



5/1/01  
12/21/00

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

**MEMORANDUM**

**DATE** : December 18, 2000  
**TO** : HS  
**Through:** Sadye E. Dunn, <sup>SD</sup> Secretary  
**FROM** : Martha Kosh  
**SUBJECT:** Child-Resistant Packaging of Low Viscosity  
Hydrocarbon-containing Aerosol/Trigger, Pump  
Products

ATTACHED ARE COMMENTS ON THE CP 01-2

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CP 01-2-1	12/11/00	Michael Webb Ph.D., Chemist	Amrep Incorporated Marietta, GA
CP 01-2-2	12/14/00	Brigid Klein Sr. Counsel	Consumer Specialty Products Association 1913 Eye Street, NW Washington, DC 20006
CP 01-2-3	12/15/00	Heidi McAuliffe Counsel, Govern- ment Affairs	National Paint & Coatings Association, Inc. 1500 Rhode Island Ave, NW Washington, DC 20005
CP 01-2-4	12/15/00	Ann McCulloch	Automotive Chemical Manufacturers Council 1225 New York Ave., NW Suite 300 Washington, DC 20005
CP 01-2-5	12/12/00	Edward Piszynski Vice President, Lab. Services	Hydrosol Incorporated 8407 South 77 <sup>th</sup> Ave. Bridgeview, IL 60455



Hydrocarbon  
comment

CP01-2-1

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Jacksonville, Florida 32203  
(904) 388-5732 • Fax (904) 389-5752

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Jacksonville, Florida 32254  
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December 11, 2000

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

RE: NPR for Hydrocarbons

Dear Secretary Dunn:

Our company, Amrep Incorporated, is headquartered in Marietta, Georgia. We are a manufacturer of aerosols, packaged liquids and lubricants to the Consumer Specialties and Automotive marketplace. Many of our products incorporate hydrocarbons, so the above referenced proposed rulemaking will affect our business operations.

REC'D  
DEC 14 1999  
FEDERAL BUREAU OF INVESTIGATION  
U.S. DEPARTMENT OF JUSTICE

We have been aware for over twenty years that direct aspiration into the lung, or aspiration during vomiting, of small amounts of petroleum distillates and other similar hydrocarbon solvents can result in chemical pneumonia, pulmonary damage, and death. Accordingly, most of our consumer marketed low viscosity liquids that contain hydrocarbons are packaged with child resistant closures, and many include heat seals as an extra measure of protection.

We appreciate the efforts of the Commission to create a more consistent and comprehensive regulatory approach to child-resistant packaging for hydrocarbon-containing products. However, we disagree with the inclusion of aerosol products into the proposed rulemaking. The original reason for the exclusion of aerosol packages from the rulemaking mandating child resistant closures (CRCs) is still valid; it is highly unlikely that a sufficient quantity of liquid could be ingested from an aerosol spray to result in aspiration. We are unaware of any instances in our company's history of this happening as a result of a product dispensed from one of our aerosol containers. This historical experience, along with consideration of the physical properties of the hydrocarbon-containing mixture when dispensed as an aerosol, leaves us unconvinced that "a large volume delivered directly into the mouth could result in aspiration," as the Notice of Proposed Rulemaking (NPR) claims.

We applaud the Commission in writing the proposed rulemaking to specifically address hydrocarbons, a recognized and definitive class of chemical compounds rather than the ambiguous "petroleum distillates" used previously. Much consideration is given in the NPR to appropriate viscosity specifications of the hydrocarbons but there is no

consideration given to boiling point or vapor pressure. The Commission fails to take into account many aerosols use propane/butane mixtures as the propellants. These hydrocarbons exist in a gaseous state when expelled from the can to atmospheric pressure and therefore pose absolutely no threat for aspiration into the lungs as liquids. It would not seem prudent or even fair to count gaseous hydrocarbons toward the 10% requiring CRCs. As an example, we manufacture a white grease aerosol that contains 39% of propane/butane propellant and 0% other low-viscosity hydrocarbons, yet it would fall under the proposed rule despite posing no threat of aspiration.

Before issuing a regulation under the Poison Prevention Packaging Act (PPPA), the Commission must find that child-resistant packaging is technically feasible, practicable, and appropriate for the regulated products (15 U.S.C. 1472(a)(2)). Our company manufactured nearly 60 million total aerosol cans in 2000, all of which comply with current CPSC regulations for packaging and labeling. Of these we shipped 11,785,116 aerosol products to just one of our consumer retailers last year that would fall under the proposed rule. The NPR estimated a cost impact of \$0.005-0.02/unit; we have contacted our closure suppliers who conservatively estimate an additional \$0.045/unit for this customer, significantly above the highest NPR estimate. This increased cost will result in a total cost impact of \$530,330.22 that must be passed along to the consumer. The ability of any supplier to pass on such large increase to any retailer is limited and therefore this would become a financial hardship at least partially borne by Amrep.

Another consideration not taken duly into account is the NPR estimate of "no significant effects on the environment." We use a compact stacker cap for the majority of our aerosol products, and there are no CRC aerosol caps that do not incorporate a more bulky "double shell" design. Changing the stacker cap to a CRC would increase the non-biodegradable solid waste stream from 8909 ft<sup>3</sup> to 53,622 ft<sup>3</sup>, or six times for the customer account referred to above. This contradicts the NPR assessment that the "disposal of child-resistant closures will present the same environmental effects as do non-child-resistant closures."

We appreciate the CPSC's continued enforcement of the PPPA, especially with respect to the recognized danger associated with liquid packaged low viscosity hydrocarbons. In summary however:

- 1) We disagree with the proposed inclusion of aerosol products under the rules.
- 2) We would petition the Commission to take into account the significant economic and environmental cost incurred in exchange for a questionable increase in consumer protection.

3) Should the Commission implement the proposed rule for aerosols, we request that the Commission exempt propellant hydrocarbons from the regulation.

If you have any questions regarding this letter please contact me at (904) 981-4172.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael E. Webb". The signature is fluid and cursive, with a long horizontal stroke at the end.

Michael E. Webb, Ph.D.  
Chemist

P S. Our company has recently changed its name from Petro Chemical to Amrep. I apologize that the letterhead stationary contains the old logo.

*Hydrocarbon  
comment*

CP01-2-2



Hand Delivered

December 14, 2000

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

2000 DEC 15 P 2 19  
SECRETARY

RE: Child-resistant packaging of low viscosity hydrocarbons-containing aerosol/trigger, pump products

Dear Sir/Madam:

These comments are submitted on behalf of the Consumer Specialty Products Association (CSPA) formerly known as the Chemical Specialties Manufacturers Association (CSMA) regarding the treatment of aerosol/trigger/pump sprays under the proposed hydrocarbon rule. CSPA is a voluntary, nonprofit trade association composed of several hundred companies engaged in the manufacture, formulation, distribution, and sale of non-agricultural pesticides, antimicrobials, detergents and cleaning compounds, industrial and automotive specialty chemicals and polishes and floor maintenance products for household, institutional and industrial uses. Many of our member companies market consumer products containing hydrocarbons and, therefore, CSPA is keenly interested in the proposed rule.

