

**BEFORE THE CONSUMER PRODUCT SAFETY
COMMISSION**

Petition

To Amend the Statement of Interpretation and Enforcement Policy regarding
Labeling of Household Products containing Methylene Chloride issued by
the Commission under the Federal Hazardous Substances Act,
52 Fed. Reg. 34,698 (September 14, 1987)

Halogenated Solvents Industry Alliance, Inc.
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Of Counsel:

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July 7, 2016

2016 JUL 11 P 5:19

Petition

The Halogenated Solvents Industry Alliance, Inc. ("HSIA") represents manufacturers and users of chlorinated solvents, including methylene chloride (dichloromethane or "DCM"). A list of HSIA's members is attached (Attachment A).

HSIA hereby petitions the Consumer Product Safety Commission ("CPSC") to amend the Statement of Interpretation and Enforcement Policy regarding labeling of household products containing DCM (hereafter the "Statement") issued by the Commission under the Federal Hazardous Substances Act ("FHSA"). 52 Fed. Reg. 34,698 (Sept. 14, 1987). CPSC has clear authority to take the action requested in this petition.¹ Moreover, in light of the guidance received from CPSC staff on May 26, 2016, discussed below, we believe a revised Statement must be published to avoid a conflict as to the cautionary labeling required under the FHSA.

In the Statement, the Commission determined that 13 classes of household products containing methylene chloride were hazardous substances that expose consumers to significant amounts of DCM vapor. The hazard addressed was potential human carcinogenicity, based on studies that showed an increased incidence of certain tumors in animals exposed to high concentrations of DCM. To the best of HSIA's knowledge, every container of DCM-based paint stripper and other products containing DCM sold for consumer use in the United States since 1988 has borne the cautionary labeling required by the FHSA, as specified in the Statement. Clearly there has been widespread acceptance of the enforcement policy.

Need for Action/Specific Request

This Petition seeks to expand the labeling required by the FHSA to address not just chronic but acute risk. The Commission has recognized that the FHSA "defines the term

¹ Although the Statement "is not a binding rule," 52 Fed. Reg. at 34703, we understand from Commission staff that a petition is the appropriate avenue to seek Commission action to amend the Statement. This petition provides the information requirements and recommendations set out at 16 C.F.R. § 1051.5, although it is not a petition for rulemaking.

'toxic' very broadly," and "[t]his broad statutory definition covers both acute and chronic toxicity."²

In 2012, the Centers for Disease Control's Morbidity and Mortality Weekly Report identified 13 deaths associated with use of DCM-based paint strippers by professional bathtub refinishing operations during 2000–2012.³ Thereafter, the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) identified an additional worker death since 2000 related to bathtub refinishing with stripping agents containing methylene chloride, and published a Hazard Alert.⁴ Bathtub refinishing is the process of restoring the surface of an old bathtub to improve the bathtub's appearance and repair surface damage. The process commonly involves removing the bathtub's existing finish before applying a new coating, usually a synthetic finish such as polyurethane or epoxy.

When consumers use methylene chloride to strip coatings from bathtubs, they often spray or pour a bathtub stripping product into the basin of the bathtub and then brush the product onto the tub surface. Many stripping products contain substantial amounts of methylene chloride. Use of these chemicals in bathrooms, which are often small, enclosed spaces with little or no ventilation, can be very dangerous. As methylene chloride is a volatile organic compound that will evaporate faster when sprayed, brushed, or poured, its vapors can quickly build up in small spaces. Moreover, because methylene chloride has a high vapor pressure it evaporates quickly and the vapors can collect in the bottom of a bathtub and in the consumer's breathing zone when working in the bathtub. This situation

² Labeling Requirements for Art Materials Presenting Chronic Hazards, Guidelines for Determining Chronic Toxicity of Products Subject to the FHSA; Supplementary Definition of "Toxic" under the Federal Hazardous Substances Act, 57 Fed. Reg. 46,626, 46,656 (Oct. 9, 1992).

