United States
Consumer Product Safety Commission

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Memorandum

TO: The Commission
Alberta E. Mills, Secretary

DATE: July 20, 2022

THROUGH: Austin C. Schlick, General Counsel
Jason Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel, Regulatory Affairs
David M. DiMatteo, Attorney, Regulatory Affairs

SUBJECT: Petition Requesting Rulemaking to Establish Safety Standard for Aerosol Duster Products (Petition CP 21-1)

BALLOT VOTE DUE: Tuesday, July 26, 2022

CPSC staff is forwarding to the Commission a briefing package regarding a petition for rulemaking submitted by Families United Against Inhalant Abuse. The petition requests that the Commission initiate rulemaking to adopt a mandatory CPSC safety standard to address the hazards associated with aerosol duster products containing the chemical 1,1-Difluoroethane or any derivative thereof. On June 29, 2021, the Commission published a *Federal Register* notice seeking comment on the petition. In the attached briefing package, staff recommends that the Commission defer the petition to allow staff further time to research issues related to the hazard identified in the petition.

Please indicate your vote on the following options:

I. Grant the petition, and direct staff to initiate rulemaking.

_____ _____
(Signature) (Date)

II. Defer the petition.

_____ _____
(Signature) (Date)

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

cpsc.gov

This memorandum was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

III. Deny the petition.

(Signature) (Date)

IV. Take other action specified below.

(Signature) (Date)

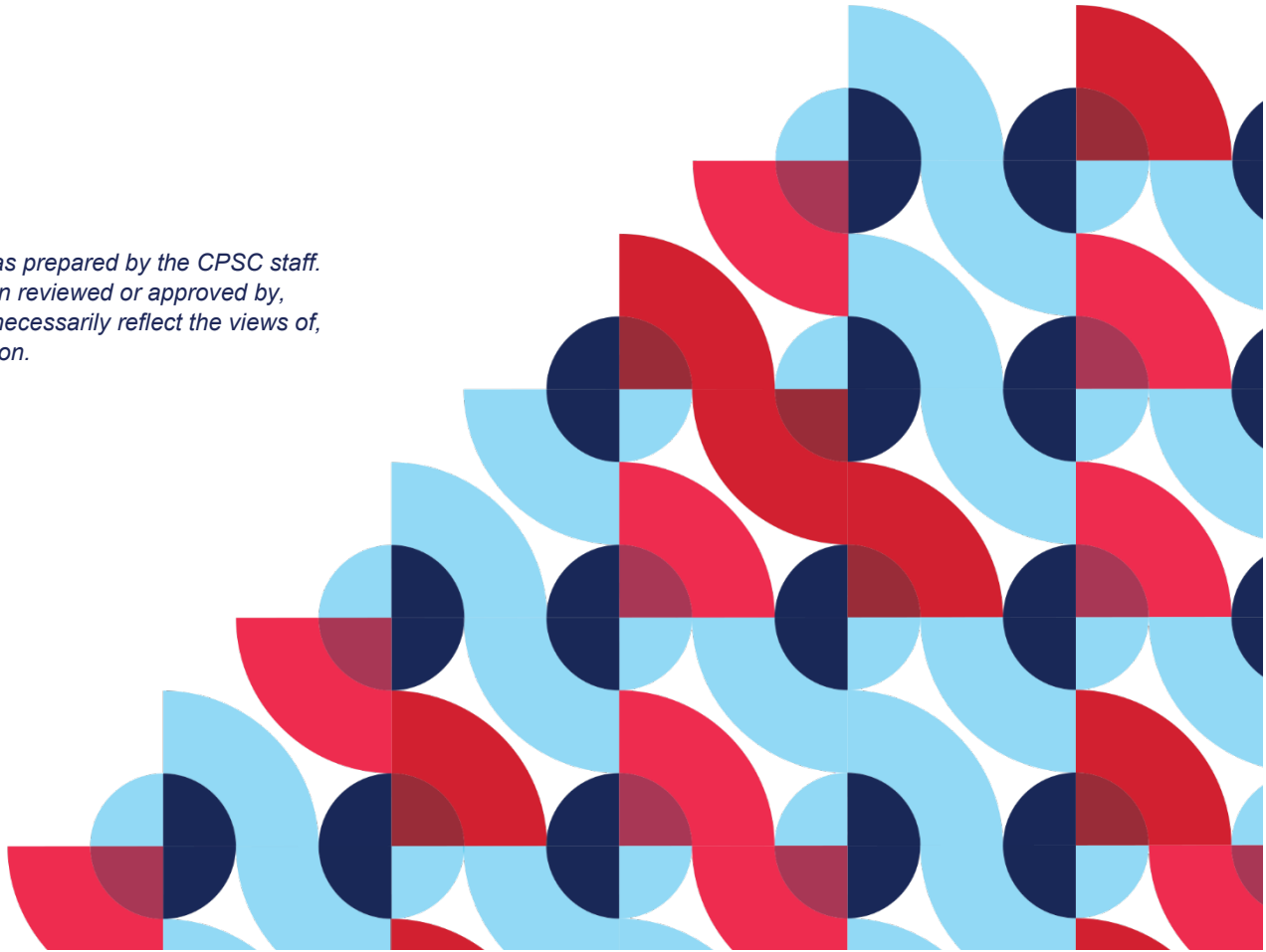
Attachment: *Staff Briefing Package on Petition CP 21-1*

United States
Consumer Product Safety Commission

Staff Briefing Package – Aerosol Dusters

July 20, 2022

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.



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Executive Summary

On April 2, 2021, Families United Against Inhalant Abuse (FUAIA, Petitioner), submitted a petition, requesting that the U.S. Consumer Product Safety Commission initiate rulemaking to adopt a mandatory safety standard "to address the hazards associated with aerosol "duster" products containing the chemical 1,1-difluorethane, or any derivative thereof."[1] This petition contains two requests: (1) to mandate a performance standard requiring that manufacturers add an aversive (bitterant other than denatonium benzoate) to all duster aerosol cans at a level of 30-40 ppm; and (2) to require use of a warning stating: "DANGER: DEATH – This product can kill you if you breath [sic] it."[2]

CPSC staff concluded that the 1,1-difluoroethane (DFE) used as a propellant in aerosol duster products is toxic. A review of CPSC's Consumer Product Safety Risk Management System (CPSRMS) database disclosed 1,126 deaths due to the intentional abuse of aerosol dusters from 2006 to 2020. Staff recommends, however, that no bitterant should be required for use in aerosol duster products, given a lack of efficacy of bitterants. As for the Petitioner's second request, to require a warning label citing DANGER and DEATH, among other key signal words, staff cannot determine at this time whether the Petitioner's request for a warning label would reduce the likelihood of injury or death. Staff notes that all aerosol duster products examined by staff used one or more of the FHSA warning language examples and met the format of the type-size requirements provided in 16 CFR § 1500.121.

A key concern related to warnings in this circumstance is that a consumer's motivation would be a driving factor about whether the warning label would be relevant to their actions.[3] Specifically, warning labels do not prevent consumer exposure to hazards that consumers intentionally seek out.[4] Furthermore, staff cautions that the Petitioner's recommended warning may have the unintended consequence of encouraging risky behavior by consumers who may not be able to self-regulate their emotions or actions when it comes to using aerosol duster products. Staff understands that inhalant abusers will continue their behavior, even if aerosol duster products become unavailable.[5] Staff recommends that the Commission defer the petition to allow staff to conduct further research on issues related to death and addiction from abuse of aerosol duster products to inform potential ways to address these hazards. Staff further recommends pursuing voluntary standards activity to investigate whether any other mitigation of the hazards might be possible through voluntary standards.

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[1] https://cpsc-d8-media-prod.s3.amazonaws.com/s3fs-public/Petition-from-Families-United-Against-Inhalant-Abuse-FUAIA.pdfn

[2] Staff notes that the Petitioner's suggestion to address this hazard, by limiting the number of dusters a consumer can buy at one time or within a specified period, is beyond the scope of CPSC's jurisdiction.

[3] Argo, J. J., & Main, K. J. (2004). Meta-Analyses of the Effectiveness of Warning Labels. *Journal of Public Policy & Marketing*, *23*(2), 193–208. https://doi.org/10.1509/jppm.23.2.193.51400

[4] Sanders, M. S., & McCormick, E. J. (1993). *Human factors in engineering and design* (7th ed.). New York City, NY: McGrawHill, Inc.

[5] Lipari, RN (2017) Understanding adolescent inhalant use. The CBHSZ Report: June 13,2017. SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health.

Briefing Memorandum

TO:	The Commission Alberta E. Mills, Secretary	**DATE:** July 20, 2022
THROUGH:	Austin C. Schlick, General Counsel Mary T. Boyle, Executive Director DeWane Ray, Deputy Executive Director for Safety Operations	
FROM:	Duane E. Boniface, Assistant Executive Director Office of Hazard Identification and Reduction Cheryl Scorpio, Ph.D. Project Manager, Aerosol Duster Petition Division of Pharmacology and Physiology Assessment Directorate of Health Sciences	
SUBJECT:	CP 21-1 Duster Aerosol Petition Staff Briefing Package	

I. Introduction

Families United Against Inhalant Abuse (FUAIA, Petitioner) submitted a petition to the U.S. Consumer Product Safety Commission on April 2, 2021, requesting that the Commission initiate rulemaking to adopt a mandatory safety standard "to address the hazards associated with "duster" aerosol products containing the chemical 1,1-difluorethane, or any derivative thereof."

The Petitioner requests that CPSC promulgate a mandatory safety standard that includes the following requirements:

- A performance standard. "Require manufacturers to add an aversive (bitterant other than Denatonium Benzoate) to all duster aerosol cans at a level of 30-40 ppm. There (sic) injection technology must be improved to ensure that the bitterant actually gets into the can and will also appear in the spray at the designated level. These cans must be tested annually by an outside agency as a means of quality control."

- Warning requirements. "Place a "much stronger" warning on the can. An example of this warning could be: "DANGER: DEATH – This product can kill you if you breath (sic) it. The warning text could be a full 50% of the front panel in bright red letters with a graphic of skull and crossbones."

The Petitioner also requests that the Commission "require retailers to monitor and limit individuals from continually purchasing multiple cans of Duster from their stores during a designated (one month) period of time." CPSC's Office of the General Counsel (OGC), however, has determined that requiring merchants to monitor how many aerosol dusters an individual purchases in each period would be beyond CPSC's statutory authority.

The Directive Implementing Procedure 302 for Petitions, section 4(c)(1) states the following regarding staff's responsibilities:

> Prepare a briefing memorandum to advise the Commission regarding the petition. The briefing memorandum shall provide the Commission with preliminary information concerning the petition so the Commission can make an initial assessment. The information and analyses in the briefing memorandum generally will be concise and based on existing or easily obtainable data, and will vary, depending on the petition.