In comments filed on the ANPR, CSPA argued that all aerosol products should be exempt from the proposed rulemaking, see Attachment 1. The great weight of all available data indicates that pressurized aerosols with low viscosity hydrocarbons are not a problem. In fact, one CSPA member company reports that between 1991 and 1996 it sold 302 million pressurized aerosols, which contained hydrocarbons. Poison control center data for these products also indicates that there were no reported cases of aspiration following exposures to this member's products during this timeframe.

In the proposed rule, CPSC exempted aerosols that spray in a mist, but included those that spray in a stream. In comments filed on the proposed rule, CSPA asked that all aerosols be exempt from the rule, see Attachment 2. The data from our member companies as well as data reviewed by our members indicates that there is no problem with aerosol products containing low viscosity hydrocarbons.

Assuming that CPSC might have data justifying an aerosol stream definition, we had asked that CPSC define the term stream and provided a definition for consideration. Despite the lack of information supporting the need for any aerosol child-resistant closures, CPSC has moved forward with a test method of aerosol products that dispense contents in a stream.

On November 14, 2000, CPSC held a meeting with interested parties to discuss the aerosol issue, principally the definition of stream offered by CSPA. Commission staff presented their test method to determine if aerosol/trigger/pump products that dispense hydrocarbon of low viscosity would require child-resistant packaging. As stated in the meeting, we believe that it *does not accurately measure the amount of hydrocarbons released because this measurement would include the mass of propellant released in addition to any hydrocarbons.* It is improper to test the amount of product expelled for an aerosol product based upon container weight loss. The propellant would not be ingested since it would readily volatilize. Giving consideration to the significance of this issue, CSPA recommended that the hydrocarbons in aerosol products be determined by collecting the expelled product (not including propellant) and weighing it. Based on subsequent review of this issue it is evident that any test method would need to be "arbitrary" in nature since there is no evidence to suggest that existing low viscosity hydrocarbon containing aerosols have produced any aspiration injuries. In fact, as noted below, extensive market experience with aerosols demonstrate the safety of these products in this regard.

At the November 14<sup>th</sup> meeting, CPSC staff indicated that they reviewed additional aerosol data since the ANPR was drafted to learn what children do with aerosol products. CSPA received this data through a Freedom of Information Act request and reviewed the reports with our poison control and medical experts. We received 14 case reports with detailed information. We were also provided a one-inch stack of cases with only face sheets, thus this data was insufficient to draw any conclusion as to the nature or circumstances of the exposure. *Of the 14 cases with more detailed information, 7 involve spray bottles, 6 involve aerosols and 1 involves a flip top bottle. All 7 of the spray bottle products were left within reach of children, either left out after use or stored with easy access.*

Of the 6 aerosol cases, 3 involved oven cleaners already subject to child-resistant overcap requirements. In 4 of these cases the product was accessed by a child because it was not properly stored (i.e. one child obtained a can of a commercial, *Industrial* strength, oven cleaner which sat out on a deck for several days). *Four cases involved infants being sprayed by siblings. In one of those cases involving an aerosol product, an older sibling (7 years old) sprayed a younger sibling, which a child-resistant closure would not prevent.*

In all incidents, including those involving corrosive oven cleaner, *ingestion* of quantities sufficient to produce significant injury did not occur. In those cases

where any effects were noted the pattern of reported effects suggested "incidental" mucosal/skin contact or at the most, wetting of the oral cavity. There was no evidence of children ingesting quantities capable of resulting in aspiration. The typical disposition coding was TREATED & RELEASED, OR EXAMINED & RELEASED WITHOUT TREATMENT. In 5 cases (3 involving corrosive oven cleaners) where "hospitalization" was reported, the typical course was observation and/or completion of precautionary procedures to insure that significant injury did not occur. Of the 2 non-oven cleaner cases, both were spray bottles. In one of these cases the mother refused the interview saying no ingestion occurred. In the other case, a poison center recommended a child be given milk after a suspected exposure to an automotive product in a pump sprayer. The child vomited soon after. Later, it was revealed that the child was allergic to milk. Accident Investigation determined that the child was apparently hospitalized for observation and released with no reports of subsequent injury

Based upon a review of both the CSPA member generated/reviewed data and the data made available by the CPSC to the CSPA, there is no data to support the inclusion of low viscosity hydrocarbon products delivered in aerosol form in the scope of the proposed rule. It also does not make sense from a technical perspective. 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 stun the child and cause the child to drop the can without an ingestion occurring. This is confirmed from the Agency's own NEISS data through examination of the nature or reported effects subsequent to children gaining access to corrosive aerosol oven-cleaners. There were no reports of significant injury/effects.

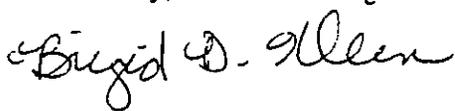
In developing standards for special packaging, the Commission is required to consider the following factors:

- 1 The reasonableness of such standards;
- 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

To summarize, the body of available data does not support a requirement for child-resistant closures for aerosol products containing low viscosity hydrocarbons. Such a requirement would not satisfy the factors set forth in the Poison Prevention Packaging Act listed above since there is no data to support it

CSPA appreciates the opportunity to comment on the treatment of aerosol products under the proposed hydrocarbon rule. Aerosols should be exempt from a child-resistant closure requirement since they do not present an aspiration hazard.

Sincerely,

A handwritten signature in black ink that reads "Brigid D. Klein". The signature is written in a cursive style with a small flourish at the end.

Brigid D. Klein  
Senior Counsel

Attachments (2)

cc Chairman Ann Brown  
Commissioner Mary Sheila Gall  
Commissioner Thomas Moore  
Dr. Suzanne Barone

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

Submitted July 11, 1997





Founded 1914

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Washington, DC 20006

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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 injury<sup>1</sup> 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.

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<sup>1</sup>The 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

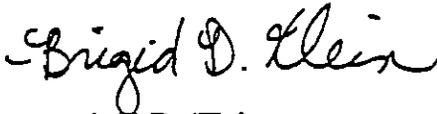
Several CSMA member companies had Dr. Richard Kingston a senior clinical toxicologist with the International Poison Center review proprietary data of products that would be affected by the new rulemaking. Aerosol products containing concentrations of petroleum distillate in excess of 10% by weight were 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 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

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

## Toxicological Studies on Hydrocarbons

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

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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; Daescanner 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  $LD_{50}$ /intra-tracheal  $LD_{50}$  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 Noüy 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 wire-mesh 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

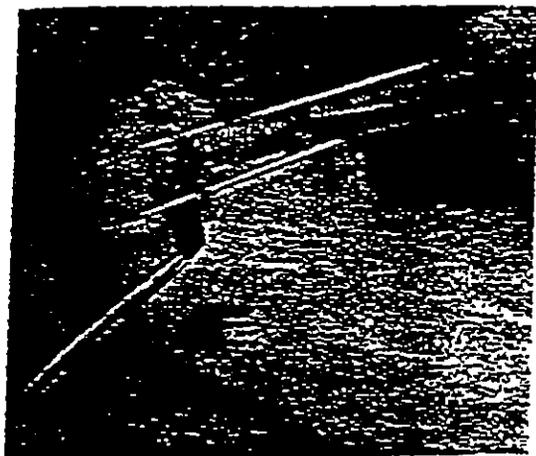


Fig. 1.—Procedure for inducing pulmonary aspiration in rats.

