UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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This document has been electronically approved and signed.

DATE: March 7, 2018

BALLOT VOTE SHEET

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Barbara E. Little, Attorney, OGC

SUBJECT: Update to Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride; Supplemental Guidance

BALLOT VOTE DUE Tuesday, March 13, 2018

The Halogenated Solvents Industry Alliance, Inc. (HSIA) petitioned the Commission to amend the 1987 Statement of Interpretation and Enforcement Policy regarding labeling of household products containing methylene chloride (1987 Statement) to address acute hazards from inhalation of methylene chloride vapors in addition to the chronic hazards addressed by the 1987 Statement. On June 2, 2017, the Commission voted unanimously (5-0) to grant the petition (HP 16-1) and direct CPSC staff to draft a policy statement that addresses labeling for acute hazards from inhaling methylene chloride vapors from paint strippers.

Staff is forwarding to the Commission a briefing package that addresses labeling for acute hazards from inhaling methylene chloride vapors from paint strippers. The Office of the General Counsel is providing for the Commission's consideration a draft *Federal Register* notice that would update the 1987 Statement to address labeling for acute hazards from inhaling methylene chloride vapors from paint strippers.

Please indicate your vote on the following options:

I. Approve publication of the attached document in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

II. Approve publication of the attached document in the *Federal Register*, with changes. (Please specify.)

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_____ _____

(Signature) (Date)

III. Do not approve publication of the attached document in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

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_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* Notice regarding Labeling of Certain Household Products Containing Methylene Chloride; Supplemental Guidance

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Chapter II

[Docket No. CPSC-2016-2019]

Labeling of Certain Household Products Containing Methylene Chloride; Supplemental Guidance

AGENCY: Consumer Product Safety Commission.

ACTION: Guidance.

SUMMARY: The Halogenated Solvents Industry Alliance petitioned the Consumer Product Safety Commission to amend its 1987 policy statement regarding the labeling of certain products containing methylene chloride to address acute hazards from inhaling methylene chloride vapors in addition to the chronic hazards addressed in the policy statement. In this notice, the Commission updates the 1987 policy statement to provide guidance regarding the labeling to warn of acute hazards associated with paint strippers containing methylene chloride.

DATES: This guidance document becomes effective on [**INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

FOR FURTHER INFORMATION CONTACT: Carol Afflerbach, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission; 4330 East West Highway, Bethesda, MD 20814; email: cafflerbach@cpsc.gov; telephone: (301) 504-7529.

SUPPLEMENTARY INFORMATION:

I. Background

In 1987, the U.S. Consumer Product Safety Commission (CPSC or Commission) issued a Statement of Interpretation and Enforcement Policy regarding the labeling of certain household

products containing methylene chloride (1987 Statement), 52 FR 34698 (Sept. 14, 1987). The 1987 Statement noted that the Commission considers certain household products containing methylene chloride (DCM) to be "hazardous substances" under the FHSA and may pose a risk of carcinogenicity. The 1987 Statement identified several categories of products that contained methylene chloride that could expose consumers to significant amounts of methylene chloride vapor, and were thus hazardous substances. Paint strippers were one of these product categories. The 1987 Statement advised manufacturers of the FHSA's labeling requirements and provided guidance for labeling those products, including paint strippers, to warn of the cancer risk from inhaling methylene chloride vapor.

On July 7, 2016, the Halogenated Solvents Industry Alliance (HSIA or petitioner) petitioned the CPSC to amend its 1987 Statement to recognize the acute hazard posed by using household products containing DCM in enclosed spaces with inadequate ventilation. The petitioner stated that using household products containing DCM in bathrooms, or other enclosed spaces, with inadequate ventilation can be dangerous. 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 of these stripping products contain substantial amounts of methylene chloride. According to the petitioner, methylene chloride is a volatile organic compound that will evaporate quickly when sprayed, brushed, or poured, so that its vapor can quickly build up in small spaces. The petitioner stated that DCM has a high vapor pressure, which causes vapors to collect in the bottom of a bathtub and in a consumer's breathing zone when working in a bathtub. This situation can create dangerously high concentrations of DCM, and in some cases, replace the breathable air. The

petitioner asked the Commission to expand the cautionary labeling guidance so that it also warns of the threat of asphyxiation if DCM-based paint strippers are used in an enclosed space.

CPSC staff prepared a briefing package in response to the petition and submitted the package to the Commission on May 26, 2017. On June 2, 2017, the Commission voted unanimously (5-0) to grant the petition (HP 16-1) and directed CPSC staff to draft a policy statement that addresses labeling for acute hazards from inhaling methylene chloride vapors from paint strippers.

II. EPA Rulemaking

The EPA has initiated rulemaking under section 6(a) of the Toxic Substances Control Act (TSCA) to address risks posed by DCM when used in paint and coating removal products. Specifically, EPA has issued a proposed rule that provides an assessment of the health hazards posed by DCM and that proposes to determine that DCM in these products presents an unreasonable risk of injury to health. Based on this determination, and after considering regulatory alternatives, EPA proposed to prohibit the manufacture (including import), processing, and distribution in commerce of DCM for all consumer and most commercial paint removal products, and to prohibit commercial use. 82 FR 7464 (Jan. 19, 2017). EPA's rulemaking would address both consumer and worker exposures to DCM used for paint and coating removal. While developing its rulemaking, EPA consulted with CPSC staff. Under EPA's rulemaking (if finalized as proposed), paint and coating removal products containing DCM would no longer be on the market for consumers or commercial workers, except in limited circumstances. To date, EPA has not finalized its rulemaking. Accordingly, the Commission believes that updating CPSC's 1987 Statement would provide more immediate guidance and clarity to industry and consumers regarding the acute hazards associated with using DCM-

containing paint strippers while those products remain on the market. By updating the 1987 Statement, we do not suggest that labeling will address all hazards EPA identified in its proposed rulemaking.

III. Federal Hazardous Substances Act (FHSA) Labeling Requirements

The CPSC regulates hazardous household substances under the FHSA, 15 U.S.C. 1261-1276. Section 2(p)(1) of the FHSA, 15 U.S.C. 1261(p)(1), requires that a hazardous substance bear certain cautionary statements on its label in a prominent and conspicuous manner so that consumers can safely use and store the product in and around the household. A product is a "hazardous substance" under the FHSA if the substance or a mixture of substances is toxic, corrosive, an irritant, a strong sensitizer, is flammable or combustible, or generates pressure through decomposition, heat, or other means, and if the substance or mixture of substances may cause substantial personal injury or substantial illness during customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

The FHSA defines "toxic" as "any substance . . . which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." 15 U.S.C. 1261(g). The Commission has issued a regulation at 16 CFR 1500.3(c), which supplements the statutory definition of "toxic" based on the outcome of any of the approved test methods described in CPSC's animal testing policy set forth at 16 CFR 1500.232. This definition also includes chronic toxicity and states that a substance is toxic if it presents a chronic hazard, if it is a known or probable human carcinogen, neurotoxin, or developmental or reproductive toxicant.

Under the FHSA, an article that is intended, or packaged in a form suitable for household use and meets the definition of "hazardous substance" is a "misbranded hazardous substance"

unless its packaging or labeling warns of the hazard in accordance with the requirements of section 2(p). 15 U.S.C. 1261(p). Thus, cautionary statements are required for household substances meeting the definition of "hazardous substance" under the FHSA, whether the hazard is acute or chronic.

IV. Staff's Review of Toxicity and Incident Data

A. Acute Toxicity Data

CPSC staff reviewed relevant data to evaluate the acute toxicity risk to consumers from using DCM-containing products in residential settings. Staff's petition briefing package provided detailed information about staff's review. (https://www.cpsc.gov/s3fs-public/RCA%20-%20Petition%20HP%2016-1%20Labeling%20of%20Household%20Products%20Containing%20Methylene%20Chloride%20082316.pdf).

DCM is a highly volatile, colorless, organic substance used as a solvent in a variety of consumer and commercial products, including paint strippers, adhesives and adhesive removers, spray paint, spray shoe polish, and cleaners. DCM's high volatility makes inhalation its primary route of exposure.[1] The acute toxicity risks for consumers using DCM-based products in residential settings range from upper respiratory, ocular and dermal irritation, to severe effects, such as respiratory suppression, loss of consciousness, and death.[2] Both consumer and worker deaths have been attributed to scenarios where the individuals were working alone in an enclosed and/or poorly ventilated space (*e.g.*, bathrooms, basements, sheds) without respiratory protection.

[1] ATSDR. 2000a. TOXICOLOGICAL PROFILE FOR METHYLENE CHLORIDE. 3.13; CDC. 2012. Fatal Exposure to Methylene Chloride Among Bathtub Refinishers—United States, 2000-2011. *MMWR.* 61:4; EPA. 2014. TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. *EPA Document # 740-R1-4003.* August 2014:279.

[2] EPA. 2009. INTERIM ACUTE EXPOSURE GUIDELINE LEVELS (AEGLs) for METHYLENE CHLORIDE. Interim 1: 12/2008:110.