Section 4(c)(3) further states regarding the content of a briefing package:

> The briefing memorandum shall contain a brief assessment of the petition and staff's recommendation of whether the Commission should grant, deny, or defer action on the petition. Generally, and to the extent it is available from existing or easily obtainable data, the briefing memorandum should provide preliminary information about the following, if feasible. [Followed by a list of topics that should be addressed in a briefing package].

The preliminary information provided in this briefing memorandum is intended to assist the Commission in making its initial assessment on whether to grant or deny the aerosol duster petition.

The Commission published a notice in the *Federal Register* on June 29, 2021, inviting comments on the petition. 86 Fed. Reg. 34171. CPSC received 16 comments. Staff's briefing package summarizes and addresses the comments. The Petitioner twice submitted additional data outside of the comment period and the data are generally consistent with CPSC data and are addressed in Tab F. The data are docketed with the other comments.

Staff reviewed the petition and evaluated injury data in the CPSC databases and considered the effectiveness of a bitterant proposed by the Petitioner to discourage the abuse of aerosol dusters. In addition, staff evaluated the effectiveness of the proposed warning label to mitigate the abuse of aerosol dusters and evaluated the aerosol duster market and costs associated with implementing the warning proposed by the Petitioner. The Briefing Memorandum summarizes staff's findings. The memorandum also provides staff's responses to the public comments we received.

II. Factors Relevant to the Commission's Decision on a Petition

The CPSC's petition regulation describes the factors the Commission must consider when deciding whether to grant or deny a petition. The relevant factors include:

> (1) Whether the product involved presents an unreasonable risk of injury;

(2) Whether a rule is reasonably necessary to eliminate or reduce the risk of injury; and

(3) Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product.

16 CFR § 1051.9(a).

The regulation also states: "[I]n considering these factors, the Commission will treat as an important component of each one the relative priority of the risk of injury associated with the product about which the petition has been filed and the Commission's resources available for rulemaking to activities with respect to that risk of injury." 16 CFR § 1051.9(b).

Staff considered these factors when evaluating the aerosol duster petition and in developing the recommendations detailed in the briefing package.

III. Discussion

A. Health Sciences

1. Toxicity of Difluoroethane (Tab A)

Many everyday items, although safe if used as intended, can cause lingering toxic effects, and even death, if abused (Forrester, 2019; Perron, 2021). Given these products are readily available, inexpensive, and not illegal to possess, aerosol inhalants are often targets of abuse (Dingle, 2019). As reported by Ossiander in 2015, 12 percent to 15 percent of eighth graders have used an inhalant at least once. Felt tip markers have been used as an inhalant by 6.7 percent of abusers, compared to 1 percent of those who abuse aerosol duster cleaners (Lipari, 2017.) Use of an inhalant may lead to abuse or dependance in 10 percent to 50 percent of cases, depending on the characteristics of the population studied (Perron, 2021).

In 2010, the numbers for inhalant abuse of propellants, including aerosol dusters, sharply increased in the United States.[6] In contrast, the numbers for other inhalant types declined (Marsolek et al., 2010). Commonly abused inhalants include amyl nitrite, correction fluid, gasoline, glue, shoe polish, toluene, halothane, ether, paint solvents, butane, propane, nitrous oxide and aerosol sprays (Perron et al., 2021). According to data published in 2019, by SAMHSA (Substance Abuse and Mental Health Services Administration),[7] in comparison to other commonly abused inhalants, difluoroethane from computer cleaners or air dusters is relatively[8] popular, but it is less frequently abused than some other inhalants, such as nitrous oxide, amyl nitrite, and felt-tip pens/markers.

[6] As seen in MECAP data (2016-2021). See Tab A

[7] Source: SAMHSA (2019). https://www.samhsa.gov/data/sites/default/files/reports/rpt29394/NSDUHDetailedTabs2019/NSDUHDetTabsSect1pe2019.htm?msclkid=8cc4960bb12611eca2d540e0507affc1

[8] According to 2019 data published by SAMHSA (Substance Abuse and Mental Health Services Administration), in comparison to other commonly abused inhalants, difluoroethane from computer cleaners or air dusters is relatively popular but is less frequently

Inhalants can be breathed into the nose or mouth, and they are quickly absorbed through the lungs into the blood stream through a variety of methods (Lipari, 2017). Sniffing or spraying refers to inhaling or spraying the substance into the nose or mouth directly from the container. Huffing refers to placing a bag saturated with a substance over the mouth and using the nose or mouth to inhale the concentrated fumes. Bagging refers to inhaling concentrated fumes, specifically from a plastic bag (Koehler, 2014). In this memo, this abuse is referred to as "huffing" or "inhalation."

Adolescents who initially used inhalants were less likely to use a new drug, compared to adolescents who initially used marijuana. By the second year of the observation period, the probability of using a new drug was approximately 10 percent for an abuser who initially used inhalants. By the eighth year of the observation period, the probability of using a new drug by an abuser who initially used inhalants is 50 percent and 70 percent to 80 percent for other drug users (Zhang, 2021). Those who begin abusing drugs with inhalers tend not to use new classes of drugs, compared to those who begin with other drugs. However, adolescents who initiate drug use with inhalants may be at risk of using other drugs over time.

Staff understands from the previous study that if an inhalant product becomes unavailable, abusers will possibly substitute another inhalant product to achieve their high. There are many inhalants available to substitute, as well as many aerosol products, such as insect repellants and personal care items, that contain DFE.[9]

Although aerosol duster products have been referred to as "air dusters," they do not contain air. They contain aerosol propellants, like 1,1 difluoroethane (DFE)(HFC-152a), 1,1,1,2-tetrafluoroethene (HFC-134a), and 1,3,3,3-tetrafluoropropene (HFO-1234ze). The propellant 1,3,3,3-tetrafluorane is also commonly used when a non-flammable propellant is needed, or a more environmentally friendly choice is desired.

Toxicity in humans can occur after acute or chronic exposure to DFE (Poisindex, 2021). The risk is greatest when DFE is injected directly into the mouth using the sniffing or spraying method (Koehler, 2014). Severe toxicity can cause depressed mental status, respiratory depression, pulmonary edema, hepatic renal injury, ventricular dysrhythmias, and sudden death.[10] Additional systemic effects on the circulatory and gastrointestinal system can also occur. Mild-to-moderate toxic effects include headache, mucous membrane and ocular irritation, and defatting injury of the skin. Frostbite after exposure to cold gas can occur. High-pressure digit injury resulting in digital ischemia has been reported (Poisindex, 2021). The lack of a toxicity-dose relationship of aerosol duster products makes it difficult to predict the toxicity after someone inhales a specified number of aerosol duster canisters.

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abused than some other inhalants, such as nitrous oxide, amyl nitrite, and felt-tip pens/markers. More than half of the 25 million estimated lifetime inhalant-use cases among persons ages 12 and older, nitrous oxide was involved. The same study estimated 2.9 million lifetime uses of computer cleaners or air dusters, and 1.4 million lifetime uses of other aerosol sprays.

[9] https://www.whatsinproducts.com/chemicals/index/1

[10] Sudden sniffing death syndrome (SSDS) was first described 47 years ago. Patients inhale fluorinated hydrocarbons to become "high," and if physical exertion or stress occurs, and catecholamines are released, the inhaler may collapse and die. (Smeeton, 1985; Kamm, 1975; Poisindex, 2021). Recently, sudden death has also been reported to occur without the release of catecholamines (Kamm, 1975;Dingle, 2019).

The Federal Hazardous Substances Act (FHSA) defines "toxic" as "any substance (other than a radioactive 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). Although there are no clear dose-response toxicity data, there are many examples of human injuries and deaths caused by aerosol duster products. Therefore, CPSC staff concludes that aerosol duster products containing the chemical 1,1-difluoroethane or similar halogenated hydrofluorocarbons are "toxic."

2. Efficacy and Safety of Bitterants (Tab B)

Several U.S. companies have introduced products with a synthetic bitterant,[11] known as denatonium benzoate (DB),[12] to address the abuse of aerosol dusters (huffing). Consumers who abuse aerosol duster products spray the contents of an aerosol duster can into their nose or mouth, or they inhale the fumes from a cloth or from a bag (NIDA, 2012). Current formulations of aerosol dusters provide DB at concentrations between 0.05 ppm and 0.5 ppm in the aerosol vapor phase (Perron et al., 2021; Patent, 2010). DB concentrations higher than 0.5 ppm in the aerosol vapor phase can interfere with normal use of the product.[13] To avoid such interference, and to release DB at 0.05-0.5 ppm in the vapor phase, the DB level in the liquid phase should be kept between 5 ppm and 50 ppm[14] (Patent, 2010).

In the Consumer Product Safety Improvement Act of 1990, Congress directed the CPSC to conduct a study of aversive agents. CPSC completed the report of its review of aversive agents in 1992 (CPSC, 1992). In the report, CPSC concluded that bitterants have low toxicity and recommended that the use of aversive agents should not be required as a deterrent for ingestion, due to the lack of efficacy.

The Petitioner requested that CPSC require manufacturers to add an aversive agent (bitterant *other* than DB) to all aerosol duster cans at a level of 30 ppm–40 ppm. The Petitioner stated that, to reach these levels of bitterant in the aerosol duster products, the duster-can injection technology must be improved to ensure that the bitterant gets into the can and appears in the spray at the designated level.

Staff is not aware of bitterants with demonstrated efficacy as an aversive agent for inhalants.[15] Information is lacking on the human inhalation toxicity of bitterants.[16] Fifteen percent to 30 percent of adults do not detect the taste of bitter compounds (CPSC, 1992; NIDCD, 2010; NIDCD, 2019). Mice acquired tolerance to DB after long-term exposure (PLOS One, 2018). Similar tolerance for bitterants can develop in humans too.

Health Sciences (HS) staff has concluded that there is no viable replacement for DB in aerosol duster products. Furthermore, the efficacy of current use of DB as a deterrent in inhalants is not supported by the efficacy data.

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[11] A bitterant is a chemical that is added to a product to make it taste extremely bitter. Bitterants are used to prevent poisoning from the ingestion or inhalation of other toxic chemicals.
[12] In addition to its use in aerosol dusters, denatonium is used in denatured alcohol, antifreeze, respirator mask fit test, animal repellents, liquid soaps, shampoos, and Nintendo Switch game cards to prevent accidental swallowing or choking by children.
[13] Aerosol duster users start sensing DB in the air at a level above 0.5 ppm.

[15] Staff conducted Google Scholar and PubMed search using the term "bitterant efficacy for inhalation."
[16]Staff conducted Google Scholar and PubMed search using the term "inhalation toxicity of bitterants."

The efficacy of DB used in denatured alcohol (rubbing alcohol) has also been questioned (Garcıa-Valenzuela and Baez-Gaxiola, 2021). Furthermore, the addition of DB to denatured alcohol did not prevent its consumption by adults inclined to abuse the product (PubMed, 1989).