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 polystyrene 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 (10  $\mu$ l) 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 20 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 torsion beam or torsion spring balance.

27 *Continued*

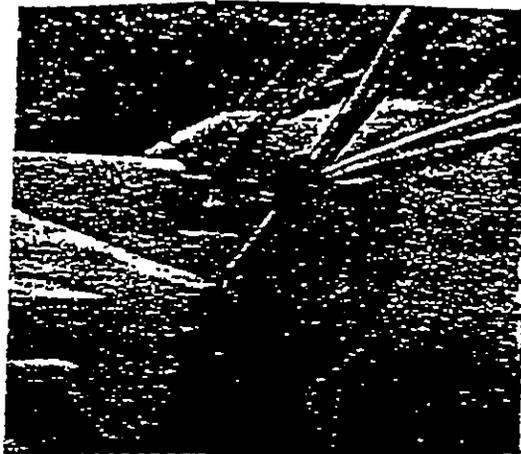


Fig. 2.—Procedure for inducing pulmonary aspiration of aerosols in rats.

## Results and Comment

*A. Individual Hydrocarbons.*—Table I summarizes the results obtained with an homologous series of liquid normal paraffin hydrocarbons. Note that *n*-heptadecane (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.

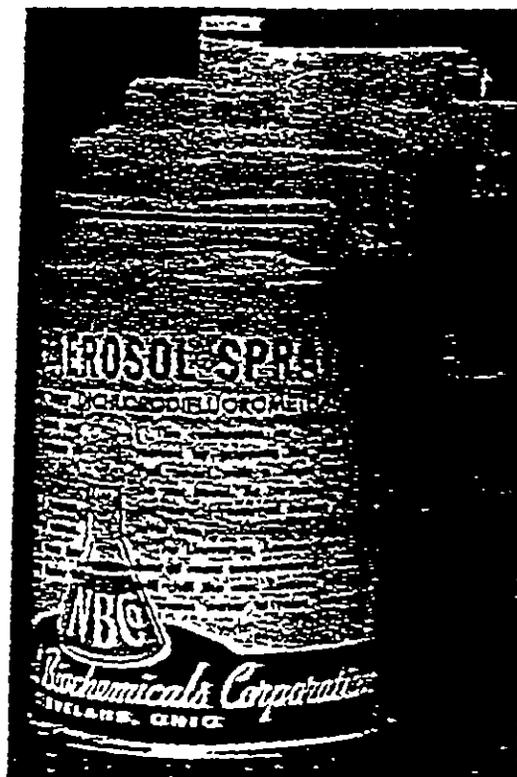


TABLE 1—Mortality and Lung Weights of Male Albino Rats 24 Hours After Aspiration of 0.2 ml. of *n*-Paraffin Hydrocarbons (*n*-Alkanes)

Hydrocarbon	Viscosity SSU (100 F)	Mortality (24 Hr.)	Lung Wt. (Gm.) * 24 Hr. After Dosing		
			Individual Values	Range	Ave.
<i>n</i> -Hexane	<11	5/5	<u>3.0</u> , <u>3.2</u> , <u>3.1</u> , <u>3.2</u> , <u>3.3</u>	3.0-3.3	3.2
<i>n</i> -Octane		5/5	<u>3.1</u> , <u>3.2</u> , <u>3.1</u> , <u>3.0</u> , <u>3.1</u>	2.9-3.2	3.1
<i>n</i> -Decane		5/5	<u>7.0</u> , <u>4.0</u> , <u>4.6</u> , <u>5.2</u> , <u>3.5</u>	3.5-7.0	4.9
<i>n</i> -Dodecane		5/5	<u>5.5</u> , <u>5.4</u> , <u>4.9</u> , <u>6.1</u> , <u>3.4</u>	3.4-6.1	5.1
<i>n</i> -Tetradecane		33	5/5	<u>3.6</u> , <u>5.7</u> , <u>4.4</u> , <u>4.5</u> , <u>3.9</u>	4.5-5.7
<i>n</i> -Hexadecane	36	1/3	<u>2.2</u> , <u>3.5</u> , <u>4.3</u> , <u>3.1</u> , <u>2.5</u>	2.2-4.5	3.4

\* Underlined weights—Animals died in less than 24 hr.  
Lung weights of 29 undosed controls: Range 1.1-1.5 gm.  
Ave. 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 C<sub>10</sub> to C<sub>14</sub> 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 (Gerard, 1959).

The results obtained with an homologous series of liquid *n*-alkanes (*n*-olefins) are summarized in Table 2. *n*-Pentane 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 SSU (100 F)	Mortality (24 Hr)	Lung Wts. (Gm.) * 24 Hrs. After Dosing		
			Individual Values	Range	Ave.
1-Hexene	<20	3/3	<u>2.0</u> <u>2.0</u> <u>2.4</u> <u>1.6</u> <u>2.4</u>	1.6-2.4	2.3
1-Octene		5/5	<u>2.4</u> <u>2.6</u> <u>3.2</u> <u>3.0</u> <u>4.0</u>	2.5-4.0	3.1
1-Decene		3/3	<u>4.7</u> <u>4.9</u> <u>4.7</u> <u>3.9</u> <u>3.4</u>	3.4-4.9	4.3
1-Dodecene		4/4	<u>5.1</u> <u>3.5</u> <u>4.1</u> <u>4.9</u>	4.1-5.1	4.9
1-Tetradecene	22	5/5	<u>3.7</u> <u>4.5</u> <u>4.7</u> <u>4.5</u> <u>4.8</u>	3.7-4.8	4.3
1-Hexadecene	33	0/3	<u>3.7</u> <u>2.4</u> <u>4.0</u> <u>3.4</u> <u>2.4</u>	2.5-4.0	2.9
1-Octadecene	38	1/3	<u>3.3</u> <u>2.1</u> <u>3.5</u> <u>3.0</u> <u>2.0</u>	2.1-3.5	2.4
2-Nonadecene	40	0/3	<u>2.8</u> <u>2.2</u> <u>2.7</u> <u>2.4</u> <u>2.7</u>	2.2-2.9	2.7

\* Underscored weights—Animals died in less than 24 hr.  
Lung weights of 22 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 C<sub>14</sub> and C<sub>16</sub> (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 X 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, 2.6, 2.2, 2.4, 1.3	1.3-2.6	2.2
1-Octyne	3/3	1.6, 2.5, 2.4, 2.5, 2.7	2.4-2.7	2.4
1-Decyne	3/3	1.4, 2.4, 2.0, 2.3, 1.6	2.0-2.4	2.0
1,6-Heptadiyne	4/5	1.3, 1.4, 2.0, 2.1, 1.4	1.4-2.1	1.5
1,7-Octadiyne	3/3	1.1, 2.4, 1.5, 2.4, 2.3	1.1-2.4	1.5
1,8-Nonadiyne	4/5	2.2, 2.7, 2.0, 1.6, 1.3	1.3-2.7	1.5