³ Morbidity and Mortality Weekly Report, Fatal Exposure to Methylene Chloride Among Bathtub Refinishers — United States, 2000–2011: 61(07), 119-122 (February 24, 2012); http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6107a2.htm?s_cid=mm6107a2_e

⁴ Methylene Chloride Hazards for Bathtub Refinishers; https://www.osha.gov/dts/hazardalerts/methylene_chloride_hazard_alert.html

can create dangerously high concentrations of methylene chloride, in some cases even replacing the breathable air.⁵

The OSHA Hazard Alert recommends a number of measures that can reduce or eliminate the risk posed by use of DCM-based paint strippers in refinishing bathtubs. While this was an appropriate and helpful response, HSIA believes that prevention of such fatalities in the future can best be accomplished by the Commission using its authority under the FHSA. As the Commission has already determined that “household products which can expose consumers to methylene chloride vapor are hazardous substances because they may pose a carcinogenic risk to humans,” all that is needed is to extend the cautionary labeling so that it also warns of the threat of asphyxiation if DCM-based products are used in an enclosed space.

In late 2015, HSIA developed appropriate warning language for consideration by Commission staff. Indeed, the labeling proposed by HSIA went beyond precautionary measures and stated “Do Not Use To Strip Bathtubs,” with a corresponding pictogram. By letter dated May 26, 2016 (Attachment B), Commission staff largely accepted the proposed language, notifying HSIA that “[t]he recommended cautionary labeling statements for the acute hazards presented in this letter provide CPSC staff’s guidance on the specific statements to be used to meet the minimum cautionary labeling requirements of the FHSA.” It noted that the pictogram submitted was neither required nor prohibited by the FHSA, but that such graphics could serve to draw attention to the danger of using the product to strip bathtubs. HSIA has circulated the staff guidance widely throughout the industry, as requested by Commission staff, along with a sample label which includes the pictogram (Attachment C).

The May 26 letter further states that “[c]urrently, staff does not have plans to recommend that the Commission make changes to the September 14, 1987 Notice of Interpretation and Enforcement Policy or establish mandatory requirements through rulemaking.” HSIA continues to believe, however, that widespread compliance with the FHSA will be best achieved by the Commission taking action to revise the Statement of Interpretation and Enforcement Policy. A Federal Register notice receives much greater

⁵ *Id.*

publicity and public attention than a letter circulated by industry associations to their members. Moreover, there is a danger that, absent revision of the Statement, there will be confusion among the paint stripping product manufacturers as to whether strictly to conform to the Statement (focused on chronic hazard) or to warn against other risks as well in accordance with the staff guidance. Thus, HSIA respectfully requests the Commission to determine that household products containing DCM must bear the cautionary labeling statements presented in the May 26 letter in order to meet the minimum cautionary labeling requirements of the FHSA and to be appropriately labeled under FHSA § 2(p).

Statutory and Regulatory Background

Under FHSA § 3(a), the Commission is authorized to classify as “hazardous substances” consumer products used for household purposes that are toxic, if such substance “may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use.” See FHSA § 2(f). FHSA § 2(g) defines “toxic” to mean any substance that has “the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.” When a product is declared to be a hazardous substance, cautionary labeling of the product becomes mandatory under FHSA § 2(p).

In 1986, the Commission issued a proposed rule under FHSA § 3(a) to declare DCM a hazardous substance, based on concerns raised by animal bioassay results. 51 Fed. Reg. 29,778 (Aug. 20, 1986). After considering the comments on the proposed rule, the Commission concluded that the animal data were sufficient to conclude that DCM might cause a carcinogenic risk to humans and that products containing it should be considered hazardous substances. The Commission further concluded that while “there is little or no uncertainty involved in a determination that household products containing methylene chloride, and presenting significant exposures to consumers, may pose a carcinogenic risk to humans. . . it is unnecessary to make a conclusive determination of all these issues at this time for the purpose of determining that there is sufficient uncontested evidence to warrant a finding that methylene chloride. . . is a hazardous substance.” 52 Fed. Reg. at 34,700. Thus, the Commission found that it was unnecessary to continue with the rulemaking proceeding and determined instead to issue the Statement. *Id.*

Once household products containing DCM were determined by the Commission to be "hazardous substances," it became necessary that they be labeled in accordance with FHSA § 2(p) in order to avoid meeting the definition of a "misbranded hazardous substance" contained in that subsection. The introduction of a misbranded hazardous substance into interstate commerce is prohibited by FHSA § 4(a), subject to civil or criminal penalties as provided in FHSA § 5.