In the past, DB was an active ingredient in nail-biting and thumb-sucking deterrents. The Food and Drug Administration removed the approval for these products, citing the lack of efficacy data (CPSC, 1992). Recent epidemiology studies have also demonstrated that adding bitterants to antifreeze in several U.S. states did not prevent pediatric ingestions or suicidal ingestions of antifreeze (White et al., 2008, 2009; PLOS One, 2015).

The addition of DB to Nintendo Switch gaming cartridges, to deter small children and pets from eating them, led to the unintended consequence of gamers licking the game cartridges, the exact opposite of what Nintendo expected to happen (TechWorm, 2020). Although the use of bitterants may seem like a promising idea, the available data do not support their usefulness in the real world.

There are many unresolved issues with the proposed use of bitterants for aerosol duster products. The most important of them are the absence of efficacy data for bitterants for inhalation abuse and the lack of data for bitterants' inhalation toxicity, in general.

Staff analyzed the data available for 22 synthetic and natural bitterants. The most potent alternative bitterants were humulone and sucrose octaacetate or SOA. Humulone has not been found to be used in aerosol formulations. There is a patented SOA aerosol formulation with a recommended range in the liquid phase from 5 ppm to 50 ppm. Concentrations stated for SOA formulations were the same as in the earlier patent application for DB (Patent, 2010). Yet, SOA is 500-fold less bitter than DB (see Tab B). It has not been demonstrated that the deterrent effect is achievable in the aerosol formulation. A high level of bitterants in an aerosol duster is detrimental to people using the product as intended.

The Petitioner stated that DB was often not injected into the cans during the manufacturing process and requested CPSC to improve the injection technology. Staff could not verify this statement by the Petitioner and did not identify any improvements in the bitterant injection technology during manufacturing.

As discussed, HS staff has concluded that DB, or any other bitterant, should not be required for use in aerosol duster products, due to the lack of efficacy data.

B. Human Factors (Tab C)

1. Assessment of Product Labeling

Staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), evaluated 12 different aerosol duster products to get a better understanding of the format, content, and placement of on-product labeling on existing products in the market. CPSC sets forth labeling requirements for products that are subject to the FHSA and 16 CFR § 1500.121.

The labeling requirements for hazardous substances in 16 CFR § 1500.121 provide, at a minimum, the language that should be on the label. Some examples are: "HARMFUL OR FATAL IF SWALLOWED"; "VAPOR HARMFUL"; or "Keep out of the reach of children." Staff

verified that all the aerosol duster products use one or more of these example statements provided in FHSA. Furthermore, ESHF staff's observation of examined aerosol duster products met the format of the type-size requirements provided in 16 CFR § 1500.121.[17]

Staff also assessed the use of signal words, compared to the voluntary standard, ANSI Z535.4, American National Standard for Product Safety Signs and Labels (the primary voluntary standard in the United States for product safety signs and labels), to evaluate the adequacy of warning labels (ANSI, 2011). Although all the aerosol duster products examined used signal words, the signal words did not adhere to the formatting required by ANSI Z535.4. The voluntary standard states: "If DANGER is used, it shall be in safety white letters on safety red background." If "WARNING is used, it shall be in safety black letters on safety orange background." If "CAUTION is used, it shall be in safety black letters on a safety yellow background."

ESHF staff observed the aerosol duster products contained statements to inform of intentional misuse, inhalation abuse, and the potential consequences of either. Although misuse and abuse are not the same concept, the examined aerosol duster products are observed using messages regarding both concerns. From the aerosol duster products examined, there was language describing the severity of the hazard (*e.g.*, dangerous and fatal).

Although the statements were not placed uniformly across the products examined, the common wording observed on nearly all aerosol duster products stated: "INTENTIONAL MISUSE BY DELIBERATELY CONCENTRATING THE CONTENTS OF THIS CAN AND INHALING MAY BE HARMFUL OR FATAL."[18] Seven of the aerosol duster products examined used signal words to draw greater awareness to the severity of the consequences. Five of the examined aerosol duster products contained statements on the label addressing misuse and intentional abuse on the label. A few examples of "inhalant abuse" statements used included: "INHALANT ABUSE CAN BE FATAL!" or "INHALANT ABUSE IS ILLEGAL AND CAN CAUSE PERMANENT INJURY OR BE FATAL."

From the examined aerosol duster products, two contained "Public Service Announcements" (PSAs) about inhalation misuse or abuse. The PSA statement was highlighted with a bold framed box around the message to stand out from the remainder of the information on the label. In addition, four of the examined aerosol duster products directed the consumer to websites like "inhalants.com" and "inhalants.org," which provide a plethora of information, resources, and education regarding inhalant abuse and recovery.

2. Petitioner's Proposed Warning Label

The Petitioner proposed placing a "much stronger" warning on aerosol duster products. The Petitioner suggests using "DANGER: DEATH – This product can kill you if you breath [sic] it," as an example of wording for a label. The Petitioner also proposed that the warning text be "a full 50% of the front panel in bright red letters with a graphic of a skull and crossbones."

[17] One aerosol duster product contained a precautionary statement that just barely met the type-size requirement.

[18] One aerosol duster product did not contain any "intentional misuse or abuse" type of statements.

ESHF staff consulted ANSI Z535.4. ESHF staff's assessment of the Petitioner's recommendation is summarized below:

- Signal word: The Petitioner proposes using the signal word "DANGER"; according to ANSI Z535.4, "DANGER indicates a hazardous situation that, if not avoided, will result in death or serious injury." On the other hand, "WARNING indicates a hazardous situation that, if not avoided, could result in death or serious injury"; and "CAUTION" indicates a hazardous situation that, if not avoided, could result in minor or moderate injury" (ANSI, 2011). Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), reviewed the CPSRMS database and identified 1,126 incidents resulting in death from aerosol duster products from January 1, 2006 to December 31, 2020 (Tab D). Furthermore, ESHF staff notes that some of the duster products examined state: "DANGER" and provide some level of information to explain the dangers of inhaling the product and provide guidance on what to do after the inhalation has occurred within the "First Aid" information. Therefore, ESHF staff assesses that the signal word "DANGER" is appropriate.
- Hazard: The Petitioner describes the hazard and consequences of aerosol duster products with the following proposed text: "DEATH – This product can kill you if you breath [sic] it." However, when used as directed, aerosol duster products do not pose a risk of death. The proposed text fails to discuss accurately the conditions that may lead to death, and the text may erroneously create a false alarm to consumers who would use it as intended. Human injuries and death can occur if the product is abused, as discussed by staff of CPSC's Directorate for Health Sciences, Division of Pharmacology and Physiology (HSPP) (Tab A).
- Label Size and Location: The Petitioner suggests covering half of the front panel of aerosol duster products with the proposed warning label. The ANSI Z535.4 requires that product safety signs and labels be placed on a location so that it is readily visible to the intended viewer. ESHF staff is unaware of such a large label placed on a consumer product with similar hazard scenarios (*i.e.*, potential abuse). Staff is aware of upcoming regulations for cigarette packaging that will require a warning label to comprise at least the top 50 percent of the front and rear panels of the cigarette package. Staff cautions that the warnings on both products are based on different uses; cigarette warning labels warn the user about the consequences of intentional use of cigarettes, the intended use of aerosol duster products does not pose the same risks as unintended use.
- Color: The Petitioner suggests using red for the proposed label. As discussed in the assessment of current labeling section, ANSI Z535 requires different colors for different signal word panels: "if DANGER is used, it shall be in safety white letter on safety red background"; if "WARNING is used, it shall be in safety black letters on safety orange background"; and if "CAUTION is used, it shall be in safety black letters on a safety yellow background" (ANSI, 2011). Based on the high severity of the outcome discussed above, the signal word panel containing the word "DANGER" would have letters in safety white on a safety red background. In addition, although the Petitioner did not specifically propose this, ANSI Z535.4 recommends the safety alert symbol (exclamation mark in a triangle) to be the same color as the signal word lettering. The same standard states the message panel be either in safety black lettering on a safety white background or in safety white lettering on a safety black background.

- Graphic containing skull and crossbones: The skull and crossbones are required for certain materials, as stated in 16 CFR § 1500.14. Based on HS staff's analysis, the ingredients in aerosol duster products do not contain the highly toxic hazardous substances listed in 16 CFR § 1500.14. Therefore, ESHF staff concludes that a graphic containing a skull and crossbones does not apply to aerosol duster products.

3. ESHF Summary

The petition discusses the abuse of aerosol duster products when an individual uses the product in a manner, not recommended by the manufacturer, to satisfy a desired state of feeling. The Petitioner proposes various remedies to address the hazard of aerosol duster abuse. ESHF staff's evaluation of several aerosol duster products provides a baseline level of understanding of the labeling and statements used on aerosol duster products currently on the market. All the aerosol duster products examined by ESHF staff contain labeling with information and messaging about inhalant abuse, misuse, potential consequences, albeit in various locations and formats.

Aerosol duster products pose a difficult challenge. Although aerosol duster products provide consumers the ability to clean tiny spaces with ease, incident data discussed in Tab D show the product's design may be susceptible to misuse or abuse. Staff notes that although designing out the hazard may address the risk with the subject aerosol duster products, it does not deter users from abusing other household products. Data show that a variety of household products have been inhaled, such as felt-tip pens and markers, felt-tip markers, glue, shoe polish, or toluene, spray paints, gasoline or lighter fluid, computer cleaner/aerosol duster, correction fluid, degreaser, or cleaning fluid, lacquer thinner or other paint solvents, amyl nitrate, poppers, locker room deodorizers, nitrous oxide or whippets, lighter gases (butane, propane), halothane, ether or other anesthetics, or other aerosol sprays (Lipari, 2017).

ESHF staff notes that the message delivered by the petition's proposed warning label may have the unintended consequence of encouraging risky behavior by consumers who may not be able to self-regulate their emotions or actions. In other words, it is possible that the suggested label could have the perverse consequence of leading consumers inclined to abuse inhalants directly to products that are labeled as such. A key concern related to warnings in this circumstance is that a consumer's motivation would be a driving factor about whether the warning label would be relevant to their actions (Argo & Main, 2004). Warning labels do not prevent consumer exposure to hazards they intentionally seek (Sanders & McCormick, 1993). Based on available information, it is unknown whether warning labels may deter misuse or abuse of aerosol duster products or may encourage some consumers struggling with addiction or a panoply of emotions, to misuse or abuse aerosol duster products.

ESHF staff also notes that parents who are unaware of the intentional abuse and misuse associated with aerosol duster products may benefit from a noticeable, easy-to-understand, and concise on-product warning label that aims to increase consumers' awareness of the hazard, and likewise, influence their behavior, such as keeping the product away not only from children, but also teenagers. Based on the analysis by CPSC's Directorate for Economic Analysis (EC), with adequate warnings, parents may also make an informed choice not to purchase in bulk, a case of 12 aerosol duster products. Although retailers employ incentive pricing to sell aerosol

duster products to consumers in cases of 12, parents may determine that it is not safe to keep a "bulk" case of aerosol duster products in the home when they are aware of the hazards related to the product (Tab E). ESHF staff also concludes that based on warning research, having a clear symbol could help with alerting consumers to the inhalation hazard. However, most incidents staff analyzed (86% of NEISS injuries and 97% of CPSRMS incidents) involved adult consumers (Tab D).