The toxic effects are from DCM as well as carbon monoxide (CO), which is a metabolite of DCM. Bystanders are also at risk of acute health effects while in the home when paint strippers and similar DCM-based products are being applied.[3]

The primary route of exposure for DCM is inhalation; however, DCM can readily be absorbed through dermal (skin) contact as well. To protect against skin absorption, butyl rubber or polyvinyl alcohol gloves must be worn because latex gloves will not protect against skin absorption.[4] DCM should only be used in a well-ventilated area. In 2013, CPSC staff developed a pamphlet concerning paint strippers which provides guidance to consumers on ventilation practices when they use DCM-containing paint strippers. The CPSC pamphlet recommends that paint-stripping work be done professionally if the work area has low-ventilation conditions.[5] The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) indicates in its hazard alerts that bathroom fans and/or open windows do not provide adequate ventilation when using these paint strippers in an enclosed space, such as a bathroom.[6] Inhalation exposure to as little as six ounces is sufficient to cause death.[7] While working with DCM, consumers and workers must use respiratory protective equipment, such as tight-fitting, full-face, self-contained supplied-air respirators or gas masks with vapor canisters, to reduce exposure.[8] Because DCM vapors are heavier than air, they can remain in the work area and become very hazardous to users. For example, if using a DCM-containing paint stripper to

[3] EPA, 2014.
[4] CDC, 2012. CPSC. 1987b. Statement of Policy for Methylene Chloride. FindLaw; IRIS, 2011.
[5] CPSC, 2013. What You Should Know About Using Paint Strippers. 423.
[6] OSHA, 2013. Hazard Alert. "Methylene Chloride Hazards for Bathtub Refinishers"; OSHA, 2016. FATAL Facts, Ho. 13-2016, "Lethal Exposure to Methylene Chloride during Bathtub Refinishing."
[7] OSHA, 2013.
[8] OSHA DCM regulations, 29 C.F.R. § 1910.1052, require employers to supply employees with respirators, and require employees to use the respirator when exposures are likely to exceed the regulatory limits.

renovate a bathtub, inhalation exposure could occur due to the vapors remaining in the bathtub after application.[9] This exposure may lead to death if proper precautions, such as protective equipment and ventilation, are not used.[10] To obtain adequate ventilation, use a qualified occupational health and safety specialist to assist in designing and installing local exhaust ventilation to effectively control vapors to below applicable personal exposure levels.

B. Incident Data

Staff searched CPSC databases for information about incidents reported to CPSC associated with DCM-based paint strippers and other household products containing DCM. Staff also searched the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS).

Between January 1, 2000 and November 30, 2017, there were 30 incidents associated with household products containing or likely containing DCM reported to CPSC by December 5, 2017. The majority of the incidents (28) were associated with paint strippers; one incident was associated with an unspecified solvent; and one incident was associated with a sealant. The incident reports mentioned fumes, inhalations, skin and lung irritation, leaking, and spilling. Based on information provided by consumers, 17 incidents were associated with DCM-based household products (the incidents either mentioned DCM or provided the product SKU# that allowed CPSC staff to identify a DCM-based product). Thirteen incident reports named paint strippers containing DCM.[11] CPSC staff determined that these incidents are likely associated with DCM-based paint strippers. Among the 30 reported incidents, there were 6 fatalities, 1

[9] CDC, 2012.
[10] ATSDR, 2000b; CDC, 2012; EPA, 2014.
[11] California Department of Public Health, "Guide to choosing paint stripping products: Safety considerations" http://www.cdph.ca.gov/programs/hesis/Documents/Paint-Removal-Methods.pdf

hospital admission, 1 emergency department visit, 15 injuries/adverse health problems, 4 non-injury incidents, and 3 incidents without enough information to determine whether an injury occurred.

CPSC staff is aware of six deaths involving DCM-based products[12] that occurred between January 1, 2000, and November 30, 2017. The victims were males between 45 and 80 years old. In most of the cases (5 deaths), CPSC staff was not able determine whether the incidents were associated with a consumer or a worker. These fatal incidents are described in more detail in the petition briefing package. The Commission has since learned of an incident that occurred in October 2017, in Charleston, SC, involving a paint stripper, which resulted in death from acute DCM and methanol toxicity. This case is still under investigation to determine whether it is a consumer or worker incident.

In 2002, a 64-year-old male fell into a tank of paint stripper at work. The paint stripper contained DCM. The cause of death was recorded as a cardiac arrest and respiratory toxicity. Although this case is a work-related incident, and therefore, not within CPSC's jurisdiction, the case, nonetheless, indicates the potential hazard of the product. Another incident that occurred in 2002 involved a 52-year-old male. He died as a consequence of inhaling fumes from a DCM-based solvent in a bathroom. In 2007, a 45-year-old male died after inhaling paint remover fumes during a bathroom renovation. The cause of death was determined to be asphyxia due to inhaling DCM. In 2013, an 80-year-old male died after inhaling DCM fumes while using a paint stripper in a shed. Also reported in 2013, a 50-year-old male died after inhaling DCM fumes while stripping an apartment's bathroom. In 2016, a 48-year-old male was sealing bathroom

[12] These DCM-based products included four paint removers, one unspecified solvent, and one sealer.

shower tiles with a DCM-based sealer in a bathroom. He died as a consequence of asphyxiation from exposure to toxic DCM fumes.

VI. Labeling Paint Strippers Containing Methylene Chloride

This section contains guidance on minimum recommendations for how the acute and chronic health risks of DCM use could be conveyed in the Principal Display Panel (PDP) and the back or other panel to effectively inform consumers and motivate their safe use of paint stripping products containing DCM.

Currently, there are few suitable alternatives to DCM, and protective measures, such as moving products outdoors to apply the stripper can be inconvenient. Providing warning information does not prevent consumer exposure to hazards, but instead, relies upon persuading consumers to alter their behavior in some way to avoid the hazard. In addition, warnings research demonstrates that even small inconveniences to the consumer can have a substantial negative effect on behavioral compliance with a warning.[13] Therefore, it is imperative that warning labels are formatted and contain information so that they are likely to be noticed, read, understood, and heeded.

A. General Principles of Warning Labels

1. Format of Warning Label

Research has shown that warning information is more effective when it is conspicuous.[14] Repetition with variation and consistent reinforcement can increase the effectiveness of

[13] Ayres T.J., Gross M.M., Wood C.T., Horst D.P, Beyer R.R., & Robinson J.N. (1989). What is a Warning and When Will it Work? *Proceedings of the Human Factors Society Annual Meeting,* 33. 426-430; Riley, D.M. (2006). Beliefs, Attitudes, and Motivation. In M.S. Wogalter (Ed.), *Handbook of Warnings* (pp. 289-300). Mahwah, NJ: Lawrence Erlbaum Associates.

[14] Wogalter, M.S., DeJoy, D., & Laughery, K.R. (Eds.). (1999). *Warnings and risk communication.* Philadelphia, PA: Taylor & Francis.

messages.[15] Strategic use of capitalization, bolding, underlining, and other forms of highlighting information can steer the consumer's attention to the most pertinent information by making it stand out from the surrounding text. [16]

2. Order of Safety Information

Experts in the communication of safety information agree that associated hazards and symptoms should be mentioned from most-to-least severe.[17] Research indicates that many consumers will only read as much of the safety information as they think they have to read and only if the rewards meet or exceed the efforts.[18] If lesser hazards and symptoms of overexposure to DCM precede more severe hazards and symptoms on the label, then the consumer might stop reading the label before reaching the more severe hazards and symptoms. Mentioning lethality of vapor inhalation at the start raises the likelihood that the consumer is informed of the possibility of death. By highlighting the pertinent information and beginning with the risk of death, the warning information is more apt to prove to the consumer that the warning contains useful information, and is, thereby, more likely to be read in its entirety. Furthermore, the Commission believes that if lesser symptoms of overexposure were to precede more severe symptoms on the warning labels, then consumers may expect lesser symptoms to happen before more severe symptoms present, which may not be the case. For example, if consumers read that DCM inhalation can cause nausea and dizziness, before reading that DCM can cause death, consumers may infer, incorrectly, that they will not be killed by the product without first exhibiting nausea or dizziness. Presenting effects of overexposure from most to least severe,

[15] Food and Drug Administration. (2011). *Communicating risks and benefits: An evidence-based user's guide* (DHHS). B. Fischhoff, N.T. Brewer & J.S.Downs (Eds.).
[16] Wogalter, M.S., Conzola, V.C., & Smith-Jackson, T.L. (2002). Research-based guidelines for warning design and evaluation. *Applied Ergonomics, 33,* 219-230.
[17] Wogalter et al., 1999.
[18] Robinson, 2009; Schriver, 1997.

along with stating that symptoms may not be noticeable, helps to dispel the false expectation that the way the consumer is using the DCM-containing paint stripper is safe, or that the consumer can use it in an unsafe manner, until s/he notices lesser symptoms of overexposure.

