alone. There is also no data that suggests a patient requires any specific treatment just because they are admitted to a hospital. Routine, precautionary monitoring in the absence of any symptoms is common, especially if the physician is unfamiliar or uncomfortable with the "poison" or the exposure circumstances in question. There may be methods of interpreting multiple data fields in an attempt to study a patient's risk of injury after a given exposure but use of the "admitted for medical care" field alone cannot provide this.

In TESS data reported by the Agency the category of "medical outcome" was used to suggest a given degree of severity. An issue in using "medical outcome" as an estimate of a products' degree of hazard regards the accuracy of this recorded parameter. Since the relationship of any signs and symptoms to the substance in question is a subjective evaluation by the Poison Information Specialist it is important to understand how accurately that parameter is recorded in the database. Reports of accuracy audits carried out on the database in the past have suggested that the outcome parameter has been incorrect as much as 38.1% of the time in select audits.

The significance of all the information I have presented here is that TESS data must be interpreted with caution. Despite its limitations the TESS database is a valuable surveillance tool when used in conjunction with other systems of public health surveillance. The database is exceptionally useful in helping to establish a safety record for products or categories of substances where large numbers of exposures are reported with minor or no adverse consequences. Since toxicity and outcome are more likely to be over estimated in this database, lack of adverse consequence may help confirm or establish a positive safety record.

The use of the database to establish the toxicity of a given substance or category of substances is more difficult especially if the numbers of cases relative to the total category are small. It is especially imperative that when using cases with reported outcomes of significance that the "*original*" case record be reviewed to assure accurate coding of outcome and appropriate and precise identification of the substance where possible.

A summary of limitations in the TESS data referred to in the Agency's information include:

- * There is no ability to separate regulated from unregulated products
- * The data does not include the type of "clinical effects" reported in each case which resulted in the assigned outcome
- * Since the type of clinical effects is unknown it is unknown what percentage of

cases resulted in targeted effect of "aspiration"

- * There is no ability to identify behaviors or other mitigating circumstances typically associated with many of the exposures such as misuse of the product, condition of the container closure (regardless of whether the product was subject to child resistant packaging or not), storage specifics, quantity involved (hands to mouth taste quantities vs consuming from a free flowing container), transfer of contents to a beverage container, etc.

- * Accuracy issues related to the "outcome" category as a whole generally suggest that review of specific case records is warranted

- * Although a relatively small number of cases with major symptoms were documented they were not defined in any meaningful way and the actual case records were not reviewed

Despite the listed limitations in TESS data it can be used to generate hypothesis on exposure related cases from specific products or categories of products. The Agency has identified "pine oil" containing products as one such category. It is reasonable that the agency should review cases of consequence involving these products and gather additional data to identify specifically which products are involved and contain what concentration of pine oil. It is my recommendation that these exposures be evaluated separately from other petroleum distillate containing products and collect better information to identify if a problem exists. Based on these findings I would encourage the Agency to work with the CSMA and poison centers to collect better information on specific cases of consequence. This will help assure that appropriate products in need of further special packaging regulation can be identified.

4. Special Investigation of Two Deaths Related to Petroleum Distillate Containing Products: The agency included in its assessment of this issue two cases of death related to petroleum distillate containing products.

In the first case a 1 year old child apparently ingested a product listed as "Auto magic" or "Magic Dressing". Unfortunately the exact product or its composition was never identified and the only clue to identity of its contents was the warning labeling which read in part "Hydrocarbons, Petroleum Distillate, Do not induce vomiting". It is believed that the product had no "safety cap" but as with the balance of information collected on the case, specific details are not clear. One thing that was reported was that the mother "induced vomiting" after the exposure. Attempts to gain additional information were unsuccessful.