An effective warning label alerting consumers to the intentional abuse of aerosol duster products must be balanced with the possibility that the label may potentially encourage risky behavior from consumers struggling with addiction. Thus, this might lead to the very behavior the label is intended to protect against. Furthermore, for a warning label to be effective, it must be noticed, read, understood, and heeded. The intentional abuse of aerosol duster products may present competing incentives for users who have sought out these products specifically for misuse, which might reduce the likelihood of warnings being heeded.

C. Economics (Tab E)

1. Market Information

Aerosol duster products are widely available online, and in brick-and-mortar general retail, office supply, and home improvement stores. The total market for aerosol duster products is approximately 20 million units sold per year, at a typical price range of $5 to $20 per 10-ounce can. Other small battery-powered air compressors are available, some marketed specifically as "keyboard dusters" that provide similar functionality and compete with these products.

There are dozens of products advertised as keyboard cleaners, computer aerosol dusters, electronic equipment dusters, and camera cleaners that are within the Petitioner's defined scope of "aerosol dusters." Some of these products are advertised or labeled as "canned air." As noted in the HS staff memorandum, although aerosol duster products have been referred to as "air dusters," they do not contain "air." (See Tab A.) Regardless, staff is currently aware of nine aerosol duster products that use the term "air" directly on the product.[19] In addition, online retailers sell aerosol duster products within the product category of "compressed air dusters" and describe products as "canned air." The Petitioner indicates that when retailers advertise dusters as "'air," it misleads young individuals, who may believe that the product is just that. According to comments we received, at least one member of industry agrees, to some extent, that it could be misleading to label an aerosol duster product as "air." This commenter also indicates that they never use the term "air in a can" to describe their product. This commenter notes that they actively discourage their retail partners and others from using the term.

Staff analysis finds that suppliers tend to offer discounts for purchasing aerosol duster products in bulk. The in-store brand of a major office supply chain sells a 10-ounce can of aerosol duster in their online store for $10.29. However, the retailer provides a discount for purchasing in bulk,

[19] Since the original review, completed in February 2022, staff have identified two additional aerosol duster products that use the term "air" directly on the product, bringing the total to 11 aerosol duster products that use the term "air".

and charges $5.20 per can for a case of 12 cans, excluding tax. At a large discount retail chain store, prices online for a single can start around $8, or $3 per can in a case of 12.

Some aerosol duster products sold at office supply stores, chain drug stores, and general retailers contain a bitterant. Most aerosol duster products containing a bitterant do not specify, either on the can or on the Safety Data Sheet, which bitterant is used. However, several widely available brands advertise specifically that they do not contain any bitterant, supposedly because the bitterant can damage sensitive electronics.

If the Commission decides to grant the petition and proceed to rulemaking, it will be necessary to define in-scope products. The product defined by the Petitioner is "duster" aerosol products "used for cleaning electronics and other items and containing the chemical 1,1-Difluorethane, or any derivative thereof." Staff conducted a preliminary estimate of societal costs of the hazard and assumed for the purposes of the preliminary estimate performed in the Economics memorandum that in-scope products would include aerosol products using the same propellant marketed for cleaning. These estimates are preliminary, and if a future rulemaking involves a different scope, this might affect the estimates.

According to information available from the Consumer Product Information Database, 1,1-Difluoroethane (DFE) can be found in a variety of concentrations in many consumer products that are not used for electronics dusting.[20] These products include pesticides, like insect repellent, which uses DFE as a propellent in a concentration of 1.0 to 5.0 percent, and ant and roach killer aerosols that use DFE in a concentration of 89.65 percent. DFE is also found in oven-grill cleaning aerosols in a concentration of 4.25 percent. DFE is in auto products, like tire glaze, in concentrations ranging from 40 percent to 60 percent. The chemical DFE is used as a propellent in a range of concentrations, in a variety of personal care items, like hair spray and hair-styling mousse.

2. Preliminary Estimate of Societal Costs from the Hazard

Based on the economic analysis using CPSC's Injury Cost Model, staff preliminarily estimates societal costs could be as much as $141 million per year for injuries and $690 million for deaths from aerosol duster products. Nevertheless, it is uncertain what impact any potential rulemaking would have on these societal costs. Based on the analysis by Human Factors staff, provided in Tab C, it is currently uncertain whether the warnings would deter abuse. Based on the analysis by HS staff provided in Tab B, the use of bitterants would not be an effective deterrent. However, staff finds that there may be other performance standards not found in the preparation of this package that might be found to be effective. If an effective solution is found, a reduction in the number of deaths associated with inhalant abuse of aerosol dusters by any amount could provide a significant benefit to society.

Based on the results of the CPSC's Injury Cost Model (ICM), staff estimates there were more than 4,275 medically treated aerosol duster inhalation injuries per year from 2006 through 2020. This included emergency room treatments, hospital admissions, and doctor's office visits. For aerosol duster inhalation injuries, the average cost per case is about $3,000 for medical treatment. When considering lost productivity and long-term pain and suffering, the average

[20] https://www.whatsinproducts.com/chemicals/index/1.

cost per case exceeds $32,000. The value of the societal costs of these injuries (in 2018 dollars) amounted to about $141 million per year, using the average number of cases per year for the past 15 years. Overall, medical costs and work losses account for about 20 percent of the total costs, or about $32 million per year; the intangible costs associated with pain and suffering accounted for the remaining 80 percent, or $109 million. Medical costs alone are estimated to exceed $13 million per year.

The Value of a Statistical Life (VSL) is a measure of society's willingness to pay for small reductions in mortality risks. It is commonly used in cost/benefit analysis of federal regulations, particularly those by EPA and DOT, and in economic analysis of proposed health policies and safety measures. CPSC uses EPA's estimate for VSL, but we adjust for inflation, so that the current value in CPSC's Injury Cost Model (ICM) is $10.5 million in 2021 dollars. According to CPSC's epidemiology data collected from the CPSRMS, from 2006 to 2020, there were 1,126 deaths related to aerosol duster products, or, on average, roughly 75 deaths per year over the period. (Tab D.)

D. Relevant Existing Standards and Laws

Staff is unaware of any relevant voluntary standards related to the Petitioner's request. The CPSC does have a Parent's Guide to Inhalant Abuse safety education page on the CPSC website.[21]

It is illegal in 47 states (Alaska, Montana and New Jersey excluded) to knowingly use inhalants. It is also illegal to drive and use inhalants in 13 states (Alaska, Colorado, Georgia, Kentucky, Michigan, Montana, New Jersey, New Mexico, Oregon, Texas, Utah, Vermont and Wyoming).[22]

E. Epidemiology (Tab D)

The reported incidents from CPSC's Consumer Product Safety Risk Management System (CPSRMS) are from January 1, 2006 through December 31, 2020. Data collection is ongoing in CPSRMS, and reporting is considered incomplete for the latest 3 years. The National Electronic Injury Surveillance System (NEISS)–based injury estimates are from January 1, 2006 to December 31, 2020. Finalized NEISS data and estimates will be available in spring 2022.

1. CPSRMS

Between 2006 and 2020, CPSC received reports for 1,133 unique incidents involving huffing hazards from aerosol duster products.

An overwhelming majority (99.4%) of the aerosol duster inhalation incidents in CPSRMS between 2006 and 2020 resulted in deaths. Most of the CPSRMS incident data were comprised of death certificates (947 of 1,133) from the states and from medical examiners and coroners (165 of 1,133). The remaining incident data were received from consumers, manufacturers/retailers, online news, health care professionals or unspecified sources. Around

[21] https://www.cpsc.gov/safety-education/safety-guides/containers-and-packaging/parents-guide-preventing-inhalant-abuse.

[22] This information is based on searches of state-level inhalant abuse laws. Sources included articles from the Connecticut General Assembly, National TASC and NHTSA, as well as articles and information from local news sources and local attorneys' websites.

70 percent of the victims were male, and more than 92 percent of victims were between the ages of 18 to 54. The age of all victims ranged between 13 and 70 years old. Nine-hundred of the 1,133 incidents took place in the period from 2013 to 2020.

Between 2006 and 2020, there were an additional 1,023 CPSRMS incidents that mentioned either difluoroethane toxicity from an unspecified product, or difluoroethane, freon, or hydrocarbon inhalation from unspecified aerosol products. All these incidents resulted in deaths. As the scope of the analyses was determined to include only incidents explicitly mentioning an aerosol duster product, these additional incidents are not included among the 1,133 incidents in the analyses above, and they are mentioned only to provide information on, and context for, the excluded incidents.

2. NEISS

Between 2006 and 2020, it is estimated that there were 25,300 emergency department- (ED) treated injuries in the United States, resulting from abusing aerosol duster products. This estimate is based on a sample of 562 NEISS injury cases. An estimated 16,000 of these injuries (63%) occurred between 2013 and 2020. An estimated 16,400 of the injuries (65%) occurred to males, and an estimated 21,200 of the injuries (83%) occurred among individuals ages 18–54 years.

F. Public Comments (Tab F)

Several consumers commented that they supported the petition. Commenters stressed that education about inhalant abuse can help prevent deaths and that the addition of a bitterant would make the aerosol unpalatable to the abuser. Several manufacturers also commented. One manufacturer indicated that preventing tragedies associated with inhalant abuse is a problem they have been working on for more than 30 years, adding that they have developed a three-pronged approach to curb, if not eradicate, the problem. First, they note, they put a bitterant in the product; second, they educate consumers about the problem of inhalant abuse; and lastly, they support listing propellants as inhalable, making them illegal under DUI laws. It was also noted that the Petitioner used data from all products that contained 1,1,-difluoroethane, and that this would include more products than just aerosol dusters in their data set.

IV. Summary

The petition was docketed for two requested actions. The first requested action was adding a mandatory, but unspecified, bitterant to the aerosol dusters at a specific concentration. The second requested action was to place a “much stronger” warning on the front of the can, indicating death can occur, along with the picture of a skull and crossbones.

It is of note that this product is safe when used as intended and dangerous when not used as intended.

HS staff has concluded that, due to the lack of efficacy, DB, or any other bitterant, should not be required for use in aerosol duster products.