HSIA submits that the Commission's reasoning in 1987 resulting in issuance of the Statement applies at least equally to the requested modification of the Statement to include cautionary labeling to guard against acute overexposures. There is no dispute that acute overexposure to DCM in a closed room can lead to death. Moreover, the Commission was guided in large part by the fact that "[i]f the rulemaking proceeding were continued, there is a potential that there would be a subsequent adjudicatory hearing, as well as subsequent appeals to the Commission and to a court of appeals, which could delay the effective date of the rule for up to several years." 52 Fed. Reg. at 34,700. The Commission's concern about delay remains equally true today.

Preemption

Revision of the Statement is also important to ensure against inconsistent labeling requirements at the state or local level directed at the same risk being given effect. FHSA § 18(b)(1)(A) provides that a cautionary labeling requirement under § 2(p) has limited preemptive effect against state or local statutes or regulations that establish cautionary labeling requirements designed to protect against the same risk of illness or injury, except to the extent such requirements are identical. It is important that the acute hazard warning language have the same legal effect under the FHSA as the chronic hazard language, and this can only be accomplished by a Commission determination that the acute warning is required under FHSA § 2(p).

Conclusion

The Commission should without delay issue a revised Statement that includes cautionary labeling that warns expressly of the risk of asphyxiation and death if DCM-based products are used to refinish bathtubs in an enclosed space. HSIA would be happy to

provide any additional information that might be helpful to the Commission in acting upon this petition.

Attachments

ATTACHMENT A

2016 HSIA MEMBERSHIP LIST

Sustaining Members

Axiall Corporation
440 College Park Drive
Monroeville, PA 15146

INOVYN Americas
7444 Harbour Isle
Indianapolis, IN 46240

Occidental Chemical Company
5005 LBJ Freeway
Suite 2200
Dallas, TX 75244

Olin Blue Cube Operations
1821 Larkin Center Drive
Midland, MI 48640

Associate and Supporting Members

Benco Sales, Inc.
305 Williams Avenue
Madison, TN 37115

Brenntag Mid-South, Inc.
P. O. Box 20
Henderson, KY 42419

CRC Industries, Inc.
885 Louis Drive
Warminster, PA 18974

Dow Chemical
1111 Washington Street
Midland, MI 48640

Drycleaning and Laundry Institute
14700 Sweizer Lane
Laurel, MD 20707

National Cleaners Association
252 W. 29th Street
New York, NY 10001

Packaging Service Company
1904 Mykawa Road
Pearland, TX 77584

Parts Cleaning Technologies
26400 Capitol
Redford, MI 48239

Pero USA Cleaning Systems
900 River Street #G
Windsor, CT 06095

Precision Machined Products Association
6700 W. Snowville Road
Brecksville, OH 44141

Recochem
8725 Holgate Crescent
Milton, Ontario
Canada L9T 5Q7

Savogran
P.O. Box 130
Norwood, MA 02062

Sterlitech Corporation
22027 70th Avenue South
Kent, WA 98032

TCTA
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Fairfield, NJ 07004

Vapor Engineering, Inc.
P. O. Box 15209
Pensacola, FL 32514

W.M. Barr
6750 Lenox Center Court
Memphis, TN 38115

ATTACHMENT B



U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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May 26, 2016

Via Certified Mail/caffey.norman@squirepb.com

Caffey Norman
Squire Patton Boggs (US) LLP
2550 M Street, NW
Washington, DC 20037

Re: Cautionary Labeling of Methylene Chloride-Containing Paint Stripper Products

Dear Mr. Norman:

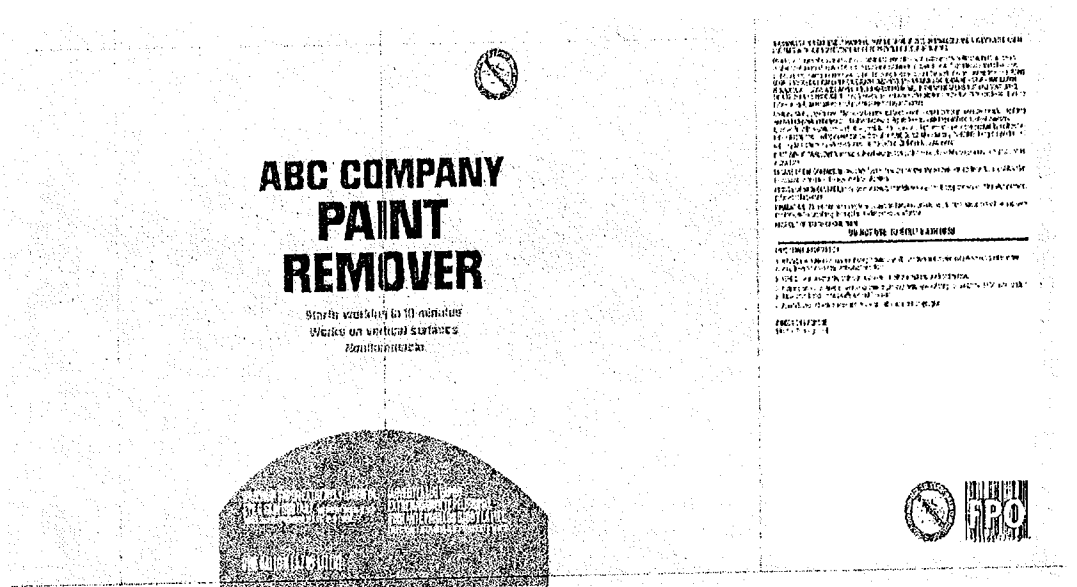
This letter responds to a request by the Halogenated Solvents Industry Alliance (HSIA) that U.S. Consumer Product Safety Commission (CPSC) staff comment on its proposed modified label for methylene chloride-containing paint stripper products under 16 C.F.R. § 1500.128. The proposed label includes enhanced cautionary statements, warning of acute hazards posed with reasonably foreseeable use of methylene chloride-containing paint stripper products in an enclosed space.

On September 14, 1987, the CPSC published a Notice of Interpretation and Enforcement Policy for Labeling of Certain Household Products Containing Methylene Chloride, including paint strippers, which can expose consumers to significant amounts of methylene chloride vapor. *Vol. 52 Federal Register No. 177 Pg. 34698*. The document provided CPSC's recommendations for cautionary labeling to warn consumers of the chronic hazard of carcinogenicity.

The minimum cautionary labeling required under the Federal Hazardous Substances Act (FHSA) is determined by the quantitative formulation of a product and addresses the risk of substantial personal injury or substantial illness during, or as a proximate result of, any customary and reasonably foreseeable use of the product. 15 U.S.C. § 1261(p). The FHSA requires cautionary statements to warn consumers of acute and chronic hazards, to enable consumers to safely use and store the products in and around the household. The recommended cautionary labeling statements for the acute hazards presented in this letter provide CPSC staff's guidance on the specific statements to be used to meet the minimum cautionary labeling requirements of the FHSA.

HSIA submitted the draft label and requested that CPSC staff review CPSC's current labeling guidance for methylene chloride-containing stripper products to address the acute risk of overexposure and to include specific statements indicating that the products are not intended to be used as bathtub strippers. HSIA requested that CPSC staff review HSIA's draft label in response to incidents of accidental death after the products were used to strip bathtubs in bathrooms without adequate ventilation. The deaths occurred from using products that are available to consumers.

Below is the draft cautionary label submitted by HSIA for staff review and comments under 16 C.F.R. § 1500.128:



The cautionary statements on the principal display panel read:

**WARNING: VAPOR EXTREMELY HARMFUL
EYE AND SKIN IRRITANT**
Read other cautions and health hazard information on back/side panel.

CPSC staff reviewed HSIA's draft label with the minimum cautionary labeling requirements of the FHSA in mind. Based on a product's formulation, a product may require additional principal display panel (PDP) cautionary statements. Due to the reported incidents of death that have occurred over the last 10 years, CPSC staff recommends strengthening the statement of principal hazard to warn consumers that use of the product without adequate ventilation can be fatal. We recommend the following statements:

**WARNING: INHALATION OF VAPOR MAY CAUSE DEATH
EYE AND SKIN IRRITANT**
Read all cautions on back/side panel.

Below are the remaining back panel precautionary statements and instructions for use:

WARNING! VAPOR EXTREMELY HARMFUL. MAY BE FATAL IF USED IN ENCLOSED AND UNVENTILATED AREAS. USE WITH ADEQUATE VENTILATION TO PREVENT BUILDUP OF VAPORS.