In the second case an automotive tire cleaner was transferred to what appeared to be a drinking cup by family members and left within reach of two children, one 20 and the other 19 months of age. Although unwitnessed, an aunt heard the children cry out from the next room suggesting they had apparently drunk from the cup. Both children were transferred to a local hospital. The older of the two was released from the hospital without any permanent injury. The younger of the two was ultimately transferred to two subsequent hospitals where she died approximately a month after the exposure from complications secondary to aspiration. As in the first case the

exact product was not precisely identified.

Based on the clinical effects that were known in both of these cases it would be reasonable to conclude that aspiration of a low viscosity hydrocarbon likely occurred and could have involved an unregulated product currently not covered by the PPPA. Low viscosity (less than 100 SUS), petroleum distillate containing products in concentrations greater than 10% are known to exist in this general product category. These cases would tend to support the expansion of the current criteria for the PPPA to include products found in this category. However, it is interesting to note that human behaviors independent of the packaging contributed to the occurrence or severity of the exposures in both cases. In the first case vomiting, a contraindicated procedure, was induced. It is unclear what the status of container closure was prior to the child's exposure. In the second case the product was transferred to an inappropriate container. In this case special packaging could not have prevented the exposure. What is known of the details of these two cases suggest that better education efforts regarding appropriate safety practices as well appropriate basic first aid is necessary and should be embraced by all.

Company Specific Data

In addition to reviewing the data provided by the Agency I have been supplied with proprietary data from a number of large manufacturers with products that would be affected by the new rulemaking. Aerosol products containing concentrations of petroleum distillate in excess of the recommended 10% by weight were included in the review. Data from company directed product stewardship programs which monitor product exposures in the marketplace were reviewed for these products. Of specific interest is the fact that the data covered more than 400 million units of product in the marketplace. No incident of exposure resulting in an outcome of moderate or greater was identified. This data supports the premise that aerosol products do not pose the aspiration risk of similar concentrations of ingredients in the liquid form.

Final Comment

Exposures resulting in death have occurred even in regulated products in the time period 1990-1994. There were 20 deaths from petroleum distillate containing products during this time and a number of these deaths involved regulated products (see attached table). This suggests that even special packaging will not impact misuse or other dangerous and unsafe behaviors practiced by some consumers. This underscores the need for the agency and others to direct some of their limited resources toward education of the public in the area of "responsible use" regarding household and other consumer products.

**Summary of Fatalities/Children under the age of 6
AAPCC/TESS "Hydrocarbons" Category**

Year	Substance	Child's Age	Route of Exposure
1990	Charcoal lighter fluid	2 years	Ing/Inh/Ocular
1990	Kerosene	13 mos.	Ing/Inh
1990	Lamp oil (mineral oil 58%/vegetable oil 40%/ perfume oil 2%)	12 mos.	Ing/Inh
1990	Lamp oil (kerosene)	2 years	Ing/Inh
1991	Charcoal lighter fluid	17 mos.	Ing/Inh
1991	Fabric protector (mineral spirits)	3 years	Ing/Inh
1991	Gasoline	15 mos.	Ing/Inh
1991	Gasoline	2 years	Ing/Inh
1991	Kerosene	11 mos.	Ing/Inh
1991	Kerosene	11 mos.	Ing/Inh
1991	Kerosene	2 years	Ing/Inh
1991	Lamp oil (liquid paraffin)	11 mos.	Ing/Inh
1992	Kerosene	13 mos.	Ing/Inh
1993	Gasoline	15 mos.	Aspir/Ing
1993	Gasoline	18 mos.	Aspir/Ing
1993	Unknown hydrocarbon	15 mos.	Aspir/Ing
1994	Chlorofluorocarbon	3 years	Inhalation
1994	Chlorofluorocarbon	4 years	Inhalation
1994	Kerosene lamp oil	14 mos.	Asp/Ing
1994	Kerosene	3 years	Asp/Ing

AEROSOLS

- We understand that aerosols that spray in a mist will be exempt from the proposed rule; however, aerosols that spray in a stream will be included in the rule. CSMA believes that all aerosols should be exempt from the rule, regardless of spray pattern (mist, stream or foam). The great weight of the 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, which contained petroleum distillates. 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.
- Currently there are no child-resistant/senior friendly overcaps for aerosols. Therefore, if any aerosols are included in the scope of the rule, than it would have to be clarified that they are exempt from the senior-friendly requirements.