\* Underscored weights—Animals died in less than 24 hr.  
Lung weights of 20 underscored controls: Range 1.1-1.3 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	2.5, 1.2, 2.3
Cyclooctane	3/3	2.7, 2.1, 2.4
Methylcyclopentane	3/3	2.2, 2.7, 1.5
Methylcyclohexane	3/3	2.2, 2.2, 2.2
Vinylcyclohexane	3/3	2.2, 2.7, 2.8
<i>n</i> -Butylcyclohexane	1/3	2.4, 4.0, 4.0
Phenylcyclohexane	3/3	1.6, 1.0, 4.6
Cycloolefins		
Cyclopentene	0/3	1.5, 1.2, 1.4
Cyclohexene	1/3	1.1, 2.0, 2.2
Cycloheptene	3/3	2.7, 2.6, 2.3
4-Methylcyclohexene-1	2/3	2.5, 2.2, 2.4
1,3-Cyclooctadiene	2/3	2.1, 2.2, 1.5
1,4-Cyclooctadiene	0/3	2.1, 2.1, 1.3
Cyclooctatetraene	0/3	1.0, 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<sub>6</sub>, C<sub>7</sub>, C<sub>8</sub>) 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.	2.7, 2.4, 2.4
Toluene	Died instantly, cardiac arrest.	3.0, 2.2, 2.2
Ethylbenzene	Died instantly.	2.3, 2.2, 2.9
<i>n</i> -Propylbenzene	Died in a few sec.	2.0, 2.0, 2.7
<i>n</i> -Butylbenzene	Died instantly.	3.7, 2.4, 2.5
<i>n</i> -Hexylbenzene	Died in 1-2 min.	4.1, 2.7
	Died in 18 min.	7.5
1-Phenyldodecane	Killed in 1 hr.	2.0, 2.0, 1.3

\* 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.

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

Name of Mixture	Mortality (24 Hr.)
<b>Fuels &amp; Solvents</b>	
Lighter fluid	2/2 †
Gesoline	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
<b>Lubricants</b>	
Multigrade motor oil (S.A.E. 10W-30W-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 additive	0/3
Multigrade motor oil	0/3
<b>Protective Coatings &amp; Adhesives</b>	
Exterior primer paint (mineral spirits 15.7%)	0/2
Enamel (aliphatic hydrocarbons 22.7%)	0/2
Alkyd enamel (mineral spirits 21.5%)	0/2
Polybutadiene liquid	0/2

\* Arranged in approximate order of increasing viscosity

† Death instantaneous.

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 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, 8.0, 2.7	2.5-8.0	4.2
50	58	30.5	0/10	2.5, 4.4, 3.1, 4.8, 1.3	1.3-1.9	1.7
				1.8, 1.4, 1.8, 1.5, 1.3		
43	81	31.6	0/10	1.7, 1.2, 1.3, 1.2, 1.4	1.3-1.9	1.5
				1.8, 1.4, 1.8, 1.5, 1.3		
35	122	31.8	0/10	1.7, 1.2, 1.3, 1.3, 1.4	1.3-1.7	1.4
				1.8, 1.4, 1.8, 1.5, 1.3		
28	187	32.0	0/10	1.3, 1.1, 1.2, 1.2, 1.5	1.3-1.7	1.4
				1.2, 1.8, 1.2, 1.1, 1.7		
20	285	32.0	0/10	1.7, 1.4, 1.3, 1.4, 1.4	1.3-4.0	1.8
				1.1, 2.4, 4.0, 1.4, 1.3		

\* Underscored weights—Animals died in less than 24 hr.  
Lung weights of 22 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

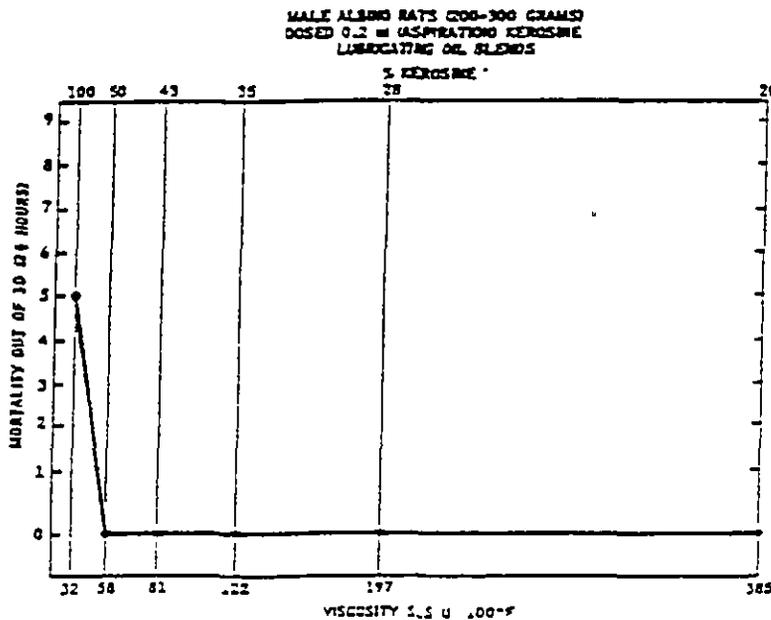


Fig. 6.—The relationship of viscosity to mortality in rats dosed with kerosene-lubricating oil blends.

MALE ALBINO RATS 200-300 GRAMS  
DOSED 0.2 ml ASPIRATION KEROSENE  
LUBRICATING OIL BLENDS

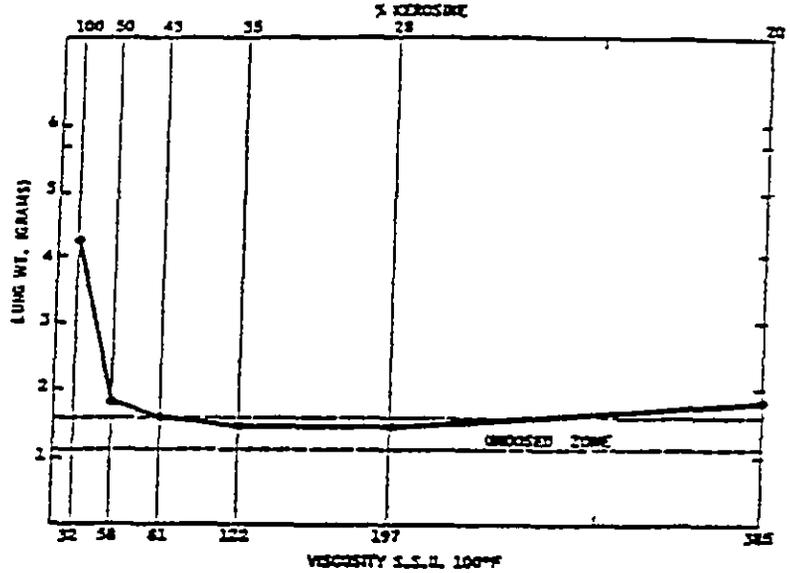


Fig. 7—Lung weights of rats 24 hours after dosing with kerosene-lubricating oil blends of varying viscosity.