Do not use in areas where vapors can accumulate and concentrate, such as basements, bathrooms, bathtubs, closets, or other small enclosed areas. Whenever possible, use outdoors in an open air area. If using indoors, open all windows and doors, and cross ventilate by moving fresh air across the work area and across the floor. **IF STRONG ODOR IS NOTICED, OR YOU EXPERIENCE SLIGHT DIZZINESS, EYE-WATERING, OR HEADACHE – STOP! VENTILATION IS INADEQUATE. LEAVE AREA IMMEDIATELY, AND GET FRESH AIR. IF THE WORK AREA IS NOT WELL-VENTILATED, DO NOT USE THIS PRODUCT.** If used properly, a respirator may offer additional protection. Obtain professional advice before using. A dust mask does not provide protection against vapors.

Contains: Methylene Chloride. Methylene Chloride has been shown to cause cancer in laboratory animals. The risk to your health depends on the level and duration of exposure. Reports have associated neurological and other physiological damage to repeated and prolonged overexposure to solvents. Intentional misuse of this product, by deliberately concentrating and inhaling vapors, can be harmful or fatal. Do not take internally. **WARNING:** Using this product will expose you to chemicals that are known to the State of California to cause cancer.

FIRST AID – IF SWALLOWED, immediately call your poison control center, hospital emergency room or physician for instructions.

IN CASE OF EYE CONTACT, immediately flush with water, remove any contact lenses, continue flushing with water for at least 15 minutes, then get medical attention.

IN CASE OF SKIN CONTACT, irritation may result. Immediately wash with soap and water. If irritation persists, get medical attention.

INHALATION: If inhalation of this material occurs, and adverse effects result, move person to fresh air and keep comfortable for breathing, then get medical attention.

KEEP OUT OF THE REACH OF CHILDREN

DO NOT USE TO STRIP BATHTUBS

IMPORTANT INFORMATION

1. ALWAYS use outdoors, if possible. If using indoors, open ALL windows and interior and exterior doors, and maintain moving fresh air across the workplace and floor.
2. NEVER use in basements, bathrooms, closets, or other small and enclosed spaces.
3. If strong odor is noticed, or you experience slight dizziness, eye watering, or headache, STOP using product and leave work area immediately, and get fresh air.
4. ALWAYS wear chemical-resistant gloves and chemical-splash goggles.

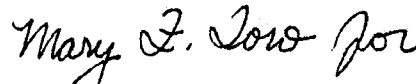
CPSC staff made very few revisions to the HSIA-proposed back panel labeling for methylene chloride-containing paint strippers, and we noted the revisions in the text above. CPSC staff does not have any additional statements to recommend. In addition, the HSIA label proposed the use of a pictogram depicting a bathtub with the prohibition mark through the bathtub. Although the FHSA does not require using pictograms, other than the skull and crossbones, and the special pictogram for charcoal briquette labeling, the FHSA does not prohibit using pictograms. CPSC staff believes that graphics may draw the user's attention to the danger of using the product to strip bathtubs.

Currently, staff does not have plans to recommend that the Commission make changes to the September 14, 1987 Notice of Interpretation and Enforcement Policy or establish mandatory requirements through rulemaking. Under the FHSA, manufacturers must review their product's formulation over time, and adjust the cautionary labeling to best address risks of injury or illness that become known to the manufacturer from using their product. CPSC staff encourages manufacturers to review the cautionary labeling of their methylene chloride-containing paint stripper products, and ensure that adequate labeling is present to address the acute hazards associated with the use of methylene chloride-containing paint strippers and the risk to consumers. Providing a copy of this letter to your members would be helpful to ensure that all manufacturers of methylene chloride paint strippers warn of the hazard of using the paint strippers in enclosed areas.

This letter contains an interpretation by CPSC staff, and has not been reviewed by the Commission. Additional or new information could change our position, and the views could be changed by the Commission.

Please contact me if you have questions about this letter.

Sincerely,



Carol A. Afflerbach

ATTACHMENT C

ATTACHMENT C