TRIGGER SPRAYERS

- Trigger sprayers should have a specified exemption as follows:
 - ii) Those products packaged in containers with mechanical pumps and triggers proved that the pump/trigger mechanism is permanently affixed to the container.
- Clarification is needed on how CPSC would determine if a trigger is "permanently affixed."

GENERIC EXEMPTIONS

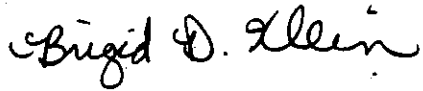
- Under 16 CFR 1500.83 there are a series of exemptions for products which are "not free flowing." At the November 18th you indicated that the staff want to be sure that this exemption covers all appropriate product types. We submit that the following list of automotive type products which should be exempt:
 - Impregnated sponges or application pads with the product enclosed.
 - Liquid dispensers that include an attached applicator or pad
 - Wipes or towels in either flexible pouches or in pull out canisters

SINGLE USE PRODUCTS

- We support an exemption for single use products that use the following packaging systems:
 - Fiber cans with pull-tab tops
 - Thermal or radio wave foil seal on the package

Thank you for consideration of our comments, we look forward to continuing to work with you on the development of this rule.

Sincerely,

A handwritten signature in cursive script that reads "Brigid D. Klein".

Brigid D. Klein
Regulatory Counsel



1 6.797-2-21

6/9/97

Parts Engineering and Identification
Ford Customer Service Division
Ford Motor Company

Fairlane Business Park #4
17225 Federal Drive Suite 140
Allen Park, MI 48101

July 9, 1997

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

Dear Sir or Madam:

Attached please find five (5) copies of Ford's comments on the Advanced Notice of Proposed Rulemaking for Petroleum Distillates. Thank you for the opportunity to comment. Please contact me at the above address if you have any questions regarding these comments.

Sincerely,

A handwritten signature in cursive script that reads "D. Groh for".

Dennis G. Groh
Section Supervisor

Attachment

**COMMENTS OF FORD CUSTOMER SERVICE DIVISION ON
THE CONSUMER PRODUCT SAFETY COMMISSION'S**

ANPR FOR PETROLEUM DISTILLATES

February 26, 1997

D. G. Groh
Section Supervisor
Chemicals and Lubricants
Ford Customer Service Division
Ford Motor Company

July 9, 1997

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

From: D. G. Groh
Ford Customer Service Division

Subject: Comments on the Advanced Notice of Proposed Rulemaking (ANPR) for Petroleum
Distillates 16 CFR Part 1700 (February 26, 1997)

Date: July 9, 1997

Thank you for the opportunity to submit comments in response to the Consumer Product Safety Commission's ("the Commission's") February 26, 1997 Federal Register Notice. Ford Customer Service Division ("Ford") appreciates the opportunity to assist the Commission in establishing effective regulations to protect children from the potential dangers of chemical products. Ford is an active distributor of consumer chemicals for use, primarily by trained technicians, in maintaining and repairing automobiles. Ford submits the following comments and concerns regarding the Commission's proposed rules:

Ford fully supports efforts to protect children from accidental exposure to potentially hazardous substances involving Ford branded products. However, Ford believes that child-resistant packaging of products containing petroleum distillates or other hydrocarbons within a certain viscosity is not likely to bring about substantial benefit.

Ford has examined Poison Control Center data on the reported cases alleged to be attributable to Ford products containing greater than 10% petroleum distillates or hydrocarbons and viscosities of concern over the last four years. There have only been three reported cases involving such products during this time frame. In all cases, the effects were transient and minor, such as irritation and some swelling of affected tissues. None of these cases required hospitalization. The data suggests that child-resistant packaging of affected Ford products may not be warranted in light of the infrequency of exposures, minimal effects, and satisfactory outcomes with existing packaging.