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>1.2</u> , <u>1.5</u> , <u>2.0</u> , <u>3.1</u> , <u>4.7</u> <u>4.0</u> , <u>2.5</u> , <u>3.0</u> , <u>4.0</u> , <u>3.5</u>	2.0-4.0	4.7
59	32.5	2/10	<u>2.5</u> , <u>2.7</u> , <u>4.0</u> , <u>1.1</u> , <u>2.1</u> <u>4.4</u> , <u>4.2</u> , <u>1.5</u> , <u>1.0</u> , <u>1.0</u>	1.4-4.4	2.9
71	32.3	1/10	<u>1.6</u> , <u>2.0</u> , <u>3.2</u> , <u>1.5</u> , <u>4.1</u> <u>1.3</u> , <u>2.5</u> , <u>2.1</u> , <u>1.5</u> , <u>1.0</u>	1.3-4.1	2.5
83	32.3	0/10	<u>4.2</u> , <u>2.5</u> , <u>1.0</u> , <u>1.5</u> , <u>2.5</u> <u>2.0</u> , <u>1.5</u> , <u>4.2</u> , <u>2.5</u> , <u>1.0</u>	1.4-4.2	2.5
109	33.2	0/10	<u>2.0</u> , <u>1.5</u> , <u>1.5</u> , <u>1.6</u> , <u>1.7</u> <u>2.0</u> , <u>1.5</u> , <u>1.2</u> , <u>1.5</u> , <u>1.5</u>	1.5-2.0	1.7
156	33.4	0/10	<u>1.5</u> , <u>1.5</u> , <u>1.5</u> , <u>1.7</u> , <u>1.7</u> <u>1.2</u> , <u>1.5</u> , <u>1.5</u> , <u>1.1</u> , <u>1.5</u>	1.1-1.5	1.4

\* Underlined weights—Animals died in less than 24 hr

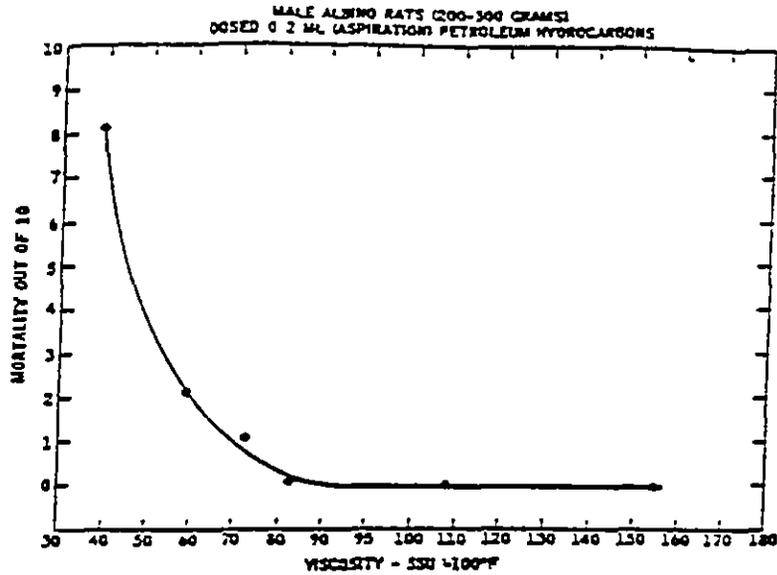


Fig. 8—Mortality in rats dosed with petroleum hydrocarbons varying in viscosity.

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

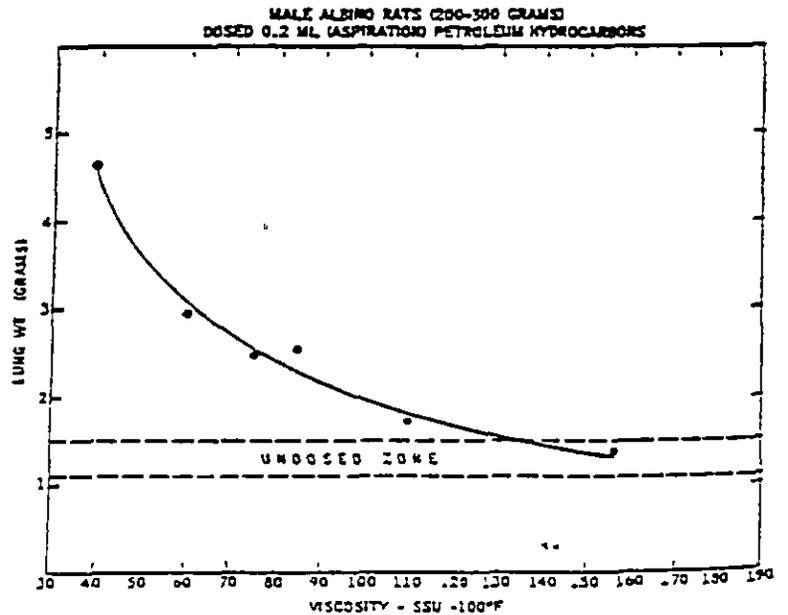


TABLE 9.—Mortality and Lung Weights of 10 Male Albino Rats Dosed with 1.0 ml. of Kerosene Aerosol (Killed 24 Hours After Dosing)

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.	1.12, 1.21, 1.22, 1.06, 1.12 1.22, 1.12, 1.18, 1.42, 1.20	1.23	Lungs normal on inspection

\* Lung weights of 20 undosed controls: Range 1.1-1.3 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

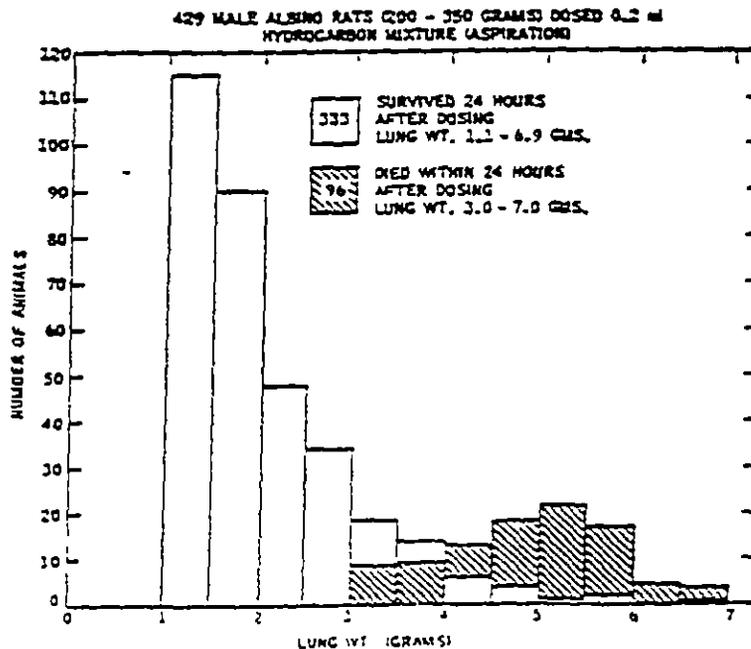


Fig. 10—Histogram of lung weights of rats succumbing and surviving within 24 hours after aspirating 0.2 ml. of hydrocarbon mixtures.