3. Warning Label Comprehension

It is important for warning information not only to be noticed and read, but also understood. Warnings should be free of ambiguity to better ensure that the intended message is received and not easily misinterpreted.[19] For example, the phrase "adequate ventilation" is ambiguous and can encourage inappropriate methods of circumvention; from "adequate ventilation" the consumer may infer that any addition of ventilation to the application area, such as opening a window, will be sufficient to make the product safe for indoor use. Such an inference can lead to overexposure to DCM-containing vapors, potentially resulting in death. Similarly, unclear wording, such as, "use in enclosed areas may kill you," carries the risk of being misread as simply, "use in enclosed areas," because the word "use" in this context can be read as a verb, such as "use this product," rather than read as a noun, such as "use of this product," and because the consumer may stop reading the statement before reaching "may kill you."

To increase the likelihood of consumers heeding a warning despite inconveniences imposed by necessary precautions, the phrasing of warning information should be vivid and relatable.[20] The Commission recommends using the phrase "can kill you," as opposed to wording like: "may cause death." These phrases have the same denotation; however, the impact on the reader can be different in meaningful ways. The Commission believes lethality is more

[19]Wogalter et al., 1999.

[20] Murray-Johnson, L., & Witte, K. (2003). Looking toward the future: Health message design strategies. In T.L. Thompson, A. Dorsey, K.I. Miller, & R. Parrot (Eds.), *Handbook of health communication* (pp.473-495). New York City, NY: Routledge.

salient with the statement "can kill you" because it is more personalized, directing the hazard toward the user, rather than as a possibility for users, in general. Evidence suggests that emotional communications, especially those that are fear-based, can be used to increase risk perceptions and change behaviors; and stronger fear-arousing conditions may lead to greater message acceptance.[21]

4. Effect of Consumer Experience with Product

Warning information can be formatted in a way that is noticeable, more likely to be read, understood, and motivating, and yet remain unheeded. Research indicates that consumers who are familiar or experienced with a product are less likely to search for and comply with warnings.[22] Paint strippers containing DCM have been around for decades, and incident data show that these products are sometimes applied indoors, such as in bathrooms, basements, and closets. The Commission believes that it is foreseeable that some consumers will continue to use these products indoors, despite warnings against using them in enclosed areas because of past incident-free experience with indoor use of stripping products containing DCM. Therefore, the Commission suggests including precautions for indoor use as well. However, because providing precautions for indoor use may mislead some consumers to believe it is safe to use DCM-based products indoors, the Commission recommends that the language and format of the safety information clarify that use in enclosed areas is dangerous, even with precautions, and should be avoided, if possible. The examples provided specify that indoor use is dangerous, and they employ repetition and capitalization to reinforce the point that paint-stripping products containing DCM should be used outdoors in open air areas.

B. Principal Display Panel (PDP) Minimum Labeling Recommendations

[21] Food and Drug Administration, 2011.
[22] Wogalter et al., 1999.

This section provides recommendations for labeling paint stripping products that contain methylene chloride. The following minimum labeling recommendations for the PDP meet the requirements of the FHSA. There are wide variations in the concentrations of methylene chloride in paint strippers. The precise labeling used may vary based on DCM concentration, anticipated duration of exposure, and other associated hazards.

The labels for all products subject to the FHSA are expected to comply with the requirements for prominence, placement, and conspicuousness of labeling required by section 2(p)(1) of the FHSA. The FHSA provides that required labeling statements may be placed on the PDP, or front panel, on the immediate container, and, if appropriate, on any other container or wrapper. The appropriate signal word (*i.e.,* "DANGER," "WARNING," or "CAUTION) and the statement of principal hazard[s] are required to be on the PDP. The other items of required labeling may be placed on some other display panel on the container, provided that the front panel contains the statement: "Read carefully other cautions on the [other display] panel," or its practical equivalent.

- The Commission recommends "WARNING" as the signal word for the label. Given cases of lethal exposure to DCM in household products, the Commission considered the signal word "DANGER"; however, the current DCM toxicity data do not meet the FHSA definition of "highly toxic," which is required for use of the the signal word "DANGER."
- When providing affirmative statements of all principal hazards, the Commission recommends stating: "INHALATION OF VAPOR VERY HARMFUL," followed by: "VAPOR CAN KILL YOU IN ENCLOSED AREAS."

Example from 1987 Statement of Cautionary Labeling to Be Included on the PDP[23]

[23] Given the previously limited data on the acute toxicity of overexposure to DCM, the Commission

In 1987, the Steering Committee for Methylene Chloride, a group of industry and consumer-interest representatives working with Commission staff, recommended the following labeling for the PDP for products, such as some paint strippers that contain high percentages of DCM:

CAUTION: Vapor Harmful, Read Other Cautions and HEALTH HAZARD INFORMATION on Back Panel

In the 1987 Statement, the Commission presented this labeling for the PDP as an example that would meet or exceed the minimum requirements of the FHSA.

Updated Example of Cautionary Labeling

In recognition of updated data on acute health risks of DCM use, the Commission recommends replacing the 1987 example of cautionary labeling to be included on the PDP with the information and format below:

WARNING: INHALATION OF VAPOR VERY HARMFUL
VAPOR CAN KILL YOU IN ENCLOSED AREAS
EYE AND SKIN IRRITANT. Read All Cautions on Back/Side Panel.

The format in the updated PDP example uses capital letters, repetition, and personalized language to draw attention to the most severe hazard: death from inhalation of vapor in enclosed areas. The repetition of "vapor" between the first and second lines aids in communicating the source and medium by which the hazard presents itself. The inclusion of "vapor very harmful" satisfies the declaration of both the acute and the chronic hazard. When a chronic hazard exists, the additional risk of cancer should be included on the back or other panel, as appropriate under

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believed this labeling to meet, and in certain respects exceed, the minimum requirements of section 2(p)(1) of the FHSA.

the FHSA. The last line directs the consumer to the back or other panel, which provides detailed precautionary information.

C. Back or Other Panel

1. Back or Other Panel Minimum Labeling Recommendations

The Commission recommends the following information and formatting for the back or other panel of paint stripping products containing DCM. These recommendations cover both acute and chronic hazards. Again, the statements may vary based on the concentration of DCM, anticipated duration of exposure, and other associated hazards.

- The Commission recommends use of "WARNING" as the signal word for the label.
- The Commission recommends beginning the precautionary information by stating, in all capital letters, the lethality of vapor inhalation and not to use the product in enclosed areas.
- The FHSA requires disclosure of all principal hazards. The Commission recommends disclosing the acute and chronic hazards from most-to-least severe. Similarly, when symptoms are mentioned, the Commission recommends it would be most effective to state symptoms from most-to-least severe.
- Because overexposure to DCM may be sudden and can inhibit the user's capability to notice and react to the effects, the Commission recommends indicating in all capital letters that symptoms may not be noticeable.
- The Commission recommends separating precautionary statements by bullet points, if paragraph formatting is used, to aid visual distinction between precautions.[24]

[24] See the "Recommended Language Approved by Ad Hoc Task Group, Revision C" document dated November 10, 2017, published in the "Committee Documents" section of the Committee F15 ASTM

- The Commission believes it will be helpful to provide specific examples of spaces in which the product should not be used, beginning with bathrooms, basements, and closets because these locations are particularly dangerous and have been cited in incident data.
- When indicating precautions to be taken, the Commission recommends stating in all capital letters that the product should be used outdoors in an open-air area.
- The Commission recommends including precautionary information for indoor use, accompanied by language stating that indoor use is dangerous even when precautions are taken.
- The Commission recommends prohibiting foreseeable inappropriate actions, such as use of a dust mask to provide protection against vapors.[25]
- When providing instructions for first-aid, the Commission recommends listing in order of the likelihood of occurrence, the types of exposures and placing each exposure route on a separate line to aid DCM users in an urgent situation.

2. Example of Updated Safety Information to Be Included on the Back or Other Panel

In recognition of updated data on acute health risks of DCM use, the Commission recommends replacing the 1987 example of labeling to be included on the back or other panel, with the information and format below:

> **WARNING** Contains Methylene Chloride. INHALATION OF VAPOR CAN KILL YOU. DO NOT USE IN ENCLOSED AREAS, such as bathrooms, basements, or closets. SYMPTOMS MAY NOT BE NOTICEABLE. ▪Avoid contact with eyes or skin, as severe irritation can occur. ▪Methylene Chloride may cause cancer. ▪The risk to your health depends on the level and duration of exposure. ▪Keep out of the reach of children.

website.

[25] A dust mask does not provide effective protection against overexposure to vapors containing DCM.

SAFETY DIRECTIONS: ▪USE OUTDOORS IN AN OPEN AIR AREA. It is dangerous to use this product indoors. ▪If you must use indoors, cross-ventilate work area by opening all windows and doors and circulating fresh air through the work area to reduce vapor accumulation. ▪Always wear chemical-splash goggles and chemical-resistant gloves when handling this product. ▪A dust mask does not provide protection against the vapors.