ESHF staff showed that most of the aerosol duster products examined comply with existing FHSA labeling requirements, and some bear additional labeling about inhalant abuse. The proposed text fails to discuss with accuracy the conditions that may lead to death. As such, staff maintains, this may erroneously create false alarms for consumers who would use the product as intended. In addition, ESHF staff concludes that the message may inadvertently encourage risky behavior by consumers who may not be able to self-regulate their emotions or actions. In other words, it is possible, staff concludes, that the suggested label could have the perverse consequence of directing consumers who are inclined to misuse or abuse inhalants, to directly seek out the product so labeled. It is unknown whether warning labels may deter misuse or abuse, or it may encourage some consumers who may be struggling with addiction or another panoply of emotions, to misuse or abuse the product. It would take extensive CPSC research and resources to answer this question of whether abusers would be attracted to the proposed label, because working with abusers is difficult and complex. Additionally, ESHF is not certain such research would result in a definitive answer to the question.

Typically, inhalants are legal, everyday products[23] that are harmless when used as intended. However, when these products are intentionally misused to get high, they can become toxic and sometimes lethal. According to one study that used data from the National Survey on Drug Use and Health (NSDUH), young users who initiated with inhalants are at substantial risk of using other drugs over time. After 8 years, the potential for using a new drug was about 50 percent for adolescent users of inhalants and 70 percent to 80 percent for other drug users (Zhang, 2021[24]).

Therefore, staff understands from this reference that half of adolescent abusers of inhalants may continue to use inhalants, then switch to other types of drugs after 8 years of use. However, the transition from inhalants to illicit drug use might be underestimated because of the self-reporting, data-collection method of the NSDUH.

There are many inhalants available to substitute for aerosol duster products (see footnote 22), as well as many aerosol products, like insect repellants and personal care items, that contain DFE.[25]

Staff concludes that the Petitioner's suggestions to address inhalation deaths from aerosol duster products are not effective. Staff concludes that potentially effective ways to address this hazard, such as limiting the number of aerosol duster products a consumer can buy at one time or within a certain period, lie outside CPSC's jurisdiction. Although staff is unaware of any relevant existing voluntary standards related to aerosol duster products, staff proposes investigating the possibility of voluntary standards groups researching ways to address the issue of inhalant abuse with aerosol duster products. In researching this petition, staff relied on

[23] Data show that a variety of household products have been inhaled, such as felt-tip pens and markers, felt-tip markers, glue, shoe polish, or toluene, spray paints, gasoline or lighter fluid, computer cleaner/aerosol duster, correction fluid, degreaser, or cleaning fluid, lacquer thinner or other paint solvents, amyl nitrate, poppers, locker room deodorizers, nitrous oxide or whippets, lighter gases (butane, propane), halothane, ether or other anesthetics, or other aerosol sprays (Lipari, 2017).

[24] The study found that it is important to screen adolescent drug use comprehensively and to provide early interventions to prevent an escalation to other detrimental drugs.

[25] https://www.whatsinproducts.com/chemicals/index/1.

readily available data and information. Staff proposes doing further research into inhalation abuse to find out more about this serious hazard.

V. Staff's Assessment of Commission Options

The Commission may grant the petition, deny the petition, or defer action on the petition. The Commission considers several factors relevant to the Commission's decision in granting or denying a petition, which staff considered while assessing these options. Relevant considerations include whether the product involved presents an unreasonable risk of injury, whether a rule is reasonably necessary to eliminate or reduce the risk of injury, whether failure of the Commission to initiate a rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the to the risk of injury which the petitioner alleges is presented by the product, the relative priority of the risk of injury, and the Commission's resources available for rulemaking activities with respect to that risk of injury. 16 CFR § 1051.9.

A. Grant the Petition

Granting the petition is not likely to mitigate the risk of deaths due to inhalant abuse of aerosol dusters. Staff concludes that the addition of a bitterant to aerosol dusters is unlikely to be effective. Staff also concludes that the suggested label, or a similar label, is unlikely to have a significant positive impact, and it could have the perverse consequence of leading people inclined to abuse inhalants directly to the product with the enhanced warning on the label, thereby, facilitating the problem that the label was intended to avoid.

Granting a petition does not require the Commission to issue a rule under the authority cited in the petition. In addition, granting a petition does not require the Commission to issue a rule in the specific form requested by the Petitioner. 16 CFR § 1051.10(b).

B. Deny the Petition

Denying the petition would preserve limited CPSC resources, making those resources available to address priorities for other hazards that could be addressed more effectively by rulemaking. The resources required to review data, evaluate labeling strategies, and conduct economic analyses necessary to develop a rule would require significant staff commitments. Given that using a bitterant in aerosol duster products and enhancing the warning label on such products is not effective in addressing the hazard of inhalant abuse, granting the petition may have only a limited effect on addressing this hazard. "A Commission denial of a petition shall not preclude the Commission from continuing to consider matters raised in the petition." 16 CFR § 1051.11(c).

C. Defer Action on the Petition

If the Commission concludes that more information is required before it can decide whether to grant or deny the petition, the Commission may defer a decision and direct staff to collect additional information and reconsider the petition after that work is completed. Deferring the petition would enable staff to reallocate resources from other priorities and conduct further research into issues related to death and addiction from abuse of aerosol duster products to inform potential ways to address these hazards. CPSC staff also proposes adding this to the

Fiscal Year 2023 Operating Plan as an active voluntary standard activity, with the intent to request that a standards development organization, such as ASTM, establish a working group to address the issue of inhalant abuse with aerosol duster products.

VI. Staff's Recommendation and Conclusion

Although the health and medical risks that come from inhaling aerosol duster products are very serious and include the risk of death, the Petitioner's proposed recommendations to use a bitterant and to require an enhanced warning label are not effective in mitigating the risk of death from inhalation of aerosol duster products. Staff recommends that the Commission defer the petition to allow staff to do further research on issues related to death and addiction from abuse of aerosol duster products to inform potential ways to address these hazards and to request that a voluntary standards development organization establish a working group to address the problem of aerosol duster product abuse raised in the petition.

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TAB A: Toxicity of Difluoroethane Contained within Aerosol Duster Products

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Consumer Product Safety Commission
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Memorandum

TO: Cheryl Scorpio, Ph.D.,
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Assessment
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DATE: July 20, 2022

THROUGH: Stefanie Marques, Ph.D.,
Director, Division of Pharmacology and Physiology
Assessment
Directorate for Health Sciences

FROM: Adrienne Layton Ph.D.,
Pharmacologist
Division of Pharmacology and Physiology
Assessment
Directorate for Health Sciences

SUBJECT: Toxicity of Difluoroethane Contained within Aerosol Duster Products

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Introduction

This memorandum describes the toxicity of 1,1-difluoroethane (DFE), or similar derivatives, contained within aerosol duster products, based upon the medical literature and a MECAP search. CPSC staff concludes that DFE, or similar propellants contained in aerosol duster products, are "toxic" under the Federal Hazardous Substances Act (FHSA) (Section 2 of 15 U.S.C. § 1261).

Many everyday items, although safe if used as intended, can cause lingering toxic effects, and even death, if abused (Forrester, 2019; Perron, 2021). Given that inhalants are readily available, inexpensive, and legal to possess, they are often targets of abuse (Dingle, 2019).

Inhalant Abuse

A broad range of consumer products contain vapors or volatile pressurized gases. Hundreds of products containing single substances or mixtures of substances that can produce intoxication if inhaled are commercially available (Howard, 2011). Common

inhalants include glues and adhesives, felt-tip pens and markers,[26] lighters,[27] aerosols,[28] analgesic sprays,[29] anesthetics,[30] cleaning agents,[31] and solvents[32] (Howard 2011, Lipari, 2017, Williams,2007). DFE can be found in many consumer products besides aerosol duster products. These include insect repellants, aerosol roach killers, oven-grill cleaning aerosols, automotive products, and personal care items, such as hair spray. In 2015, computer aerosol dusters were not the number one inhalant of choice, according to the National Survey on Drug Use and Health (SDUH). Some 6.7 per cent of inhalers used felt tip markers,[33] compared to 1 percent of inhalers who used aerosol dusters (Lipari, 2017).

Sniffing or spraying refers to inhaling or spraying the substance into one's nose or mouth directly from the container. Huffing refers to placing a bag saturated with a substance over the mouth and using the nose or mouth to inhale the concentrated fumes. Bagging refers to inhaling concentrated fumes, specifically from a plastic bag (Koehler, 2014). Illicit drug use among adolescents included marijuana (68.72 %), inhalants (26.76%), misused prescription drugs (2.80%), hallucinogens (1.25%), and hard drugs (0.47) (Zhang S, 2021). Table 1 shows the age group of those who inhale, and Table 2 shows the number of days that adolescents inhaled.

Table 1. Inhalant Use by Age Groups in 2014

Age Range (years)	Percent
12 or 13	2.4
14 or 15	2.9
16 or 17	2.0
18 to 20	1.7
21 to 25	1.2
26 to 34	0.7
35 or older	0.2

(Lipari, 2017)

[26] Felt-tip markers
[27] Butane and propane.
[28] Spray paint, hair spray, deodorant, air fresheners.
[29] Asthma spray, fabric spray, computer aerosol dusters,
[30] Gaseous, liquids or local.
[31] Dry cleaning, spot remover, degreaser, lacquer, thinners, solvents.
[32] Nail polish remover, paint remover, paint thinner, correction fluid and thinner, fuel gas, lighter fluid, fire extinguisher, gasoline.
[33] Felt-tip markers was the number one product inhaled.

Table 2. Frequency of Inhalant Use in 2014

Number of Days	Percent
1 to 11	59.0
12 to 49	19.3
50 to 99	14.0
100 to 299	6.9
300 or more	0.7

(Lipari, 2017)

Fourteen to 15-year-olds inhaled most frequently, while those over 35 years old inhaled the least frequently. As reported in Ossiander in 2015, an estimated 12 percent to 15 percent of eighth graders have used an inhalant at least once. Most adolescents inhaled from 1 to 11 days per year. Inhalant use may lead to abuse or dependance in 10 percent to 50 percent of cases, depending on the characteristics of the population studied (Perron, 2021). In 2020, in those age 12 years or older, 0.1 percent[34] had an inhalant-use disorder in the previous 12 months.

Adolescents who initially used inhalants were less likely to use a new drug, compared to adolescents who initially used marijuana. By the second year of the of the observation period, the probability of using a new drug was approximately 10 percent for an abuser who initially used inhalants. By the eighth year of the observation period, the probability of using a new drug by an abuser who initially used inhalants is 70 percent to 80 percent and 40 percent for other drug users (Zhang, 2021). Those who begin abusing drugs with inhalers, tend not to use new classes of drugs in comparison to those who begin with other drugs.

Therefore, staff understands from this reference that half of adolescent abusers of inhalants may continue to use inhalants and then switch to other types of drugs after 8 years of use. However, the transition from inhalants to illicit drug use might be underestimated because of the self-reporting, data-collection method of the NSDUH.

There are many inhalants available to substitute for aerosol duster products,[35] as well as many aerosol products, like insect repellants and personal care items, that contain DFE.[36] The results of another report that used NSDUH data found that adolescents ages 12 to17 are vulnerable to inhalant use, and continuing efforts are needed to educate all parties, including policymakers, about the dangers and health risks of inhalant use (Lipari, 2017).