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

Dose (ML)	Mortality (Hr. After Dosing)						16 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	4/10	7/10	8/10	9/10	9/10
0.20	0/10	3/10	7/10	9/10	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  $C_{16}$  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-Phenylidodecane is less toxic than 1-hexylbenzene. It appears that further lengthening of the chain beyond  $C_6$  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.

## REFERENCES

1. American Society for Testing Materials: 1916 Race St., Philadelphia, ASTM Special Technical Publication No. 43-B (September) 1957.
2. Blatter, R. J.: Kerosene Poisoning, *J. Pediat.* 39:391-392, 1951.
3. Carithers, H. A.: Accident Prevention in Childhood: The Kerosene Hazard, *J.A.M.A.* 159:109-111, 1955.
4. Daeschner, C. W., Jr., Blatter, R. J., and Collins, V. P.: Hydrocarbon Pneumonitis, in *The Pediatric Clinics of North America*, Philadelphia, W. B. Saunders Company, 1957, pp. 243-253.
5. Gerarde, H. W.: Toxicological Studies on Hydrocarbons: V. Kerosene, *Toxicol. Appl. Pharmacol.* 1:462-474 (September) 1959.
6. Gerarde, H. W.: The Scientists' Forum—Toxicologists' Views of Regulations Under the Hazardous Substances Labeling Act, edited by B. L. Oser, *Food, Drug Cosmetic Law J.* 524 (August) 1961.
7. Lesser, L. I.; Weems, H.S., and McKay, J. D.: Pulmonary Manifestations Following Ingestion of Kerosene, *J. Pediat.* 23:352-364, 1943.
8. Public Hearing, Food and Drug Administration, Washington, D.C.: Federal Hazardous Substances Labeling Act, July 13-14, 1961.
9. Waring, J. L.: Pneumonia in Kerosene Poisoning, *Amer. J. Med. Sci.* 185:325-330, 1933.



July 3, 1997

Brigid Klem  
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 product's 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

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



1913 Eye St NW  
Washington DC 20006

**CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION**

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Hand Delivered

March 20, 2000

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

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

Dear Sir or Madam

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

**Overview**

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

## Scope of the Proposed Regulation

### Aerosols

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

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

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

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

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

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

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

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

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

### Trigger Sprayers

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

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

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

### **Single Use Products**

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

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

### **Effective Date**

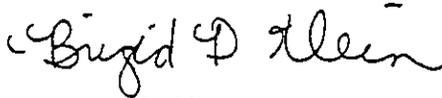
We suggest that the effective date of the rule be at least one year after the proposed rule is issued in final form. We also recommend that the Commission implement a procedure whereby companies that are unable to comply within the time, despite their best efforts, may apply for a temporary enforcement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

### **Conclusion**

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

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

Sincerely,

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

Brigid D. Klein  
Regulatory Counsel

cc. Suzanne Barone

Hydrocarbon  
Comment  
CP01-2-3  
National  
Paint &  
Coatings  
Association

December 15, 2000

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

RECEIVED  
OFFICE OF THE SECRETARY  
FEDERAL BUREAU OF INVESTIGATION  
2000 DEC 18 P 2:43

Re. Child-Resistant Packaging of Low Viscosity Hydrocarbon-containing  
Aerosol/Trigger, Pump Products

Dear Sir or Madam.

This letter is submitted in response to the Commission's request for comments on the most recently proposed test method for determining if child-resistant packaging is required for aerosol/trigger/pump products that contain low viscosity hydrocarbons.

The National Paint & Coatings Association, Inc (NPCA) is a voluntary, non-profit industry association originally organized in 1888 and comprised today of over 400 member companies which manufacture consumer paint products and industrial coatings or the raw materials used in their manufacture. NPCA represents approximately 95% of the paint and coatings manufacturers who make or fill aerosol paint. Many aerosol paint formulas contain petroleum distillates and other hydrocarbons such as toluene and xylene.

NPCA and its Spray Paint Manufacturers Committee have been very active in regulatory affairs since the advent of activities specifically focusing on aerosol spray coatings. Most recently, NPCA, through its Spray Paint Manufacturers Committee, worked diligently with the California Air Resources Board over the course of three or four years to bring to completion the very first relative reactivity rule for aerosol paint products. Towards this end, NPCA and the members of its Spray Paint Manufacturers Committee participated in numerous workshops, surveys, informal solicitations and an endless series of meetings in an effort to produce a reasonable and environmentally sound regulation. NPCA's Spray Paint Manufacturers Committee is committed to working with federal and state environmental agencies to establish reasonable, practical and technologically feasible standards for the spray paint industry.



In earlier comments on this proposed rulemaking, NPCA urged CPSC to exempt aerosol products from any requirement for child-resistant packaging due to the unique characteristics of the aerosol delivery system. These comments bear repeating as CPSC's proposed test method is irrelevant -- it makes no distinction at all between products that spray as a mist and products that spray in a stream.

1) Spray paint should not be included within any proposal to broaden the scope of products subject to the PPPA regulations for the following reasons:

- Accidental ingestion from an aerosol container is highly unlikely because the product comes out as a very fine, atomized spray mist -- not a collectible liquid<sup>1</sup>

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

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

The only way the paint product can escape is if the valve tip is appropriately depressed or the can is somehow punctured.

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

Some of the ingredients of spray paint are hazardous substances under the Federal Hazardous Substances Act, as amended. As such, each container is required to carry warnings with regard to the specific hazard presented in a container of spray paint. See 16 CFR Section 1500.14(a) and (b). These warnings, if heeded, instruct the purchaser/consumer to keep this product away from children at all times. NPCA's Paint Industry Labeling Guide (Fourth Edition), which provides guidance on hazard precautionary labeling requirements and industry trade practice contains sample labels for aerosol paints -- one for

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<sup>1</sup> Because aerosol paint is delivered in an atomized mist and cannot be collected and ingested, there is no requirement for spray paint to carry a warning against ingestion under the Federal Hazardous Substances Act, 15 U.S.C. 1261-74, as amended. See also NPCA's Paint Industry Labeling Guide (Fourth Edition, Sample Labels Nos. 7 and 8

non-flammable aerosols and one for extremely flammable aerosols. Both of these sample labels contain the precautionary statement "KEEP OUT OF REACH OF CHILDREN" in bold, capital letters. In the sample label, the statement stands alone so that it commands attention and does not lose its message in a host of other precautionary statements.