FIRST-AID:

- INHALATION: First move person to fresh air. If not breathing, give artificial respiration. Call 911, or poison control center, or emergency room.
- EYE EXPOSURE: Immediately flush affected eye(s) with water. Call 911, or poison control center, or emergency room, as soon as possible.
- SKIN EXPOSURE: Immediately wash skin with soap and water. Avoid spreading material on unaffected skin. Remove contaminated clothing and shoes, and thoroughly clean before reuse. Contact medical professional for advice.
- IF SWALLOWED: IMMEDIATELY call 911, or poison control center, or emergency room. Do NOT induce vomiting, unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

In the preceding updated back or other panel example, the most important safety information is capitalized to attract the consumer's attention; *i.e.*, if the consumer only reads the capitalized words, his/her focus is drawn to the following information: inhaling the vapor can be deadly; the product should not be used in enclosed areas; symptoms of overexposure may go unnoticed; and the product should be used outdoors. Bullet points are used to aid visual distinctions among precautions. The presentation of the hazards from most-to-least severe, coupled with the statement that symptoms may go unnoticed, helps to dismiss the false expectation that the consumer can wait for noticeable symptoms before taking appropriate precautions or escaping from a potentially lethal-use scenario. Steps for inhibiting vapor accumulation indoors are included in the back or other panel, subsequent to reiteration that household products containing DCM should be used outdoors and that indoor use is dangerous.

The instructions for first-aid are adapted from OSHA's Chemical Database.[26] The instructions are listed in order of the likelihood of exposure route per incident data. Types of exposure are capitalized and addressed on separate lines for ease of access to the information in a hurried state. The company's toll-free number is provided for consumers to seek more information about appropriate use and first-aid.

VIII. Implementation of this Guidance

In this update of the 1987 Statement, the Commission provides guidance to industry on determining the appropriate cautionary labeling for paint-stripping products that contain DCM. This guidance also provides examples of statements to convey the hazards associated with the product. This guidance does not set forth language for particular products; nor does it specify placement of this language. However, this notice does provide guidance on the factors to consider in developing the cautionary statements, and it gives examples that satisfy the FHSA. The level of hazard varies, based on the formulation of the product, the concentration of DCM, and the customary and reasonably foreseeable use of the product. If a paint stripper containing methylene chloride does not appear to be labeled appropriately, Commission staff will provide guidance to firms and assist firms with labeling their products.

Under the FHSA, manufacturers are responsible for determining whether their methylene chloride-containing products meet the definition of a "hazardous substance," and bear the appropriate cautionary statements. This determination is based on the concentration of methylene chloride, the use of the product, and whether the product presents a significant exposure to methylene chloride vapor with customary and reasonably foreseeable use. This update of the 1987 Statement provides guidance to manufacturers who must determine the

[26] OSHA Occupational Chemical Database for Methylene Chloride: https://www.osha.gov/chemicaldata/chemResult.html?recNo=572, accessed on December 8, 2017.

appropriate labeling for their paint stripper products that contain methylene chloride. In any enforcement action, Commission staff would consider on a case-by-case basis whether the product's labeling meets the requirements of the FHSA.

IX. Effect on State and Local Laws

Section 18(b)(1)(A) of the FHSA provides:

> (b)(1)(A) Except as provided in paragraphs (2) and (3) [15 U.S.C. 1261n], if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b).

15 U.S.C. 1261n. As mentioned, this document provides guidance to industry. This guidance does not have binding legal force, does not constitute a rule, and thus, does not have preemptive effect. However, the underlying duty to label a hazardous household product arises from the FHSA. This underlying statutory obligation preempts state and local non-identical cautionary labeling requirements that are designed to protect against the same risk of injury or illness.

Dated: _____

_____

Alberta E. Mills,
Secretary,
Consumer Product Safety Commission

U.S. Consumer Product Safety Commission

Staff Briefing Package

Update to Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride; Supplemental Guidance

March 7, 2018

For further information contact:
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ACKNOWLEDGMENTS

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Executive Summary

On July 7, 2016, the Halogenated Solvents Industry Alliance (HSIA) petitioned the U.S. Consumer Product Safety Commission (CPSC or Commission) to amend its 1987 Statement of Interpretation and Enforcement Policy (1987 Statement) regarding labeling of household products containing methylene chloride (dichloromethane; DCM) issued by the Commission under the Federal Hazardous Substances Act (FHSA). The petitioners asked CPSC to issue a revised Statement to recognize the acute hazard posed by using household products containing DCM in enclosed spaces with inadequate ventilation.

The Office of the General Counsel docketed the request as a petition, HP 16-1. The Commission published a request for public comment on this Petition in the *Federal Register* on September 1, 2016, and the comment period ended on October 31, 2016. (80 FR 50238). The Commission received a total of four comments.

On June 2, 2017, the Commission voted unanimously (5-0) to grant the petition (HP 16-1) and direct CPSC staff to draft a policy statement that addresses labeling for acute hazards from inhaling methylene chloride vapors from paint strippers. The petition briefing package discussed the acute toxicity risks from exposure to DCM; provided background information about Compliance staff's enforcement activities and communications with HSIA regarding the labeling of household products containing DCM; described the market for DCM-based products; and determined that costs to producers of DCM-based products to change the labels on the products were likely to be minimal. The link to the previous briefing package can be found in Appendix B.

For this briefing package, Epidemiology staff searched CPSC databases (CPSRMS and NEISS) within the period January 1, 2000 through November 30, 2017. Epidemiology staff found 30 reports in the CPSC databases associated with DCM-based household products. Six of these reports involved deaths associated with the DCM-containing products. The products identified in the incident reports could be purchased as consumer products, but CPSC staff is uncertain whether the reported deaths resulted from consumer or occupational exposures.

In the current briefing memorandum, staff provides draft language to update the 1987 Statement, as directed by the Commission. The draft language adds labeling elements for acute hazards, including the possibility of death, and the existing chronic hazards indicated for this product are retained.

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

This document has been electronically approved and signed.

Memorandum

March 7, 2018

TO : The Commission
Alberta Mills, Secretary

THROUGH : Patricia M. Hanz, General Counsel
Patricia H. Adkins, Executive Director
DeWane Ray, Deputy Executive Director for Safety Operations

FROM : George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction

John D. Gordon, Ph.D., Project Manager
Directorate for Health Sciences

SUBJECT : Update to Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride[1]

I. Introduction

The U.S. Consumer Product Safety Commission (CPSC) regulates hazardous household substances under the Federal Hazardous Substances Act (FHSA). Cautionary statements are required for household substances meeting the definition of "toxic" under the FHSA, whether the toxicity is acute or chronic. The Consumer Federation of America petitioned The Commission in 1985 to declare household products containing dichloromethane (DCM; also methylene chloride): (1) a hazardous substance, and (2) a banned hazardous substance (HP 85-1). In 1986, the Commission issued a proposed rule to declare household products containing more than contaminant levels of DCM to be "hazardous substances" under the FHSA (51 FR 29778). After considering the comments on the proposed rule, the Commission determined that a rule to declare DCM a hazardous substance was not warranted. Therefore, in 1987, the Commission issued a Statement of Interpretation and Enforcement Policy (1987 Statement) (52 FR 34698) advising that the FHSA requires that manufacturers of consumer products containing DCM have

[1] This report has been prepared by the CPSC staff; it has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

a responsibility to label the products appropriately, if those products can expose consumers to significant amounts of DCM vapor. Appropriate labeling may include warning of the cancer risk from inhalation exposure. The 1987 Statement does not specify cautionary statements for particular products; nor does it specify placement of cautionary statements. However, the 1987 Statement does provide guidance on the factors to consider in developing the cautionary statements and the requirements under the FHSA.

DCM's high volatility makes inhalation its primary route of exposure; however, DCM can readily be absorbed through dermal (skin) contact, as well (Appendix B, Tab C). The acute toxicity risks for consumers using DCM-based products in residential settings range from upper respiratory, ocular, and dermal irritation, to severe effects, such as respiratory suppression, loss of consciousness, and death. Consumers have access to DCM-containing consumer products, such as paint strippers, adhesive removers, sealants, grout sealers, cleaners, and automotive products, some of which are aerosols, (HPD, 2017), and these products can be used for do-it-yourself projects. The few documented deaths in peer-reviewed literature have been associated with DCM-containing products used for furniture and bathtub refinishing (see Appendix B, Tab C). Because DCM vapors are heavier than air, and the application is to a large surface area, vapors may remain in the work area and become very hazardous to users. Therefore, DCM should only be used in a well-ventilated area. Exposure to DCM vapors may lead to death, if proper precautions, such as protective clothing and equipment, respiratory protection, and adequate ventilation, like local exhaust ventilation,[1] are not used.

DCM is used in a variety of consumer products, and its largest market for consumer use is in paint strippers, which contain 25 to 100 percent DCM by weight. Staff concludes that costs to producers of DCM-based products related to revising the labels are likely to be minimal (Appendix B, Tab E).