[34] About 215,000 people.

1,1-Difluoroethane and Similar Propellants

Although aerosol duster products have been referred to as “air dusters,” they do not contain air. They contain aerosol propellants like 1,1-difluoroethane (HFC-152a), 1,1,1,2-tetrafluoroethene, also known as norflurane (HFC-134a), and 1,3,3,3-tetrafluoropropene (HFO-1234ze). The so-called air duster product, 1,3,3,3-tetrafluorane, is also commonly used when non-flammability is needed, or as a more environmentally friendly choice.

Pharmacokinetics

Aerosol propellants at concentrations of 60 percent to100 percent are stored as liquified gas under pressure. When the trigger is pulled on the canister, the gas exits the canister at temperatures well below freezing and immediately vaporizes.

Medical studies have demonstrated that inhalation of norflurane in minimal doses over an extended period did not cause any long-term health effects and had utility as a surgical anesthetic (Koehler, 2014). Norflurane has been phased out due to its high global warming potential.[37]

Tetrafluoroethene and other abused inhalants are extremely lipophilic,[38] rapidly absorbed into the pulmonary vasculature, and they easily cross the blood-brain barrier. The onset of intoxication is rapid, while the effects are brief and dose-related, ranging from euphoria, decreased inhibition, motor excitation, and light-headedness. Small doses can result in dysarthria,[39] sedation and anesthesia; while larger doses can result in death (Koehler, 2014).

Human Toxicology

Toxicity in humans can occur after acute or chronic exposure to DFE (Poisindex, 2021). The risk is greatest when the DFE is directly injected into the mouth, as when using the sniffing or spraying method (Koehler, 2014). Severe toxicity can cause depressed mental status, respiratory depression, pulmonary edema, hepatic, renal injury, ventricular dysrhythmias, and sudden death.[40] Additional systemic effects on the circulatory and gastrointestinal system can also occur. Mild-to-moderate toxicity effects

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[37] EPA’s July 2015 final rule under SNAP (July 20, 2015, 80 FR 42870).
[38] Lipophilic is fat soluble (see glossary).
[39] A list of medical terms is found in Appendix A.
[40] Sudden sniffing death syndrome (SSDS) was first described 47 years ago. Patients inhale fluorinated hydrocarbons to become “high,” and if physical exertion or stress occurs, and catecholamines are released, the inhaler may collapse and die. (Smeeton, 1985; Kamm, 1975; Poisindex, 2021). Recently, sudden death has also been reported to occur without the release of catecholamines (Kamm, 1975; Dingle, 2019).

include headache, mucous membrane and ocular irritation, and defatting injury of the skin. Frostbite after exposure to cold gas can occur. High-pressure digit injury, resulting in digital ischemia, has been reported (Poisindex, 2021).

Brain

The high degree of lipophilicity of DFE can cause euphoria and central nervous system (CNS) depression. Chronic use of DFE may particularly affect the cerebellum and lead to ataxia and peripheral neuropathy (Tormoehlen, 2014), generalized tonic clonic seizures (Kopec, 2014), lethargy and confusion (Arroyo, 2018), cerebral edema (Kamm,1975), confusion, agitation, dizziness, and vertigo (Hinojosa, 2020). Several volunteers were exposed to 500,000 ppm of HFC 152a for several minutes; analgesia and an impending loss of consciousness were reported (Bingham, 2001).

Bone

Heterotopic ossification and skeletal fluorosis, where bone forms in the soft tissues surrounding the joint, has been reported to occur (Peicher, 2017).

Heart

Cardiac side effects of inhalant abuse include hypotension, bradycardia, decreased cardiac output, and toxic myocarditis (Brown, 2013). These dysrhythmias occur through multiple mechanisms, including alteration of the potassium current, prolongation of repolarization, and catecholamine surge. DFE can also sensitize the myocardium to epinephrine and dopamine, leading to fatal dysrhythmias (Tormoehlen, 2014; Kamm, 1975). Dysrhythmias preceded by inhalant abuse are often refractory to standard Advanced Life Support medications (Dingle, 2019). Direct tissue injury can lead to cardiomyopathy (Poisindex, 2021).

Kidney

Inhalation of DFE can cause acute kidney dysfunction (Kumar, 2016).

Pulmonary

When inhaled, fluorinated hydrocarbons can cause bronchial constriction; they have produced a 20 percent or greater decrease in FEV1 in asthmatic patients (Sterling and Batten, 1976). Inhalation of a fluorinated hydrocarbon aerosol have caused respiratory failure (Arroyo, 2018), pneumonia (Dingle, 2019) and respiratory arrest after displacing oxygen from the lungs (Johansson, 1998). Pulmonary edema has been a finding in autopsy of fatal cases (Lehman, 1991).

Skin

Aerosol propellants, such as 1,1,1,2-tetrafluoroethane, are stored as liquid gas under pressure. When the trigger on the canister is pulled, the gas exits. If the canister is shaken or turned upside down, the liquid is released, freezing any tissues on contact and causing frostbite. (Koehler, 2014).

Frostbite of eyelids can occur and be extensive, requiring skin debridement and grafting (Kurbat,1998; Poisindex, 2021; Koehler, 2014). Frostbite can also affect the airways, oropharynx (Winston, 2015; Poisindex, 2021; Kuspis,1999), face (Koehler, 2014), and hands (Wegener 1991, Xie, 2020, Koehler, 2014).

Survey of Cases in the Medical Literature

With more than 1,133 incidents reported in CPSRMS related to computer aerosol duster inhaling, including 1,126 deaths and an estimated 25,300 emergency department-treated injuries reported from NEISS, Table 1 highlights some toxicity and death incidents following DFE inhalation derived from the medical literature. No toxicity dose response was seen in the cases below.

Table 1. Case Studies from the Medical Literature

Narrative	Reference	Number of Duster Cans Inhaled
TOXICITY		
A 12-year-old girl suffered first- and second-degree burns to her face, neck, shoulders, and chest during recreational use of DFE from an aerosol computer cleaner.	Moreno, 2007	Not known if it was her first use.
A 16-year-old boy developed frostbite of his lips and tongue, first- and second-degree burns of his larynx and vocal cords, and first-degree burns of his trachea and mainstream bronchi after deliberate inhalation of an airbrush propellant containing DFE.	Kuspis and Krenelok,1993	Abused propellants routinely
A 20-year-old man presented to the emergency department with pain, edema, and blistering of the	Koehler, 2014	N/A[41]

[41] N/A-not available

lips, cheeks, tongue, and fingers on the left hand. One hour prior, he had been inhaling aerosolized computer cleaner, until he lost consciousness. He was treated for frostbite.		
A 24-yr-old male patient was dyspneic on exertion and had difficulty balancing while walking. The patient had been inhaling several times a day for 5 days. He was diagnosed with toxic myocarditis and acute renal failure. He was discharged after 6 days and admitted to a mental health facility for suicide attempts.	Dingle, 2019	Several cans a day for 5 days
A 30-year-old man developed persistent dyspnea and a persistent abnormal cardiac T wave after using a computer aerosol duster product for a few weeks.	Sidlak, 2019	N/A
A 33-year-old man presented to the emergency department. He was huffing a computer aerosol duster, which caused dizziness and loss of consciousness. He was released and advised to stop huffing. The next day he was found with altered mental status and was brought into the emergency department. Initially, he was asymptomatic but had signs of congestive heart failure and acute kidney dysfunction. He slowly improved with supportive care and was discharged	Kumar, 2016	N/A

home after 16 days of hospitalization.		
A 33-year-old male developed skeletal fluorosis.	Peicher, 2017	2-7 cans/week for 4 years
A 54-year-old man used computer aerosol duster and glue to fix a fractured tooth. After feeling a euphoric sensation, a male used 6 cans per day until he went to the emergency department and was determined to have a 25%-30% cardiac ejection fraction. He was diagnosed with a toxic myocarditis secondary to inhaled halogenated hydrocarbons.	Brown 2013	6 cans per day
Death		
A 14-year-old male had been huffing computer aerosol duster for a couple of weeks. He was found dead in his bed with a sheet over his head and a red straw coming from his mouth and a jumbo can of computer aerosol duster between his legs. His mother discovered him.	www.consumered.org/personal-stories[42]	He had been huffing for a couple of weeks
A 20-year-old man was found dead on the floor next to a computer. A nearly full can of computer aerosol duster was found on the floor next to the deceased, and an empty can of the duster was found on the computer desk. The cans were purchased earlier in the day.	Xiong, 2004	An empty can and a nearly full can
A 26-year-old woman developed confusion and lethargy after unwitnessed inhaling of suspected 1,2-	Arroyo, 2018	N/A

[42] From the Alliance for Consumer Education (ACE) website.

difuoroethane in an aerosol cleaner. She was taken to a hospital and intubated in the emergency department for respiratory failure. Cardiac ejection fraction was below 5%, and the patient had many episodes of ventricular fibrillation. Six days after admission to the hospital, the patient died.		
A 30-year-old man with no known medical history was found dead in his room, lying on the floor, and gripping an air-duster canister. Ten empty and two unused canisters were found in the room.	Yamada, 2018	10 empty canisters
A 33-year-old male had a tonic clonic seizure, ventricular tachycardia, and he died.	Kumar, 2015	Nearly continuous huffing for 2 days
A 41-yr-old man presented to the emergency department after being found by local police in his vehicle surrounded by computer aerosol duster cans. This man had bought as case of these cans daily for the past week. He had started huffing in the previous month to stop drinking. Five hours after he arrived in the emergency department, he had an episode of ventricular fibrillation and expired after treatment.	Kopec, 2014	“Surrounded by aerosol duster cans”
A 42-year-old man was found dead, lying on the front seat of his car in the parking lot of a grocery store. The passenger compartment and	Avella, 2006	Approximately 40 cans

trunk contained approximately 40 canisters of aerosol duster. It is not known whether the canisters were completely empty. The cause of death was fatal cardiac arrythmia due to intoxication of 1,1-difuoroethane.		

The lack of a toxicity dose relationship of aerosol duster products makes it difficult to predict the toxicity after one inhales a specified number of aerosol duster canisters.

Some studies showed measurements of the concentration of DFE in the inhalant's organs following death (Table 4). Variability in the data can be related to the metabolism of the compound, time of death, and time of sample measurement.

Table 2. Concentration of DFE in Human Inhalant Organs After Death

Outcome	Brain mg/kg	Liver mg/kg	Kidney mg/kg	Lung mg/kg	Skeletal muscle mg/kg	Reference
Died,[43] inhaled a little more than a full can	43.8	92.7	24.3	91.1	80.5	Avella, 2006
Died, inhaled 10 cans	126	90	92	89	104	Yamada, 2018
Died,[44] inhaled 40 cans	117.5	87.6	N/A	60.3	N/A	Avella, 2006

Conclusion

Many aerosol consumer products are easily accessible, safe when used as intended, but can cause toxic effects, and even death, if abused through inhalation. Aerosol dusters are one of these products.