Further, given that the quantity and nature of incidents involving children does not appear to be significant, Ford believes that requiring child-resistant packaging of aerosols and some other product delivery systems would interfere with the intended use of these products without significant benefit. Our packaging and product delivery systems are designed for ease of use by our customers, who are frequently technicians in maintenance and repair facilities, taking into consideration normal and foreseeable circumstances of use and the likelihood of exposure to children.

Ford believes that the proper use of repair and maintenance products in servicing vehicles, along with warnings to keep products out of the reach of children, currently provided pursuant to the labeling requirements of the Federal Hazardous Substances Act ("FHSA"), are an effective means of protecting the safety of young children.

As the Commission works to provide the safest environment for consumers, Ford remains ready to share its experiences and otherwise assist in the process.

6660K 8/7/92

CR97-2-22

CHASE PRODUCTS COMPANY

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July 10, 1997

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

Subject: ANPR for Petroleum Distillates

Gentlemen:

I have read CPSC's notice published in the Federal Register pertaining to the proposed rule of requiring Child Resistant Packaging for household products containing petroleum distillates and possibly other hydrocarbons such as benzene, toluene, xylene, pine oil, turpentine, and limonene. I would like to share with you my opinion and concerns about this issue particularly to its applicability to aerosol products. I do agree that child-resistant packaging may be required on some household products whose contents are readily accessible to children who are five years old and younger. However, I do not believe that this rule should be made applicable to all types of household products regardless of the container type in which these products are packaged. Container type should be one of the criteria that CPSC should take into consideration during the rulemaking process for the above issue.

Child Resistant Packaging in my opinion may be extended to those household products containing petroleum distillates and other hydrocarbons such as benzene, xylene, pine oil, turpentine, limonene (depending on the percentage (%) amount of the hazardous ingredients in the product, and viscosity of the final product), only if the products are in non self-pressurized liquid packages. Products packaged in aerosol containers should be excepted. The degree or nature of the hazard to children in this type of packaging is negligible. As you know self-pressurized container, such as an aerosol package, is tightly sealed. The product is dispensed, only when the actuator or spray head is depressed. As soon as the pressure on the spray head is released, dispensing of contents out of the aerosol container stops. Spray rate is also very slow and so therefore only a few millimeters of the product is



68 YEARS OF SPECIALTY PACKAGING SERVICE



expelled at a time. It will take a great deal of efforts for a child who is five years old or younger, to hold down the sprayhead for a continuous sprayout over a long period of time. For these reasons, overexposure through inhalation or ingestion is unlikely to happen from the use, or accidental misuse of the product. There are no sufficient evidences known to date, pertaining to serious injuries incurred by children 5 years and younger, from overexposure to aerosols, that can support the need to require aerosols containing petroleum distillates and/or other hydrocarbons to be packaged in a Child Resistant Packaging.

Current HAZARD WARNING statements required under the Federal Hazardous Substances Labeling Act and Federal Caustic Poison Act applicable to aerosol products should suffice to safeguard public health and safety including potential to cause serious injury to children.

Contents of aerosol products are under pressure, hence corresponding product labeling indicates specific directions to store the product in a dry, cool area away from heat, sparks, open flame, direct sunlight, or where temperature will exceed 120°F. It also highlights the statement: KEEP OUT OF REACH OF CHILDREN

I strongly believe that extending the Child Resistant Packaging requirement to aerosol products will just cause unnecessary economic burden to manufacturers, which of course will eventually be passed on to consumers of these products. Increased in cost in changing over to a special packaging is not warranted based on the facts cited above.

Please consider the facts about aerosols as mentioned above during your evaluation of the issues surrounding the requirement for special packaging for products containing petroleum distillates and/or other hydrocarbons.

Very Truly yours,



Aludia B. Hernandez
Technical & Regulatory
Compliance Manager