From January 1, 2000 through November 30, 2017, six fatalities from the acute effects of DCM have been reported (CPSC, 2017; Stewart, 1976; CDC, 2012; EPA, 2009; Iowa, 2012). These fatalities resulted from using DCM-containing paint strippers without adequate ventilation while refinishing bathtubs. The fatalities included both occupational and consumer exposures, although it is not always known whether the victim was a consumer or a worker. However, we are aware that a 13-year-old child and an 18-year-old worker died from exposure to DCM.

On July 7, 2016, the Halogenated Solvents Industry Alliance (HSIA) petitioned (HSIA, 2016) the CPSC to amend its Statement regarding labeling of household products containing DCM issued by the Commission under the FHSA. The petitioners requested that the CPSC issue a revised statement to recognize the acute hazard posed by the use of paint strippers containing DCM in enclosed spaces with inadequate ventilation.

CPSC staff prepared a briefing package in response to the petition and submitted the package to the Commission on May 26, 2017. On June 2, 2017, the Commission voted unanimously (5-0) to grant the petition (HP 16-1) and directed CPSC staff to draft a policy statement that addresses labeling for acute hazards from inhalation of methylene chloride vapors.

[1] A bathroom fan and/or open windows are not sufficient ventilation.

As indicated in the May 2017 briefing package, the Environmental Protection Agency (EPA) has initiated rulemaking under section 6(a) of the Toxic Substances Control Act (TSCA) to address risks posed by DCM when used in paint and coating removal products. Specifically, EPA has issued a proposed rule that provides an assessment of the health hazards posed by DCM and that proposes to determine that DCM in these products presents an unreasonable risk of injury to health. Based on this determination, and after considering regulatory alternatives, EPA proposes to prohibit the manufacture (including import), processing, and distribution in commerce of DCM for all consumer and most commercial paint removal products, and to prohibit commercial use. 82 FR 7464 (Jan. 19, 2017). EPA's rulemaking would address both consumer and worker exposures to DCM used for paint and coating removal. While developing its rulemaking, EPA consulted with CPSC staff. In a June 2016 letter from the CPSC Executive Director to EPA, CPSC acknowledged that, because TSCA gives EPA the ability to reach both occupational and consumer uses, staff recognizes that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner because CPSC lacks the authority to address occupational hazards. Under EPA's rulemaking (if finalized as proposed), paint and coating removal products containing DCM would no longer be on the market for consumers or commercial workers, except in limited circumstances. Accordingly, staff believes that providing an update to the 1987 Statement would serve to provide more immediate guidance and clarity to industry and consumers regarding the acute hazards associated with the use of DCM-containing household products. Staff does not view updating the 1987 Statement as an indication that labeling will be sufficient to address all hazards that EPA seeks to address in its rulemaking.

This briefing package contains: (1) a Human Factors analysis of examples of appropriate labeling to address acute hazards from inhalation of methylene chloride vapors (TAB A); (2) an updated report of incidents associated with household products containing methylene chloride (TAB B); (3) an updated memorandum from the Office of Compliance (TAB C); and (4) a draft of the update to the 1987 Statement that provides guidance for labeling DCM-containing paint strippers to warn of acute hazards.

II. Background

Paint strippers are used to remove paint from a surface for refinishing. Paint strippers containing DCM are sold to consumers through most home and hardware/paint stores and are available from major online retailers in containers ranging in size from 1 quart to 5 gallons.

DCM is a highly volatile, colorless, organic substance used as a solvent in a variety of consumer and commercial products, including paint strippers, adhesives, adhesive removers, and cleaners. DCM's high volatility makes inhalation its primary route of exposure. The primary target organs for DCM toxicity are the lungs, liver, and brain. The acute toxicity risks for consumers using DCM-based products in residential settings range from upper respiratory, ocular and dermal

irritation, to more severe effects, such as respiratory suppression, loss of consciousness, and death.[1]

Using household products containing DCM in bathrooms, or other enclosed spaces, with little or no ventilation, can be dangerous because DCM is a volatile organic compound and will evaporate quickly when sprayed, brushed, or poured; this can cause a buildup of DCM vapors in a small space. In turn, this can create dangerously high concentrations of DCM, and in some cases, replace the breathable air.

III. Staff Assessment

Health Sciences Assessment

In the May 26, 2017, Staff Briefing Package, Health Sciences evaluated the acute toxicity risk associated with DCM. After extensive searches, staff found no new technical information to update the May 2017 memorandum. However, staff is aware of an incident in October 2017, in Charleston, SC, which resulted in death from acute DCM and methanol toxicity. CPSC staff has the consumer product safety data sheet and coroner's report. This case is still under investigation to determine whether it is a consumer or worker incident. We provide a brief summary of the key information below.

Health Sciences has determined that there is an acute toxicity risk for consumers using DCM-based products in residential settings. Acute health risks range from upper respiratory, ocular and dermal irritation, to severe effects, such as skin burns, respiratory suppression, loss of consciousness, and death. This toxicity results from the vapors produced by DCM. Health Sciences has further determined that DCM should be considered acutely toxic under the FHSA; however, it is not considered "highly toxic," based on human experience and the available animal test data. 16 C.F.R. §1500.3(b)(6). Both consumer and worker deaths have been attributed to scenarios where the individuals were working alone in an enclosed and/or poorly ventilated space (*e.g.*, bathrooms, basements, sheds) without respiratory protection. Bathroom fans and/or open windows do not provide adequate ventilation. CPSC staff agrees that use of DCM-containing paint strippers in enclosed spaces is hazardous, and that it may be very difficult to provide adequate ventilation in enclosed spaces like bathrooms. Therefore, the 1987 Statement should be updated to include this acute hazard in the labeling. Staff also recognizes that other household products containing DCM may also present acute hazards if used in an enclosed space with inadequate ventilation; and under the FHSA, firms are responsible for labeling their products accordingly.

More detailed information can be found in the original Health Sciences memo. See Appendix B Tab B of the petition briefing package.

[1] See Appendix B, Tab C.

Epidemiology Assessment

From January 1, 2000 through November 30, 2017, CPSC's CPSRMS and NEISS databases contained 30 reports associated with DCM-based household products. Most of these reports, 28 incidents, were associated with a paint stripper. These incidents mentioned inhalation, skin irritation, and lung irritation from leaking and spilling of DCM-based household products (see Tab B for an update from the 2017 briefing package). Of these 28 incidents, there were six reports of deaths associated with inhaling DCM from DCM-based household products; however, in some cases, staff could not determine whether the victim was a consumer or a worker.

The sample size was insufficient to obtain stable national estimates of injury/adverse health problems associated with DCM-based household products. (See Appendix B Tab D of the petition briefing package for the original Epidemiology memo).

Economic Analysis Assessment

Staff has not received additional information that would warrant updates to the original Economic Analysis Assessment memo from the petition briefing package presented in May 2017. Briefly, costs to producers of DCM-based products related to changing the labels on products are likely to be minimal. The costs of any changes to labels are amortized over the entire production run of the product, and on a per-unit basis, these label changes would represent a very small cost to manufacturers. Moreover, under the FHSA, manufacturers are responsible for properly labeling their products to reflect the associated hazards. The draft update to the 1987 Statement would merely provide guidance for labeling DCM products for the known acute hazards associated with inhaling methylene chloride vapors. Therefore, there should be little impact on industry. Updating the 1987 Statement would provide firms with guidance on how to comply with the FHSA labeling requirements, given CPSC's staff's understanding of the hazards associated with consumer use of DCM-based paint strippers in small, enclosed spaces with inadequate ventilation. Staff recognizes that proper labeling of hazards on consumer products allows consumers to make more informed choices concerning their use of products. Revising the 1987 Statement to include warnings on acute hazards is expected to help consumers adjust their use of DCM-based products to mitigate the risks to the extent that a warning label improves consumer understanding of the acute and chronic hazards associated with these products when used in enclosed spaces (Appendix B, Tab E).

Compliance and Regulatory Enforcement Assessment

Due to the reports of deaths from using DCM-containing paint strippers to strip bathtubs, CPSC staff believes updating the 1987 Statement's consumer warnings regarding the acute hazards is appropriate. (See Tab C for updated Compliance memo). See Appendix B Tab F of the petition briefing package for the original memo from Compliance.

Staff is aware that EPA is in the process of rulemaking to address the risks related to DCM in paint removal products. Compliance staff supports EPA in its efforts to address the risks associated with these DCM containing products. Updating the 1987 Statement would serve to provide clarity to consumers regarding the risks associated with DCM containing consumer products while EPA conducts its rulemaking.

Human Factors Assessment

A review of the incident data indicates that some consumers use household products containing DCM indoors, such as in bathrooms, basements, and closets (See Appendix A – Staff Briefing Package - Tab D, May 2017). Engineering Sciences Human Factors (ESHF) staff believes it is foreseeable that some consumers will likely continue to use these products indoors, despite warnings against use in enclosed areas. Therefore, CPSC staff concludes that precautions for indoor use should be included. ESHF staff cautions that providing instructions for indoor use may mislead some consumers to believe it is safe to use such products indoors. ESHF staff concludes that updating the language and format of the safety information should make it clear that use in enclosed areas is dangerous, even with precautions, and should be avoided if possible. The examples provided in the ESHF memorandum (Tab A) employ repetition to reinforce the point that household products containing DCM should be used outdoors in open air areas. The examples will include warnings about acute hazards on both the principal display panel and side or other panel.

