



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

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

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November 27, 2000

Dear Sir/Madam:

The staff of the U.S. Consumer Product Safety Commission (CPSC) met with several trade associations and other interested parties as scheduled on November 14, 2000 to discuss a draft test method the staff recommends for use in determining if aerosol/trigger/pump products that dispense hydrocarbons of low viscosity would require child-resistant packaging. Copies of the meeting log, attendees list, and the draft test method are enclosed. In response to the request made at the meeting, the list of the types of products evaluated in developing the draft test method is as follows; furniture polish, belt dressing, spray lubricant, paint, protectant, tire dressing, engine cleaners, carburetor cleaner, and shoe waterproofing.

If you have additional comments on the draft test method, please send them to the Office of the Secretary by December 15, 2000. Please identify the comments with the title, "**Child-resistant packaging of low viscosity hydrocarbon-containing aerosol/trigger, pump products.**" Before preparing a briefing package for the Commission on a proposed test method, the staff will review any comments received by that date.

As discussed at the November 14th meeting, the staff briefing package to the Commission on the test method will also likely recommend withdrawal of the existing Poison Prevention Packaging Act (PPPA) regulations for petroleum distillate-containing products and recommend proposing a senior-friendly requirement for child-resistant aerosol packaging. Depending on the outcome of Commission consideration of the briefing package, a public comment period on the draft test method and the other issues noted above would then be provided via a supplemental *Federal Register* notice of proposed rulemaking.

Sincerely,

Suzanne Barone, Ph.D.

Enclosures

CPSA 6(b)(1) Cleared
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LOG OF MEETING

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

DATE OF MEETING: November 14, 2000

PLACE: Room 714 CPSC Headquarters

LOG ENTRY SOURCE: Suzanne Barone, Ph.D., Pharmacologist, HS *zy*

COMMISSION REPRESENTATIVES: See attached sheet

NON-COMMISSION REPRESENTATIVES: See attached sheet

SUMMARY OF MEETING:

The CPSC staff sent a letter dated October 26, 2000 to 16 trade associations and three government agencies inviting them to attend this meeting to discuss a draft test method the staff recommends for determining if child-resistant packaging would be required for aerosol/trigger/pump products that contain hydrocarbons of low viscosity. The agenda and the draft test method are attached.

Following the introductions, the CPSC staff opened the meeting by summarizing the Federal Register (FR) notice of January 3, 2000 (65 FR 93) which proposed child-resistant packaging requirements for household chemical products regulated by FHSA and cosmetics and drugs regulated by FDCA that contain 10% or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F. Certain products were exempted from the rule including products in packages in which the only non-child-resistant access to the contents is by a spray device (e.g., an aerosol, or pump-or-trigger-actuated spray) that expels the product solely as a mist.

In response to the FR notice, the Chemical Specialty Manufacturers Association (CSMA) provided a written comment stating that aerosols should not be included in the rule but if they are included, the CSMA requested that CPSC define what constitutes a "stream." They proposed a test method that specified that a stream is a product having a spray pattern of <2 inches diameter at a distance of 12 inches. The CPSC staff does not believe that the method proposed by the CSMA adequately defines "stream."

The staff described the test method developed by CPSC staff in response to the CSMA comment. The method tests whether an aerosol or trigger/pump spray can deliver the volume of a child's swallow in a short period of time which would increase the likelihood of aspiration. This would be the criterion for determining the requirement for child-resistant packaging. For

test development purposes, a swallow volume of 5 mls was selected. A time of 2 seconds was selected to approximate the time a child might activate the aerosol with the addition of a reasonable safety factor. In order to develop a reproducible test method the staff chose mass rather than volume as the preferred measurement endpoint. Since hydrocarbons have a density less than water, the staff used a specific gravity of 0.8 to convert volume to mass. The 0.8 was derived from the specific gravity of a range of hydrocarbons and products. The 5mls converts to 4g in 2 seconds. The staff had concerns about accurately conducting the test in a 2-second time period and increased the product discharge time to 5 seconds to reduce the measurement error of the method. The mass was raised correspondingly to 10g for the 5-second time period.

The staff described that the aerosol test is conducted with a new, unused can. First, the can is weighed. Next, the actuator is fully depressed for 5 seconds and the can is reweighed. If the mass loss is 10g or more the package would require a child-resistant overcap.

Under the proposed test method, trigger and pump sprayer packages must have a child-resistant or permanent attachment of the spraying device to the bottle. For triggers/pumps, the package must be fully primed and the discharge set at the position with maximal output. If the mass of two consecutive full mechanical strokes is 10 g or more then the spray mechanism must be child-resistant.

The staff stated that the distinction between mists and streams exists for FHSA cautionary labeling. However, in labeling their products, the industry does not appear to make that distinction since all products examined by the CPSC staff contained the labeling, "Harmful or fatal if swallowed."

The staff also examined the papers by Gerarde¹ that gave the results of animal testing done with aerosol products. The staff had concerns about the methods used. In his work dealing with aerosols, an amount of liquid product five times the volume of the rat's mouth was aerosolized and administered to rats. However, it is unclear whether aspiration was forced in the anesthetized rats. It should be noted, however, that if the staff proposed the discharge rate used in Gerarde's studies, all aerosols would require child-resistant packaging. Gerarde did conclude that if a volume of aerosol sufficient to pool is delivered into the mouth, it could be aspirated. This is the premise of the CPSC staff test method.