[43] Previously published tissue distribution of a 20-year-old man after autopsy (Xiong, 2004).
[44] Tissues of a 42-year-old man after autopsy.

Inhalation by humans of aerosol duster products that contain DFE can affect various organ systems, including the brain, bones, heart, lungs, kidneys, and skin, and can result in death. It is difficult to predict the toxicity of inhaling a certain number of aerosol duster canisters because there is no clear dose-response evident in the available inhalation data. Inhaling approximately one can has resulted in death (Xiong, 2004), while inhaling two to seven aerosol duster cans a year for 4 years did not cause death (Peicher, 2017).

Under the FHSA, "toxic" is defined by the statute as "any substance (other than a radioactive 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). Under this definition, DFE is a toxic substance.

In 2020, in those age 12 years or older, 0.1 percent [45] had an inhalant-use disorder in the past 12 months (NIDA, 2021). MECAP data, from 2008 to 2021, recorded 159 deaths from inhaling aerosol duster cans, including four 16-year-old adolescents and a 17-year-old (Lipari, 2017). More than 1,133 incidents reported in CPSRMS were related to aerosol duster huffing, including 1,126 deaths; in addition, an estimated 25,300 emergency department-treated injuries (NEISS) were reported (Zhang, 2022 memo).

Although there is not clear dose-response toxicity data on humans, there are many examples of human injuries and deaths caused by aerosol duster products. Therefore, CPSC staff concludes that the chemical DFE, or similar halogenated hydrocarbons contained in aerosol duster products, are "toxic" as defined in 15 U.S.C. § 1261 (g) of the FHSA.

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Appendix A.

Glossary

Acute kidney dysfunction is when kidneys suddenly become unable to filter waste products from the blood.

Ataxia is a lack of muscle control or coordination of voluntary movements, such as walking.

Blood brain barrier is a filtering mechanism of the capillaries that carry blood to the brain and spinal cord tissue.

Bradycardia is a slower-than-normal heart rate.

Cardiac output is the amount of blood that a heart pumps through the circulatory system.

Cardiomyopathy is a disease of the heart muscle that makes it difficult for the heart to pump blood to other parts of the body.

Catecholamines is an organic compound that acts like a neurotransmitter, such as epinephrine or dopamine.

Cerebellum is the part of the brain at the back of the skull that coordinates and regulates muscle activity.

Cerebral edema is a swelling in the brain caused by excess fluid.

Debridement and grafting are procedures to remove debris or infected or dead tissue from a wound and transplant new skin on the injured site.

Defatting injury is the dissolving of dermal tissue by a chemical agent.

Derivative is a compound that is derived from a similar compound by a chemical reaction, to replace an atom by another atom, or group of atoms.

Dyspnea is shortness of breath.

Digital ischemia is a restriction in the blood supply to the fingers or toes.

Dopamine is a neuromodulatory molecule that sends messages between nerve cells.

Dysarthria is slurred or slow speech when one has difficulty controlling the muscles used for speech.

Epinephrine is a hormone secreted by the adrenal gland in response to physical or mental stress.

FEV1- (Forced Expiratory Volume) is the maximum amount of air you can forcefully exhale in one second.

Generalized tonic clonic seizures are grand mal seizures involving unconsciousness and violent contractions.

Heterotopic ossification is bone formation in the soft tissues surrounding the joint where bone does not normally exist.

High pressure digit injury is a fingertip injury caused by high pressure.

Hypotension is low blood pressure.

Hypoxemia is blood oxygen levels that are lower than normal.

Lipophilic is having an affinity for fats.

Lipophilicity is the ability of a chemical compound to dissolve in fats and oils.

Liquified gas is a gas that has been turned into a liquid using high pressure.

Myocarditis is inflammation of the heart muscle.

Oropharynx is the section of throat located at the back of the mouth.

Peripheral Neuropathy is a disease affecting peripheral nerves that causes weakness, numbness, and pain in the feet and hands.

Pulmonary edema is a condition where fluid accumulates in lung tissues, causing shortness of breath, wheezing, and coughing up blood.

Repolarization is the restoration of the difference in charge between the inside and outside of the cell membrane.

RFc- is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure of the human population (including sensitive subgroups) that is likely to be without appreciable deleterious effect during a lifetime.

Skeletal fluorosis is a bone disease caused by an accumulation of fluoride that leads to weakened bones. It can be painful and cause damage to bones and joints in advanced cases.

Ventricular dysrhythmia is a disturbance in the normal rhythm of the electrical activity of the heart that arises in the ventricles, one of two large chambers toward the bottom of the heart that collect and expel blood towards the lungs and the rest of the body.

Vertigo is a feeling of spinning, even when you are not moving, which is caused by a problem with your inner ear or your central nervous system.

Whippets are canisters full of nitrous oxide gas that are abused as recreational drugs.

Appendix B.

Number of Deaths Reported in MECAP (2008 to 2021)

Age (years)	Number of incidents	Age (years)	Number of incidents	Age (years)	Number of incidents
15	1	34	3	53	0
16	1	35	11	54	2
17	1	36	7	55	2
18	2	37	3	56	1
19	2	38	9	57	0
20	1	39	1	58	0
21	1	40	6	59	1
22	4	41	1	60	0
23	8	42	1	61	1
24	7	43	4	62	0
25	5	44	1	63	1
26	3	45	1	64	0
27	5	46	7	65	0
28	8	47	4		
29	6	48	1		
30	10	49	4		
31	5	50	4		
32	6	51	1		
33	7	52	4		

Number of Deaths Reported in MECAP (2008 to 2021)

Year	Number of incidents
2006	2
2007	3
2008	2
2009	4
2010	3
2011	5
2012	6
2013	17
2014	7
2015	18
2016	17
2017	24
2018	21

2019	17
2020	19

TAB B: Aerosol Duster Petition: Bitterants

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Cheryl Scorpio, Ph.D.,
Project Manager, Aerosol Duster Petition
Directorate of Health Sciences

DATE: July 20, 2022

THROUGH: Stefanie Marques, Ph.D.,
Director, Division of Pharmacology and Physiology Assessment, Directorate of Health Sciences

FROM: Andrei Komarov, M.D., Ph.D., DABT
Physiologist, Division of Pharmacology and Physiology Assessment, Directorate of Health Sciences

SUBJECT: Aerosol Duster Petition: Bitterants

I. Introduction

Congress, in the Consumer Product Safety Improvement Act of 1990, directed the U.S. Consumer Product Safety Commission (CPSC) to conduct a study of the aversive agents. CPSC reviewed aversive agents for ingestion in a 1992 report (CPSC, 1992). In the report, CPSC concluded that bitterants[46] have low toxicity and recommended that the use of aversive agents, as deterrents for ingestion, should not be required, due to the lack of efficacy data.

In response to the abuse of aerosol dusters (huffing or dusting), several U.S. companies introduced similar products with a synthetic bitterant, known as denatonium benzoate (DB).[47] Abusers of these products spray the contents of the can into their nose or mouth or inhale it from a cloth or in a bag (NIDA, 2012). Current formulations of aerosol dusters provide DB at concentrations between 0.05 ppm and 0.5 ppm in the aerosol vapor phase (Perron et al., 2021; Patent, 2010). DB concentrations higher than 0.5 ppm in the aerosol vapor phase can interfere with normal use of the product.[48] To avoid such interference, and to release DB at 0.05-0.5 ppm

[46] A bitterant is a chemical that is added to a product to make it taste extremely bitter. Bitterants are used to prevent poisoning from the ingestion or inhalation of other toxic chemicals.
[47] In addition to its use in aerosol dusters, denatonium is used in denatured alcohol, antifreeze, respirator mask fit test, animal repellents, liquid soaps, shampoos, and Nintendo Switch game cards to prevent accidental swallowing or choking by children.
[48] Aerosol duster users start sensing DB in the air at a level above 0.5 ppm.

in the vapor phase, the DB level in the liquid phase should be kept between 5 ppm and 50 ppm[49] (Patent, 2010).

In 2010, the numbers for cases of inhalant abuse related to propellants, including aerosol dusters, reportedly increased sharply in the United States, while the number of cases involving other inhalant types declined (Marsolek et al., 2010). Commonly abused inhalants include amyl nitrite, correction fluid, gasoline, glue, shoe polish, toluene, halothane, ether, paint solvents, butane, propane, nitrous oxide, and aerosol sprays (Perron et al., 2021).

The Petitioner requested that CPSC require manufacturers to add an aversive agent (bitterant other than DB) to all aerosol duster cans at a level of 30–40 ppm.

II. Discussion

A. Physiology

Bitter compounds are initially recognized on the tongue and in the mouth by the TAS2R family of receptors (this is a type of cellular protein that facilitates the sensation of taste). Recently, members of the bitterant receptor family have been localized to solitary chemosensory cells of the nasal cavity (and elsewhere), where they appear to be playing a protective role[50] (Coppola and Slotnick, 2018).

Chemical structures of bitter chemicals are diverse and cover essentially all structural classes of organic and inorganic compounds (DuBois et al., 2008). There is also significant variability of the bitter taste perception in the human population. In humans, taste thresholds for sucrose octaacetate (SOA) range in relative bitterness (RB)[51] from 0.25 to 16 units (Boughter and Whitney, 1993). Fifteen percent to 30 percent of adults do not detect the taste of bitter compounds (CPSC, 1992; NIDCD, 2010; NIDCD, 2019); however, there are also individuals who express an increased sensitivity to bitter substances like DB (Perron et al., 2021).

Mice acquired tolerance to DB after long-term exposure (PLOS One, 2018). Similar tolerance for bitterants can develop in humans.

B. Toxicity

DB is a bitterant in some retail aerosol duster products. DB is a quaternary ammonium organic compound that was discovered accidentally in 1958, during research on local anesthetic agents (Hansen et al., 1993). DB has a low acute toxicity (oral LD_{50} 584 mg/kg in rats, and 508 mg/kg in rabbits) (PubChem data for DB, 2021) and a sufficient safety margin at the level of 20 to 50 ppm (CPSC, 1992). There was no adverse reaction to DB in aerosol form after acute inhalation by rats (0.1% weight/volume) for 4 hours (CPSC, 1992a; CIR, 2008). Staff found chronic oral

[49] A bitterant in the liquid phase is in equilibrium with a bitterant in the aerosol vapor phase.
[50] Many poisons are bitter chemicals.
[51] Relative bitterness of the chemical X: SOA bitterness threshold is divided by the bitterness threshold of this chemical; higher numbers indicate more bitterness. Threshold is a concentration of the chemical detected by half of the tested adults.

dosing studies (1, 6, 8, and 16 mg/kg/day) in rats (for 2 years) and monkeys (for 1 year) (CIR, 2008). In these studies, staff noted some deaths in monkeys, but there was no toxicity in rats. DB was not mutagenic (CPSC, 1992). It was not irritating in rabbits, and it was not a contact allergen in guinea pigs (CPSC, 1992; CIR, 2008).