Furthermore, the ESHF staff recognizes that the effectiveness of warning labels depends on user compliance. In addition to being clear and understandable, phrasing should be vivid and relatable to help motivate compliance.

IV. Staff Conclusions and Recommendations

Staff recommends that the Commission approve the update to the 1987 Statement regarding labeling of household products containing methylene chloride to address acute hazards from exposure to methylene chloride vapors provided in the Human factors memo (Tab A). Providing guidance on labeling paint strippers containing DCM with this acute hazard information will inform consumers about the risk of using these products in enclosed spaces and provide comprehensive compliance guidance to the industry on these products. Other household products containing DCM may also present acute hazards if used in an enclosed space. Under the FHSA, if a manufacturer determines that other household products containing DCM may present acute hazards, because, for instance, they are used in an enclosed space similar to paint strippers, the manufacturer has an obligation to label the product under section 2(p) of the FHSA.

V. References

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- Stewart, R.D.a.H., C.L. 1976. Paint-Remover Hazard. JAMA. 235:4.

- Household Products Database https://hpd.nlm.nih.gov/ Accessed 12/19/17

- Staff Briefing Package in Response to Petition HP16-1, Petition to Amend the Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride May 26, 2017.

Tab A: Directorate for Human Factors Memorandum

TAB A

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

Memorandum

Date: January 10, 2018

TO: John D. Gordon, Ph.D., Project Manager,
Division of Toxicology and Risk Assessment
Directorate for Health Sciences

THROUGH: Joel Recht, Ph.D., Associate Executive Director
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Division Director
Division of Human Factors
Directorate for Engineering Sciences

FROM : Stephen Harsanyi, Engineering Psychologist,
Division of Human Factors
Directorate for Engineering Sciences

SUBJECT: Labeling of Household Products Containing Methylene Chloride[1]

A. Introduction

The U.S. Consumer Product Safety Commission (CPSC; the Commission) voted to grant Petition HP 16-1 from the Halogenated Solvents Industry Alliance (HSIA). Petition HP 16-1 requested revision of the Commission's Statement of Interpretation and Enforcement Policy (52 Federal Register 34,698) to recognize the acute hazards posed by the use of paint stripping products containing methylene chloride (dichloromethane; DCM) in enclosed spaces with inadequate ventilation. In this memorandum, Engineering Sciences Human Factors (ESHF) staff provides guidance on the minimum recommendations for how the acute and chronic health risks of DCM use could be conveyed in the Principal Display Panel (PDP) and the side or other panel[2] to effectively inform consumers and motivate their safe use of paint stripping products containing DCM.

[1] This report was prepared by the CPSC staff; it has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.
[2] The PDP is generally the front panel of the product, and the side or other panel is generally the side or back panel.

B. Discussion

The format of warning information is critical to effectively communicate precautions and motivate safe practice. Warning information is a fallible means of protection because it does not prevent exposure of consumers to hazards; instead, it relies upon persuading consumers to alter their behavior in some way to avoid the hazard. Warnings research demonstrates that even small inconveniences on behalf of the consumer can have a substantial negative effect on behavioral compliance with a warning (Ayers et al., 1989; Riley, 2006). Currently, there are few suitable alternatives to DCM, and protective measures, such as moving products outdoors for application of the stripper, can be inconvenient. Therefore, it is imperative that warning labels are formatted in a way that is more likely to be noticed, read, understood, and heeded.

Research has shown that warning information is more effective when it is conspicuous (Wogalter, DeJoy, & Laughery, 1999). Repetition with variation and consistent reinforcement can increase the effectiveness of messages (Food and Drug Administration, 2011). Strategic use of capitalization, bolding, underlining, and other forms of highlighting information can steer the consumer's attention to the most pertinent information by making it stand out from the surrounding text (Wogalter, Conzola, & Smith-Jackson, 2002). Consequently, staff recommends capitalizing the following information in the side or other panel: "INHALATION OF VAPOR CAN KILL YOU"; "DO NOT USE IN ENCLOSED AREAS"; "SYMPTOMS MAY NOT BE NOTICEABLE"; and "USE OUTDOORS IN AN OPEN AIR AREA." Highlighting these points helps to ensure, at a minimum, that the consumer receives the most important information.

Experts in the communication of safety information agree that associated hazards and symptoms should be mentioned from most-to-least severe (Wogalter et al., 1999). Research has shown that many consumers will only read as much of the safety information as they think they have to read and only if the rewards meet or exceed the efforts (Robinson, 2009; Schriver, 1997). If lesser hazards and symptoms of overexposure to DCM precede more severe hazards and symptoms in the label, then the consumer might stop reading the label before reaching the more severe hazards and symptoms. Mentioning lethality of vapor inhalation at the start raises the likelihood that the consumer is informed of the possibility of death. Moreover, and it entices reading to prevent the risk of death. By highlighting the pertinent information and beginning with the risk of death, the warning information is more apt to prove to the consumer that the warning contains useful information, and is thereby, more likely to be read in its entirety. Furthermore, staff believes that if lesser symptoms of overexposure precede more severe symptoms in the warning labels, consumers may expect lesser symptoms to happen before more severe symptoms present, which may not be the case. For example, if the consumer reads that DCM inhalation can cause nausea and dizziness before reading that DCM can cause death, s/he may infer incorrectly that s/he will not be killed by the product without first exhibiting nausea or dizziness. Presenting effects of overexposure from most to least severe, along with stating that symptoms may not be noticeable, helps to dispel the false expectations that the way the consumer is using the DCM-containing paint stripper is safe, or that the consumer can use it in an unsafe manner, until s/he notices lesser symptoms of overexposure.

It is important for warning information to not only be noticed and read, but understood. Warnings should be free of ambiguity to better ensure the intended message is received and not easily misinterpreted (Wogalter et al., 1999). For example, the phrase "adequate ventilation" is

ambiguous and can encourage inappropriate methods of circumvention; "adequate ventilation" can be inferred by the consumer to indicate that any addition of ventilation to the application area, such as opening a window, will be sufficient to make the product safe for indoor use. Such an inference can lead to overexposure to DCM-containing vapor, potentially resulting in death. Similarly, unclear wording such as "use in enclosed areas may kill you," carries the risk of being misread as simply "use in enclosed areas," because the word "use" in this context can be read as a verb, such as "use this product," rather than as a noun, such as "use of this product," and because the consumer may stop reading the statement before reaching "may kill you."

To increase the likelihood of consumers heeding a warning despite inconveniences imposed by necessary precautions, phrasing of warning information should be vivid and relatable (Murray-Johnson & Witte, 2003). Staff recommends use of the phrase "can kill you" as opposed to wording such as "may cause death." These phrases have the same denotation; however, the impact on the reader can be different in meaningful ways. Staff believes lethality is more salient with the diction "can kill you," because it is more personalized, directing the hazard toward the user, rather than as a possibility for users in general. Evidence suggests that emotional communications, especially those that are fear-based, can be used to increase risk perceptions and change behaviors; and stronger fear-arousing conditions lead to greater message acceptance (Food and Drug Administration, 2011).

Warning information can be formatted in a way that is noticeable, more likely to be read, understood, and motivating, and yet remain unheeded. Research indicates that consumers who are familiar or experienced with a product are less likely to search for and comply with warnings (Wogalter et al., 1999). Paint strippers containing DCM have been around for decades, and incident data show that these products are sometimes applied indoors, such as in bathrooms, basements, and closets. Staff believes it is foreseeable that some consumers will continue to use these products indoors, despite warnings against use in enclosed areas, because of past incident-free experience with indoor use of stripping products containing DCM. Therefore, staff suggests including precautions for indoor use as well. However, because providing precautions for indoor use may mislead some consumers to believe it is safe to use DCM indoors, staff recommends that the language and format of the safety information clarify that use in enclosed areas is dangerous, even with precautions, and should be avoided, if possible. The suggestions in the proposed lists, and the examples below, specify that indoor use is dangerous, and employ repetition and capitalization to reinforce the point that paint-stripping products containing DCM should be used outdoors in open air areas.

C. Principal Display Panel (PDP)

PDP minimum labeling recommendations

> The following minimum labeling recommendations for the PDP complement the requirements of the Federal Hazardous Substances Act (FHSA) and may vary based on DCM concentration, anticipated duration of exposure, and other associated hazards. See section 2(p) of the FHSA (15 U.S.C. 1261(p)) for the FHSA requirements.