The draft CPSC staff method was developed after reviewing NEISS cases involving all types of spray products to see how children interact with the products. Scenarios included children

¹ Gerarde, H., Toxicological Studies on Hydrocarbons, Arch Environ. Hlth. 6:35-47, 1963.

found with the cans in their mouths, spraying into their mouths or in their eyes. Since the children can put the nozzles in their mouths and activate them, the amount of product captured closely approximates the amount of product discharged. Results of CPSC staff tests have confirmed this. Pooling of captured product, that could lead to aspiration as suggested by Gerarde, was also seen during preliminary testing. Therefore, based on these observations, the staff chose amount discharged as the test parameter.

In the meeting, the members of the trade associations and industries asked if the incident data were from hydrocarbon-containing aerosols. They requested copies of the incident data. The staff responded that they examined incidents from all products to see what children do with aerosols. There were cases involving hydrocarbon-containing products such as the spray lubricants. The staff agreed to determine if the incident data must be FOIed.

One manufacturer's representative said that the method would capture high-density paint products that release a lot of propellant. The product would be a "high mass mist." The staff asked for samples of these types of products. The representative also stated that most paints expel at 0.7-1.4 g/sec and would not require child-resistant packaging. The representative noted that the current spray paint overcaps that require a tool to open are tamper resistant and not necessarily child-resistant.

The same manufacturer claimed that the method targeted automotive products and that the majority of these types of products are sold to professionals. CPSC staff stated that this does not agree with their general experience. He stated his company is not aware of any incidents. He also stated that overcaps are difficult to open and people leave them off after initial removal. However, he believes that aerosols are inherently child-resistant because they are hard to activate.

The staff said that no product class was "targeted." However, there are many automotive products containing hydrocarbons that are formulated as aerosols or trigger sprays. The automotive products are available to the public and therefore subject to CPSC regulations.

The costs and complexities of converting to child-resistant overpackaging were discussed by one attendee.

A question about the Canadian regulations was asked. The representative from Canada stated that Canada defined mist but did not have a test method. He indicated that in Canada, the court would rule based on the common dictionary definition.

Another industry member stated that he hoped CPSC would consider the California definitions. The CPSC staff was not aware of this information, but will look into it.

The industry representatives asked what types of products CPSC analyzed by the test method. The staff will provide that information by category.

The staff also mentioned its intent to recommend withdrawal of the three existing PPPA regulations for furniture polish, kindling and illuminating preparations, and solvents for paint and other coatings. These rules would be replaced by the currently proposed general hydrocarbon rule. Thus, any aerosol furniture polish meeting the requirements would need child-resistant packaging. In addition, the staff is planning to recommend that aerosol packaging meet the senior-friendly test protocols instead of the current protocol using 18-45 year olds as packaging now exists that will meet the senior standard.

The CSMA representative asked for additional time beyond the December 11, 2000 date indicated by the staff in order to comment on the draft test method. The representative also stated that the incident data was necessary before they commented. The industry asked the CPSC staff what type of information the staff would like them to provide. CPSC staff indicated that we would be interested in the industry results of testing their products using the draft CPSC test method and any information about injuries or incidents involving their aerosol or spray hydrocarbon products.

CPSC Staff Meeting on Aerosol/Pump/Trigger Packages with Hydrocarbons of Low Viscosity

**November 14, 2000
Room 714, 10:00am**

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AGENDA
CHILD-RESISTANT PACKAGING OF LOW VISCOSITY
HYDROCARBON-CONTAINING AEROSOL/TRIGGER/PUMP PRODUCTS
NOVEMBER 14, 2000 – 10:00AM
ROOM 714

1. Introductions
2. Proposal of January 3, 2000 exempts spray devices that expel the product solely as a mist for both household chemicals and cosmetics/drugs. Copy of January 3, 2000 FR notice available.
3. Comment from CSMA dated March 20, 2000 requesting and suggesting a test method for defining "stream". Copy of comment available.
4. CPSC staff draft test method – description and background. Copy of test method attached.

Questions and comments on method. Written comments due December 11, 2000. Address to Office of the Secretary. Please identify comments with **RE: Child-resistant packaging of low viscosity hydrocarbon-containing aerosol/trigger/pump products.**

5. Other issues
 - a. Existing three PPPA regulations
 - b. Aerosol furniture polish
 - c. "Senior-friendly" aerosol packaging
6. General questions and comments.

Draft Test Method for Determining if Child-Resistant Packaging is Required for Aerosol/Trigger/Pump Products that Contain Low Viscosity Hydrocarbons

This method applies only to liquid nonemulsion products in aerosol cans, and in certain trigger or pump sprayers,¹ that contain 10 percent or more hydrocarbons by weight and have a viscosity of less than 100 SUS at 100°F ("hydrocarbon-containing products").

An aerosol hydrocarbon-containing product will require child-resistant packaging if 10 grams or more of product is expelled during an initial 5 seconds of continuous discharge with the aerosol can in an upright position and with the dispensing button or nozzle fully depressed. A trigger/pump product will require child-resistant packaging if, after fully priming the pumping system and selecting the discharge setting with maximum output, 10 grams or more of product is expelled by 2 consecutive full mechanical strokes of the trigger/pump mechanism. Each of these tests must be conducted on new, unused, representative products conditioned to room temperature (20-25°C) and prepared in accordance with the manufacturer's use instructions label (e.g. shaken). The weight discharged by each such product will be computed by subtracting the weight of the container after the discharge test from the weight of the container before the discharge test as determined using a scale accurate to at least ± 0.1 gram.

¹Trigger and pump sprayer packages must have a child-resistant or permanent attachment of the spraying device to the bottle. This method will be use to determine if the spray mechanism itself must be child-resistant.