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

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

2) CPSC's proposed test method for determining if child-resistant packaging is required for aerosol/trigger/pump products that contain low viscosity hydrocarbons is seriously flawed because it only concentrates on the discharged amount of the product, rather than the "collectible" weight.<sup>2</sup> In aerosol paint products, there is a significant difference between the discharged weight of the product and the amount that would be considered "collectible" due to the propellant. Typically, aerosol paint products contain anywhere from 20% to 30% propellant.

When an aerosol paint product is discharged, the propellant immediately dissipates or vaporizes. It is impossible to collect the propellant as a liquid because it changes to a gas due to its high vapor pressure. It does not exist as *in liquid form under ambient conditions*. CPSC's proposed test method fails to account for this chemical occurrence and consequently, a very large number of aerosol coatings products would meet the 2.0 grams/second discharge rate and be required to have child-resistant packaging under this test.

3) CPSC's test method fails to make any distinction between aerosol products that discharge product in a mist and aerosol products that discharge in the form of a stream. Instead, the test method is designed to apply to all aerosol products indiscriminately and merely take into account the discharged amount. Despite the fact that it is impossible to "collect" and ingest product discharged as a mist, under this test method, it is absolutely irrelevant what form the atomized spray takes. It is highly likely that aerosol paint products that utilize a high concentration of solids will fall within the confines of the test method and be required to use child-resistant packaging even though the product discharges a fine, atomized mist that would be impossible to ingest.

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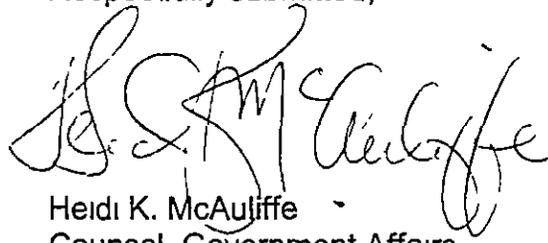
<sup>2</sup> In this instance, CPSC is using the term "collectible" in reference to small children playing with aerosol cans and/or accidentally discharging the product. NPCA disputes whether any small child under five years of age can physically activate an aerosol coating by accident or intentionally due to the strength and physical dexterity required to accomplish this task. Our member companies have no evidence or data to suggest that ingestion by a small child is foreseeable.

In light of the flaws inherent in the proposed test method and the fact that aerosol products are inherently tamper-resistant, NPCA urges CPSC to abandon this method and exempt all aerosol products, regardless of the discharged amount. In addition, NPCA urges CPSC to re-examine the injury data with regard to this issue. In this litigious age, it is hard to imagine that our member companies would be unaware of any confirmed instances where small children have accidentally inhaled spray paint from aerosols. Over the last ten years there have been no reported instances where a child has accidentally aspirated aerosol paint and during this time period eight billion aerosol paint cans have been produced.

In any event, any methodology designed to determine which aerosol/trigger/pump products should be required to have child-resistant closures should accurately reflect the complexities of our product's chemical formulations and the already existing obstacles to accidental collection and ingestion of these products by small children. CPSC's proposed draft method blatantly ignores these fundamental characteristics.

NPCA's Spray Paint Manufacturers Committee stands ready to help CPSC explore this issue further and determine a more appropriate standard. Please do not hesitate to call on us. Thank you for the opportunity to participate in the November 14 meeting. We are pleased to submit these comments and look forward to working with CPSC further on this and any other issue that affects paint products.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi K. McAuliffe". The signature is fluid and cursive, with the first name "Heidi" and last name "McAuliffe" clearly legible.

Heidi K. McAuliffe  
Counsel, Government Affairs



CP01-2-4

## **Automotive Chemical Manufacturers Council**

A Product Line Group of  
Motor and Equipment  
Manufacturers Association

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

December 15, 2000

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

Re Child-resistant packaging of low viscosity hydrocarbon-containing aerosol/trigger/pump products

Dear Sir or Madam.

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

ACMC members support the Consumer Product Safety Commission (CSPC) in its efforts to further promote and protect the health and safety of our nation's children. However, we strongly believe that aerosol products should not be included in the proposed regulation. The probability of ingesting enough liquid from an aerosol product to cause aspiration is very low, while the financial and environmental costs of compliance with the proposed regulation are prohibitive. Including aerosol products in the proposed regulation would force our members to meet new packaging requirements despite a complete lack of evidence that their products contribute to the dangers that the proposal seeks to prevent.

The spray rate set forth in the proposal primarily impacts automotive-related products, possibly the least likely of all consumer products to be used inside the home and accessed by children. Commercial and industrial consumers constitute the primary markets for aerosol engine degreasers, carburetor cleaners, aerosol adhesives, and other automotive maintenance and repair products. Children never come in contact with the vast majority of these products, because they are not purchased by individuals or brought into the home or garage. We do not believe that aerosols pose a threat of aspiration to children, but due to a lack of access,

Office of the Secretary  
Consumer Product Safety Commission  
December 14, 2000  
Page Two

automotive aerosol products would present even less potential for aspiration than other household aerosol products

Measured against this negligible risk to children is the tremendous burden this regulation would place on ACMC members, many of whom are small businesses. The aerosol products affected by this regulation may be packaged in canisters designed to minimize their size, and therefore, to minimize both shipping costs and environmental costs of packaging. The reconfiguration the lids of these products to meet child resistant requirements may not be possible using current designs for certain types of containers. Any design changes will have significant economic and environmental costs.

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

In closing, we would urge CSPC not to include aerosol products in its proposed regulation. To require child-resistant packaging of products that have no history of injury and are unlikely to be used inside the home would impose a severe and unwarranted burden on automotive aerosol manufacturers. If CSPC chooses to include aerosols, however, the test method for inclusion must recognize the chemical characteristics of hydrocarbon propulsion in aerosol products that pose no risk of aspiration.

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

# ***Automotive Chemical Manufacturers Council***

1225 New York Avenue, N.W., Suite 300, Washington, D.C. 20005

Phone: (202) 393-6362 Fax: (202) 737-3742 E-Mail: amcculloch@mema.org

## **FAX TRANSMISSION SHEET**

November 6, 2000

**TO:** Office of the Secretary  
Consumer Product Safety Commission  
(301) 504-0079

**FROM:** Ann McCulloch

**RE:** Child-resistant packaging of low viscosity hydrocarbon-containing  
aerosol/trigger/pump products.

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REVISED

Following please find ACMC's comments in the above referenced matter We are sending the original by U S mail If you need anything further, please let us know Thanks!