- Staff believes that "WARNING" is the appropriate signal word for the label. Given cases of lethal exposure to DCM in household products, staff considered the "DANGER" signal word; however, the current DCM toxicity data do not meet the FHSA definition of "highly toxic," which is required for use of the "Danger" signal word.
- When providing affirmative statements of all principal hazards, staff recommends stating: "INHALATION OF VAPOR VERY HARMFUL," followed by, "VAPOR CAN KILL YOU IN ENCLOSED AREAS."

1987 example of cautionary labeling to be included on the PDP[1]

In 1987, the Steering Committee for Methylene Chloride, a group of industry and consumer interest representatives working with the Commission's staff, recommended the following labeling for the PDP for products, such as some paint strippers that contain high percentages of DCM:

CAUTION: Vapor Harmful, Read Other
Cautions and HEALTH HAZARD
INFORMATION on Back Panel

2018 suggested example of cautionary labeling to be included on the PDP

In recognition of updated data on acute health risks of DCM use, staff recommends replacing the 1987 example of cautionary labeling to be included on the PDP with the information and format below:

WARNING: INHALATION OF VAPOR VERY HARMFUL
VAPOR CAN KILL YOU IN ENCLOSED AREAS
EYE AND SKIN IRRITANT. Read All Cautions on
Back/Side Panel.

The format in the 2018 suggested-PDP example uses capital letters, repetition, and personalized language to draw attention to the most severe hazard: death from inhalation of vapor in enclosed areas. The repetition of the word "vapor" between the first and second lines aids in communicating the source and medium by which the hazards are presented. The inclusion of "VAPOR VERY HARMFUL" satisfies the declaration of the chronic hazard, provided that the risk of cancer is clearly indicated in the side of other panel per FHSA requirements. The inclusion of "VAPOR CAN KILL YOU IN ENCLOSED AREAS" satisfies the declaration of the acute hazard. The last line directs the consumer to the side or other panel, which provides detailed precautionary information.

[1] Given the previously limited data on the acute toxicity of overexposure to DCM, the Commission believed this labeling to meet, and in certain respects exceed, the minimum requirements of section 2(p)(1) of the FHSA.

D. Side or Other Panel

Side or Other Panel minimum labeling recommendations

Staff recommends the following information and formatting for the side or other panel of paint stripping products containing DCM. The statements may vary based on the concentration of DCM, anticipated duration of exposure, and other associated hazards. See section 2(p) of the FHSA (15 U.S.C. 1261(p)) for the FHSA requirements.

- Staff believes that "WARNING" is the recommended signal word for the label.
- Staff recommends beginning the precautionary information by stating, in all capital letters, the lethality of vapor inhalation and do not use the product in enclosed areas.
- The FHSA requires disclosure of all principal hazards. Staff recommends disclosing all known acute and chronic hazards from most to least severe. Similarly, when symptoms are mentioned, staff recommends it would be most effective to state symptoms from most to least severe.
- As overexposure to DCM may be sudden and can inhibit the user's capability to notice and react to the effects, staff recommends indicating, in all capital letters, that symptoms may not be noticeable.
- Staff recommends separating precautionary statements by bullet points, if paragraph formatting is used, to aid visual discrimination between precautions.[1]
- Staff believes it will be helpful to provide specific examples of spaces in which the product should not be used, beginning with bathrooms, basements, and closets, because these locations are particularly dangerous and have been cited in incident data.
- When indicating precautions to be taken, staff recommends stating, in all capital letters, that the product should be used outdoors in an open air area.
- Staff recommends including precautionary information for indoor use, accompanied by language stating that indoor use is dangerous even when precautions are taken.
- Staff recommends prohibiting foreseeable inappropriate actions, such as use of a dust mask to provide protection against vapors.[2]
- When providing instructions for first aid, staff recommends listing in order of the likelihood of occurrence, the types of exposure and placing each exposure route on a separate line to aid DCM users in an urgent situation.

1987 example of safety information to be included on the Side or Other Panel[3]

In 1987, the Steering Committee for Methylene Chloride recommended the following labeling for the side or other panel for products, such as some paint strippers that contain high percentages of DCM:

[1] See the "Recommended Language Approved by Ad Hoc Task Group, Revision C" document dated November 10, 2017, published in the "Committee Documents" section of the Committee F15 ASTM website.
[2] A dust mask does not provide effective protection against overexposure to vapors containing DCM.
[3] This side or other panel example does not include all of the requirements of the FHSA, such as instructions for first-aid treatment.

Contains methylene chloride, which has been shown to cause cancer in certain laboratory animals. Risk to your health depends on level and duration of exposure.

Use this product outdoors, if possible. If you must use it indoors, open all windows and doors or use other means to ensure fresh air movement during application and drying. If properly used, a respirator may offer additional protection. Obtain professional advice before using. A dust mask does not provide protection against vapors. Do not use in basement or other unventilated area.

Open container carefully and close after each use. Clean up rags, papers, and waste promptly; allow solvent to evaporate, then dispose of in metal containers.

2018 example of safety information to be included on the Side or Other Panel

In recognition of updated data on acute health risks of DCM use, staff recommends replacing the 1987 example of labeling to be included on the side or other panel with the information and format below:

WARNING Contains Methylene Chloride. INHALATION OF VAPOR CAN KILL YOU. DO NOT USE IN ENCLOSED AREAS, such as bathrooms, basements, or closets. SYMPTOMS MAY NOT BE NOTICEABLE. ▪Avoid contact with eyes or skin, as severe irritation can occur. ▪Methylene Chloride may cause cancer. ▪The risk to your health depends on the level and duration of exposure. ▪Keep out of the reach of children.

SAFETY DIRECTIONS: ▪USE OUTDOORS IN AN OPEN AIR AREA. It is dangerous to use this product indoors. ▪If you must use indoors, cross-ventilate work area by opening all windows and doors and circulating fresh air through the work area to reduce vapor accumulation. ▪Always wear chemical-splash goggles and chemical-resistant gloves when handling this product. ▪A dust mask does not provide protection against the vapors.

FIRST-AID:

- INHALATION: First move person to fresh air. If not breathing, give artificial respiration. Call 911, or poison control center, or emergency room.
- EYE EXPOSURE: Immediately flush affected eye(s) with water. Call 911, or poison control center, or emergency room, as soon as possible.
- SKIN EXPOSURE: Immediately wash skin with soap and water. Avoid spreading material on unaffected skin. Remove contaminated clothing and shoes, and thoroughly clean before reuse. Contact medical professional for advice.
- IF SWALLOWED: IMMEDIATELY call 911, or poison control center, or emergency room. Do NOT induce vomiting, unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

In the 2018 proposed side or other panel example above, the most important safety information is capitalized to attract the consumer's attention; *i.e.,* if the consumer only reads the capitalized words, his/her focus is drawn to the following information: inhaling the vapor can be deadly, the product should not be used in enclosed areas, symptoms of overexposure may go unnoticed, and the product should be used outdoors. Bullet points are used to aid visual distinctions among precautions. The presentation of the hazards from most to least severe, coupled with the statement that symptoms may go unnoticed, helps to dismiss the false expectation that the consumer can wait for noticeable symptoms before taking appropriate precautions or escaping from a potentially lethal use scenario. Steps for inhibiting vapor accumulation indoors are included in the side or other panel, subsequent to reiteration that household products containing DCM should be used outdoors and that indoor use is dangerous. The instructions for first-aid are adapted from the Occupational Safety and Health Administration Occupational Chemical Database.[1] The instructions are listed in order of the likelihood of exposure route per incident data. Types of exposure are capitalized and addressed on separate lines for ease of access to the information in a hurried state. The company's toll-free number is provided for consumers to seek more information about appropriate use and first aid.

E. Conclusion

Warning label effectiveness depends on the consumer noticing, reading, understanding, and complying with the safety information. Staff believes the above suggestions for the wording and presentation of the PDP and side or other panel of paint strippers containing DCM can equip the industry in communicating better the acute and chronic hazards. By using language that is vivid, relatable, and free of ambiguity, and by highlighting the pertinent information, *e.g.,* with strategic use of capitalization, the safety information is more capable of capturing the reader's attention and motivating appropriate use.

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Tab B: Directorate for Epidemiology Memorandum

TAB B

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

Memorandum

Date: December 6, 2017

TO : John Gordon, Ph.D.
Project Manager
Division of Toxicology and Risk Assessment
Directorate for Health Sciences

THROUGH: Stephen Hanway, Division Director
Division of Hazard Analysis, Directorate for Epidemiology

FROM : Wioletta Szeszel-Fedorowicz, Ph.D.
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Reported Incidents Associated with Household Products Containing Methylene Chloride that occurred between January 1, 2000 and November 30, 2017[1]

A. Introduction

The Halogenated Solvents Industry Alliance, Inc. (HSIA) petitioned the Consumer Product Safety Commission (Petition HP 16-1) to amend the 1987 Statement of Interpretation and Enforcement Policy (1987 Statement) regarding the labeling of household products containing methylene chloride (dichloromethane; DCM) to address acute hazards from inhalation of methylene chloride vapors in addition to the chronic hazards addressed by the 1987 Statement. On June 2, 2017, the Commission voted unanimously to direct staff to draft a policy statement that addresses labeling for acute hazards from inhalation of methylene chloride vapors.

