

smooth, appropriate to the phase of flight and type of maneuver, and not in conflict with the ability of the pilot to satisfactorily change airplane flight path, speed, or attitude as needed.

b. Limit values of protected flight parameters (and if applicable, associated warning thresholds) must be compatible with the following:

i. Airplane structural limits,
ii. Required safe and controllable maneuvering of the airplane, and
iii. Margins to critical conditions. Unsafe flight characteristics/conditions must not result if dynamic maneuvering, airframe and system tolerances (both manufacturing and in-service), and non-steady atmospheric conditions, in any appropriate combination and phase of flight, can produce a limited flight parameter beyond the nominal design-limit value.

c. The airplane must be responsive to intentional dynamic maneuvering to within a suitable range of the parameter limit. Dynamic characteristics such as damping and overshoot must also be appropriate for the flight maneuver and limit parameter in question.

d. When simultaneous envelope limiting is engaged, adverse coupling or adverse priority must not result.

Failure States

a. Electronic flight-control-system failures (including sensors) must not result in a condition where a parameter is limited to such a reduced value that safe and controllable maneuvering is no longer available.

b. The crew must be alerted by suitable means if any change in envelope limiting or maneuverability is produced by single or multiple failures of the electronic flight-control system not shown to be extremely improbable.

Issued in Des Moines, Washington, on March 15, 2018.

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

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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 document, 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 applicable on March 21, 2018.

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. 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 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

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.

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 CFR 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.

⁹ CDC, 2012.

¹⁰ ATSDR, 2000b; CDC, 2012; EPA, 2014.

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 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 products¹² 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 to 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 shower tiles with a DCM-based sealer in a bathroom. He died as a consequence of asphyxiation from exposure to toxic DCM fumes.

V. 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 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

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.

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.

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, 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

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>.

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

¹⁷ Wogalter et al., 1999.

¹⁸ Robinson, 2009; Schriver, 1997.

¹⁹ Wogalter et al., 1999.

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 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

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 PDP²³

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 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.

²³ 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.

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.

²¹ Food and Drug Administration, 2011.

²² Wogalter *et al.*, 1999.

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
- 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.

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.

VI. 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 document 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 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

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 website.

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

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

whether the product's labeling meets the requirements of the FHSA.

VII. Effect on State and Local Laws

In general, the preemption language in section 18(b)(1)(A) of the FHSA provides that if a hazardous substance or its packaging is subject to a cautionary labeling requirement under the FHSA 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 a hazardous substance or packaging that is designed to protect against the same risk of illness or injury, unless the cautionary labeling requirement is identical to the labeling requirement under the FHSA. 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.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 4

[Docket No. FDA-2008-N-0424]

Immediately in Effect Guidance for Industry; Compliance Policy for Combination Product Postmarketing Safety Reporting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of an immediately in effect guidance for industry entitled "Compliance Policy for Combination Product Postmarketing Safety Reporting." This guidance describes FDA's compliance policy for combination product applicants and constituent part applicants and activities under FDA regulations that

addresses combination product postmarketing safety reporting. This guidance is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 21, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2008-N-0424 for "Compliance Policy for Combination Product Postmarketing Safety Reporting." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Office of Combination