*Hydrocarbon  
Comment  
CP01-2-5*

December 12, 2000

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

OFFICE OF THE SECRETARY  
ZMD DEC 18 P 2 42

Re Child-resistant packaging of low viscosity hydrocarbon-containing aerosol/trigger, pump products

Dear Sir or Madam

This letter is being submitted in response to the Commission's request for comments on the draft test method that has been proposed for use in determining which hydrocarbon-containing aerosol products would be required to use child-resistant packaging

Hydrosol, Inc is a private label aerosol packager. In this capacity, we represent our customers in regulatory matters that affect the aerosol products we produce for them. The proposed child-resistant packaging requirement for certain types of hydrocarbon-containing aerosol products will affect many of them. Currently, over forty individual companies, some who market their products nationally and others who market only regionally, would be required to meet the new packaging requirement for products where there has been no history of injury of the type that this proposed regulation is attempting to prevent. The proposed limited exclusion of certain types of hydrocarbon-containing aerosol products, based on spray delivery rates, from child-resistant packaging requirements does not go far enough. The exclusion simply should be for all aerosol products as is currently allowed for in the regulations.

What statistics are available to show that aerosols are abused by means of ingestion? I have been involved in aerosol formulations and packaging for over thirty years. Many of our products are used in the automotive aftermarket service and maintenance areas and contain significant amounts of hydrocarbons. Over the last ten years, we have packaged in excess of 100 million aerosol units of these types of products. In all of this time, we have never experienced an incident involving ingestion of any of our aerosol products. It is our firm belief that this proposed regulation change is unnecessary and will put an unwarranted burden on a form of packaging that does not present an aspiration hazard. Additionally, this proposed regulation seems to principally affect only one product category, i.e. automotive maintenance products, and that category almost solely would bear the unwarranted burden of the proposed regulation.

Most of the non-emulsion, hydrocarbon-containing products that we package have spray rates that are considerably less than 10 grams dispensed in 5 seconds. However, many automotive

aerosol products, such as carburetor cleaners, engine degreasers, brake parts cleaners, multi-purpose lubricants, penetrating oils, and solvent cleaners, and, to a lesser extent, other products, such as anti-seize compounds, gasket removers, greases, aerosol adhesives, automotive spray primers and undercoats, and zinc-rich primers, currently exceed that rate and would be impacted by the requirements of this proposed regulation

Many of the automotive maintenance items described are used primarily in commercial maintenance shops or garage areas where small children will not be found. In many instances, the aerosol cap, whether it is child-resistant or not, will not be replaced by the user. Liquid products require that the container be reclosed after use for safety and to prevent spillage and evaporation. This is not the case for aerosol products, no reclosure is necessary because the products are already in closed containers. In some cases, the contents of the containers are used in their entirety the first time the product is used.

Any ingestion and subsequent aspiration of material resulting from that ingestion will be the direct result of intentional abuse because an aerosol cannot simply be opened and its contents ingested accidentally. If someone were to intentionally collect the liquid content of an aerosol package for the purpose of ingesting it, does it matter if the product is dispensed as a mist or as a stream, as originally proposed, or in an amount less than or greater than 10 grams dispensed in 5 seconds, as currently proposed? In either case, exceptional methods will have to be employed in order to collect the material. Likewise, spraying directly into the mouth would be difficult for a child to accomplish. Most of the containers that would be involved in this regulation are large-sized, usually having a diameter of 2-11/16ths inch or greater and 7 or more inches in height, and heavy, generally one pound or more. For a child to grasp a container of this type and dispense the product directly into its mouth will be very difficult to do because they do not have the physical dexterity that these actions require. The large diameter of the container prevents the child from putting it into its mouth. All actuators used on these products deliver the product at a right angle to the perpendicular axis of the can. Any attempt to spray the can by pressing the actuator against the teeth will likely result in the product spraying all over the child's face. Also, because the actuators have angled tops, i.e. a finger pad designed for finger contact, and are made from plastic resins that generally are slippery, actuation of the container by pressing down on the actuator with one's teeth will likely fail because the teeth will slide off of the surface and the product will not be dispensed. It is also our belief that the child would be startled by the sound effects and spray volume of the dispensed product and that this would result in either a dropping of the container or a cessation of the spraying immediately at the time of actuation.

The Commission has alluded to reports of incidents that involved children and aerosols, yet, the Commission has not shown that any of these alleged reports describe the type of injury that this proposed regulation is attempting to prevent, ingestion of hydrocarbon solvents. Also, there does not appear to be any data that identifies the types of products that are involved in these alleged incidents. If the incidents that did occur involved aerosol products, were the products sprayed? Did the products contain hydrocarbons? Were the products non-emulsions? If the products were those that would generally be found in the home, such as glass cleaners, all-purpose cleaners, emulsion-type furniture polishes, disinfectant sprays, air fresheners, shave creams or gels, etc., then the proposed regulation will not apply to any of them and those that subsequently would be regulated would be subject to an unfair regulation.

# HYDROSOL INCORPORATED

It is our belief that the aerosol form of packaging is inherently child-resistant and that the proposed regulation should be withdrawn. However, if it is not, then there is a problem in the methodology for determining what products require child-resistant packaging. The main problem with the originally proposed regulation was that the statement "except for those packaged in pressurized spray containers that are expelled in a mist" had no clear definition as to what constitutes a "mist." The revised proposal attempts to correct this but also falls short because of limitations imposed by the proposed test method. Specifically, the test method is flawed in that it measures total discharge from the aerosol and not the delivered, collected, amount of liquid. If the product contains 25% propellant and the measured total discharge is 12 grams for the 5-second spray duration, then the actual amount of product that potentially could be collected as a liquid is 9 grams. The test method does not allow for the dissipation of the propellant, which could not be ingested because it will rapidly change physical state from a liquid to a gas due to its high vapor pressure. At ambient conditions, the propellants cannot exist as liquids and, therefore, could not be ingestible.

Under the proposed test method, some primer-type aerosol paint products that have total discharge rates of 2.0 to 2.1 grams/second would require child-resistant packaging. If the non-collectible propellant content were considered, then the spray rates would fall well below 2.0 grams/second and the products would not require child-resistant packaging. Also, other paint products with high inert loadings, such as primers and zinc-rich coatings could be affected by the proposed method because the densities of the liquids are significantly higher than regular spray paints. These high densities can exaggerate the weight of the volume of liquid dispensed per unit time and lead to unneeded regulation.

In summary, we believe that the proposed regulation is unnecessary because the aerosol package is inherently a child-resistant package in preventing the accidental ingestion of the liquid content contained within. A vast majority of the household aerosol products used in this country will not require child-resistant closures. Based on information contained in the 1999 Chemical Specialties Manufacturers Association (CSMA) Pressurized Products Survey, approximately 1.8% of the 3.2 billion aerosols packaged could be candidates for child-resistant packaging and virtually all of these would be in the automotive and industrial products categories that include carburetor cleaners, brake parts cleaners, lubricants, engine degreasers, and other miscellaneous industrial products. The number is further reduced by exports and by those products that are either emulsions or dispense less than the test protocol amount. If, however, the regulation is enacted, then the test protocol must clearly define that a collected, measured amount of product that does not include any propellant portion is the determining factor in requiring use of a child-resistant closure.

Sincerely,



Edward S. Piszynski  
Vice-President, Laboratory Services

# **HYDROSOL** INCORPORATED

Cc Chairman Ann Brown  
Commissioner Mary Sheila Gall  
Commissioner Thomas Moore  
Dr Suzanne Barone