This memorandum provides information about incidents reported to CPSC associated with DCM-based paint removers (strippers) and other household products containing DCM that occurred between January 1, 2000 and November 30, 2017. For this memorandum, CPSC staff

[1] This analysis was prepared by CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

searched two CPSC databases: the Consumer Product Safety Risk Management System (CPSRMS) and the National Electronic Injury Surveillance System (NEISS).[1] Staff searched each database using product codes: 0972 (paint or varnish remover, paintbrush cleaners), 0833 (workshop compounds or chemicals), 0955 (automotive chemicals), 0960 (paint, varnishes and shellacs), 0978 (automotive waxes, polishes, or cleaners), 0984 (solvents, other or not specified) [2]. The keywords "DCM," "dichlo," "methy," "chloride" were used when searching databases for the incidents/injuries associated with the household products to narrow the search to in-scope incidents.

B. Review of Incident Data

Overview

Between January 1, 2000 and November 30, 2017, there were 30 incidents associated with household products containing or likely containing DCM, reported to CPSC by December 5, 2017. The majority of the incidents (28) were associated with paint removers, one incident was associated with an unspecified solvent, and one incident was associated with a sealant. The incident reports mentioned fumes, inhalations, skin and lung irritation, leaking, and spilling. Based on information provided by consumers, 17 incidents were associated with DCM-based household products (the incidents either mentioned DCM or provided the product SKU# that allowed CPSC staff to identify a DCM-based paint remover). Thirteen incident reports named paint removers containing DCM.[3] CPSC staff determined that these incidents are likely associated with DCM-based paint removers. Among the 30 reported incidents, there were: 6 fatalities, 1 hospital admission, 1 emergency department visit, 15 injuries/adverse health problems, 4 non-injury incidents, and 3 incidents that did not have enough information to determine if an injury occurred.

Deaths

CPSC staff is aware of six deaths involving DCM-based products that occurred between January 1, 2000 and November 30, 2017. The victims were males between 45 and 80 years old. In most cases (5 deaths), CPSC staff was not able determine whether the incidents were associated with a consumer or a worker. The fatal incidents are described in more detail below.

[1]The National Electronic Injury Surveillance System (NEISS), database contains the emergency department-treated injuries in a sample of hospitals nationwide. The Consumer Product Safety Risk Management System (CPSRMS) combines the data from IPII (Injury or Potential Injury Incidents), DTHS (Death Certificates), and INDP (In-Depth Investigations) into one searchable incident database.

[2]The product codes used in the search adhered to the products listed in the Directorate for Economic Analysis memorandum "Economic Analysis of Petition HP-16, Labeling of Household Products Containing Methylene Chloride".

[3]California Department of Public Health, "Guide to choosing paint stripping products: Safety considerations" http://www.cdph.ca.gov/programs/hesis/Documents/Paint-Removal-Methods.pdf

In 2002, a 64-year-old male fell into a tank of paint remover at work. The paint remover contained DCM. The cause of death was recorded as cardiac arrest and respiratory toxicity. Although this case involved a work-related incident, and therefore, was not within CPSC's jurisdiction, we included the report in the memorandum to help understand the potential hazard of the product. Another incident that occurred in 2002 involved a 52-year-old male. He died from inhaling fumes from a DCM-based solvent in a bathroom.

In 2007, a 45-year-old male died after inhaling paint remover fumes during a bathroom renovation. The cause of death was determined to be asphyxia from inhaling DCM.

There were two reports of fatal incidents associated with DCM-based paint removers in 2013. An 80-year-old male died after inhaling DCM fumes while using a paint remover in a shed. The second fatal report in 2013 involved a 50-year-old male, who died after inhaling DCM fumes while stripping an apartment bathroom.

In 2016, a 48-year-old male was sealing bathroom shower tiles with a DCM-based sealer. He died of asphyxia from toxic DCM fumes.

Injury Estimates

Due to insufficient sample size, CPSC could not obtain NEISS estimates of injuries associated with DCM-based household products.

C. Summary

Incident data

- Between January 1, 2000 and November 30, 2017, CPSC databases contained 30 reports associated with DCM-based products. Most of these reports, 28 incidents, were associated with a paint remover.

- The incidents mentioned inhalation, skin and lung irritation, leaking, and spilling DCM-based products.

- There were six reports of deaths associated with the inhalation of DCM from DCM-based products; however, in some cases, staff could determine whether the victim was a consumer or a worker.

Injury data

- The sample size was insufficient to obtain stable estimates of injury/adverse health problems associated with DCM-based household products.

Tab C: Directorate for Compliance Memorandum

TAB C

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

Memorandum

Date: January 5, 2018

TO: John Gordon, Ph.D., Project Manager,
Directorate for Health Sciences,
Division of Toxicology and Risk Assessment

THROUGH: Robert Kaye, Director, Office of Compliance and Field Operations
Mary Toro, Director, Division of Regulatory Enforcement, Office of Compliance and Field Operations
John Boja, Lead Compliance Officer, Regulated Chemicals, Office of Compliance and Field Operations

FROM : Carol Afflerbach, Senior Compliance Officer,
Office of Compliance and Field Operations

SUBJECT: Update to the Statement of Interpretation and Enforcement Policy Regarding Labeling of Household Products Containing Methylene Chloride[1]

A. Introduction

On July 7, 2016, the Halogenated Solvents Industry Alliance, Inc. (HSIA) petitioned the U.S. Consumer Product Safety Commission (CPSC or Commission) requesting that the Commission revise the agency's 1987 Statement of Interpretation and Enforcement Policy (Statement) for certain household products containing methylene chloride (DCM, *52 FR 34698 (September 14, 1987)* (Petition). The Statement provides guidance on the labeling for potential cancer hazards with DCM containing products. The Statement also provides examples of the labeling for certain products, such as some paint strippers containing DCM. The petitioner asked the Commission to revise the Statement to address the acute hazards from inhalation of DCM vapors in an enclosed space that lacks adequate ventilation, in addition to the cautionary labeling statements for chronic hazards that are addressed in the current Statement.

[1] This report has been prepared by the CPSC staff; it has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

On June 2, 2017, the Commission voted unanimously to direct staff to draft a policy statement that addresses labeling for acute hazards from inhalation of methylene chloride vapors when using paint strippers in an enclosed area.

B. Discussion

Following reports of deaths associated with using DCM-containing paint strippers to strip bathtubs, CPSC staff believes that a review of the 1987 Statement and an update to the 1987 Statement's warnings to consumers is appropriate.

In revising the Statement, the Commission is providing guidance about statements that are appropriate for warning users of acute hazards that are presented with paint strippers containing DCM when used in enclosed spaces with inadequate ventilation. Compliance staff agrees that adding the enhanced cautionary statements will increase clarity for consumers of the acute hazards posed by DCM-containing paint strippers when used in an enclosed space, such as a bathroom.

The Statement also provides guidance to industry in determining the appropriate cautionary labeling for household products and provides examples of appropriate statements to convey the hazards associated with a product. The Statement does not set forth language for particular products, nor does it specify placement of those statements. However, the Statement does provide guidance on the factors to consider in developing the cautionary statements, and it gives examples that satisfy the FHSA. The level of hazard varies, based on the formulation of the product, the concentration of DCM, and the customary and reasonably foreseeable use of the product. If a paint stripper containing methylene chloride does not appear to be labeled appropriately, Commission staff will provide guidance to firms and assist firms with labeling their products.

C. Administration of the Policy Statement

Under the FHSA, manufacturers are responsible for determining whether their methylene chloride-containing products meet the definition of a "hazardous substance." This determination is based on the concentration of methylene chloride, the use of the product, and whether the product presents a significant exposure to methylene chloride vapor with customary and reasonably foreseeable use. The revision to the Statement will provide additional guidance to manufacturers who must determine the appropriate labeling for their paint stripper products that contain methylene chloride.

Before undertaking enforcement action, Commission staff will give the manufacturer an informal opportunity to present evidence that a product is labeled appropriately for the risk presented with customary and reasonably foreseeable handling or use of the product. This case-by-case approach recognizes differences in the levels of risk presented by paint-stripper products containing methylene chloride, and likewise, it allows for fair administration of the update to the 1987 Statement.

Appendix

Appendix A: Petition to amend the Statement of Interpretation and Enforcement Policy regarding labeling of household products containing methylene chloride

PDF version of petition can be found here: https://www.cpsc.gov/s3fs-public/Petition%20HP%2016-1%20Labeling%20of%20Household%20Products%20Containing%20Methylene%20Chloride%20-%20July%207%2C%202016.pdf

Appendix B: Staff Briefing Package DCM Petition 042117

https://ecpsc.cpsc.gov/apps/6b/_layouts/15/WopiFrame.aspx?sourcedoc=/apps/6b/Section%206b%20Tracking/Staff%20Briefing%20Package%20DCM%20petition.docx&action=default&DefaultItemOpen=1