In the human forearm irritation test, irritation due to DB was unlikely (CPSC, 1992). Exposure to DB was not harmful to human volunteers in oral tests using 10 ppm and 30 ppm (Sibert and Frude, 1991; Jackson and Payne, 1995). However, the DB toxicity profile is not complete; there are no data, or no valid data, on the toxicokinetic, reproductive, and developmental toxicity, carcinogenicity, and neurotoxicity (EFSA, 2012).

DB is detectable by humans in ingested substances at concentrations as low as 0.01 ppm. At 0.05 ppm, a bitter taste is noticeable, and at 10 ppm, an unpleasant bitter sensation was reported (Hansen et al., 1993). A man felt nauseated and lightheaded after DB exposure[52] (National Capital Poison Center, 2022). He tasted and smelled bitterness on his lips. These symptoms gradually resolved after rinsing his skin and mouth with water (National Capital Poison Center, 2022).

There are case reports of human hypersensitivity to DB, including asthma and allergic skin reaction (Bjorkner, 1980; Chen et al., 2019; Youakim, 2007), see Table 1 for details. Some of these cases lead to hospitalization. People with a history of allergy to disinfecting products (containing quaternary ammonium or quats)[53] should avoid exposure to DB (Chen et al., 2019).

Table 1. Case reports of human hypersensitivity to DB

Reference	Case report
Bjorkner, 1980	A 30-year-old male developed asthma and severe itching of the skin after using an insecticidal spray. The same symptoms appeared with an alcoholic skin disinfectant and other spirituous preparations denatured with DB. An open epicutaneous test (topical application of the test material to the skin) showed wheal and erythema (local skin reactions, which are caused by the release of histamine from mast cells). The author concluded that the skin reaction elicited from DB was caused by an immunologic mechanism of the immediate hypersensitivity type. Hypersensitivity reactions are exaggerated or inappropriate immunologic responses to a chemical or an allergen mediated by immunoglobulins. They occur within 24 hours of exposure.

[52] A man conducted multiple mask fit tests with 1 percent DB solution.
[53] Quats are common ingredients in disinfectant products used against the COVID-19 virus.

Reference	Case report
Chen et al., 2019	A 34-year-old female nurse rapidly developed shortness of breath, cough, and agitation after DB respirator mask fit testing. She had a history of allergy to shrimp, crab, dust mites, and disinfecting products (containing quaternary ammonium). She was diagnosed with allergic asthma. The patient showed quick responses after medical treatment. Approximately 2 weeks later, she suffered from difficulty breathing and asthmatic symptoms again when she was exposed to polished wax and disinfectant. She was treated with several medications and remained in stable condition with improvement in symptoms during follow-up.
Youakim, 2007	The author reviews eight claims submitted to the Workers' Compensation Board of British Columbia for adverse reactions related to DB respiratory mask fit testing. The adverse effects varied in severity. Most claims involved respiratory symptoms and skin irritation or swelling in the deep layers of the skin. One asthmatic required hospitalization for a severe asthmatic reaction.

The petition suggests that DB-induced bronchodilation (expansion of the bronchial air passages) can increase the toxic effect of aerosol duster spray inhalation. There are reports on in vitro bronchodilation effect of DB in mice and human samples (Deshpande et al., 2011, 2011a; Clifford and Knox, 2012; Tan and Sanderson, 2014). Perron and others (2021) hypothesized that DB might increase the physiological effects of huffing in those with asthma and other bronchoconstrictive diseases.[54] In addition, chronic exposure to DB might lead to nasal polyps and chronic inflammation of the sinuses surrounding the nasal cavity (Perron et al., 2021).

The petition requests that CPSC mandate the use of alternative bitterant at the level of 30 to 40 ppm. Because of the concerns expressed about DB, staff did not consider available denatonium derivatives like DB.[55] CPSC staff considered the following bitterant alternatives:

1. Sucrose octaacetate, or SOA, is a synthetic bitterant with a large safety margin (oral LD_{50} was more than 5000 mg/kg in rats and more than 45,000 mg/kg in rabbits) (Stagner et al., 2019; EPA, 2005), but it is also 500-fold less bitter than DB (CPSC, 1992). SOA is detected as bitter at 10 ppm by 50 percent of adults (CPSC, 1992). Only a concentration of 600 ppm can render a substance inedible. Feeding SOA to rats and rabbits at 4 g/kg/day for 3 months produced no effects. SOA had little or no activity as a skin or eye irritant (CPSC, 1992). SOA was not mutagenic (EFSA, 2011). There was no information on the carcinogenic or teratogenic potential of this compound (EPA, 2005; EFSA, 2011).
2. Quassin is a natural bitterant (oral LD_{50} was 800 mg/kg in rats) that is even less bitter than SOA with RB = 0.67 (CPSC, 1992). CPSC ruled out another natural bitterant brucine (RB = 2.20) due to its high toxicity (CPSC, 1992).

[54] Bronchoconstriction is the constriction of the airways in the lungs.
[55] Denatonium saccharide, denatonium chloride, and denatonium capsaicinate (patented in 1999).

3. There are other common natural bitterants[56] (DuBois et al., 2008; Intelmann et al., 2009). Some of these chemicals should be removed from consideration due to their known pharmacological activity[57] (nicotine, digitoxin, caffeine). Only humulone from hops (oral LD_{50} was 1,500 mg/kg in rats; Bejeuhr, 1993) demonstrates a bitterness marginally better than SOA (Intelmann et al., 2009). The toxicity profile of humulone is not complete.

C. Bitterant/Aerosol Formulation

The chemical 1,1-difluoroethane (DFE), or HFC152a, is the most common propellant used in retail aerosol dusters.

Staff identified synthetic bitterant SOA and natural bitterant humulone as the most potent bitterants that are alternatives to DB, see Table 2 for details (CPSC, 1992; DuBois et al., 2008; Intelmann et al., 2009). Humulone has not been found to be used in aerosol formulations.[58]

Table 2. DB and alternative bitterants

Chemical name	Molecular formula	Relative Bitterness	Oral LD_{50} in rats	Aerosol form
SOA	$C_{28}H_{38}O_{19}$	1.00	5,000 mg/kg	Yes
Humulone	$C_{21}H_{30}O_5$	1.25	1,500 mg/kg	No
DB[59]	$C_{28}H_{34}N_2O_3$	500.00	584 mg/kg	Yes

SOA is readily soluble in organic solvents. It has a solubility of 12 percent (volume/volume) at 95 percent ethanol at room temperature (Stagner et al., 2019). Thus, SOA solubility should not be an issue for aerosol preparation. A U.S. patent describes aerosol formulation for SOA from 5 ppm to 1175 ppm in the liquid phase (Patent, 2014). However, the recommended range of liquid-phase concentrations was from 5 ppm to 50 ppm. Higher concentrations can interfere with the use of the product (Patent, 2014). The applicants stated that SOA aerosol was bitter in the recommended range (corresponding SOA levels in the aerosol were from 0.05 ppm to 0.5 ppm). However, it is unclear if the aerosol was sufficiently bitter to prevent abuse. Concentrations stated for SOA formulation (Patent, 2014) were the same as in the earlier patent application for DB (Patent, 2010), see Table 3 for details. Yet, SOA is 500-fold less bitter than DB (Table 2).

[56] Humulone (RB = 1.250), nicotine (RB = 0.210), quinine (RB = 0.130), urea (RB = 0.067 to 0.057), limonin (RB = 0.053), digitoxin (RB = 0.041), caffeine (RB = 0.006), and catechin (RB = 0.004).
[57] Pharmacological activity means that chemicals may produce undesired health effects.
[58] Staff conducted a Google Scholar search using terms such as “humulone bitterant,” “humulone aerosol,” and “humulone duster.”
[59] Data from DuBois and others (2008) suggest that DB has an even higher RB = 625.00.

Table 3. Patented aerosol formulations for SOA and DB

Bitterant	Propellant[60]	Bitterant in vapor phase (ppm)	Bitterant in liquid phase (ppm)	Reported taste	Interference with normal use	Year patented
DB	DFE[61]	From 0.05 to 0.50	From 5.00 to 50.00	Bitter	No	2010
SOA	DFE	From 0.05 to 0.50	From 5.00 to 50.00	Bitter	No	2014

Thus, although it may be possible to prepare an aerosol formulation with a range of 30 to 40 ppm of alternative bitterant in the aerosol liquid phase,[62] it is not demonstrated that bitterant will be effective.

D. Bitterant Injection Technology

A bitterant is present in the same liquid phase as the propellant, according to both patents (Patent, 2010; Patent, 2014). The Petitioner stated[63] that recent testing documents from two major manufacturers of aerosol dusters (under several different names) show that, most often, DB was not injected into the cans during the manufacturing process (or if it was, it did not appear in the spray) and requested that CPSC to improve the injection technology. The Petitioner did not provide testing data or any references to support their statement. Therefore, staff could not verify this statement and did not identify any improvements in the bitterant injection technology.

E. Safety and Efficacy

CPSC reviewed aversive agents for ingestion in 1992 (CPSC, 1992). In that report, CPSC recommended that the use of the aversive agent should not be required, due to the lack of efficacy data (CPSC, 1992).

None of the bitterants found in the literature have demonstrated efficacy as an aversive agent for inhalants.[64] Information on the human inhalation toxicity of bitterants is lacking.[65] Furthermore, in the recent literature, staff found concerns about DB safety in aerosol dusters (Perron et al., 2021). Between 15 percent to 30 percent of the adults do not detect the taste of bitter compounds (CPSC, 1992; NIDCD, 2010; NIDCD, 2019). Mice acquired tolerance to DB after long-term exposure (PLOS One, 2018). Similar tolerance for bitterants can develop in humans too.

[60] Propellant in aerosol is an inert fluid, liquefied under pressure.
[61] Other propellants listed on this patent were 1,1,1,2-tetrafluoroethane (HFC-134a), dimethyl ether, and hydrocarbons.
[62] Corresponding SOA level in aerosol vapor phase will be less than 0.5 ppm.
[63] See page 5 of the petition.
[64] Staff conducted Google Scholar and PubMed search using the term “bitterant efficacy for inhalation.”
[65] Staff conducted Google Scholar and PubMed search using the term “inhalation toxicity of bitterants.”

Health Sciences (HS) staff has concluded that there is no viable replacement option for DB in aerosol duster products. Furthermore, the use of DB in inhalants is not supported by efficacy data and it is questionable from a safety perspective.

The safety and efficacy of DB use in another application, denatured alcohol (rubbing alcohol), have also been questioned (Garcıa-Valenzuela and Baez-Gaxiola, 2021). Furthermore, the addition of DB to denatured alcohol did not prevent its consumption by adults inclined to abuse the product (PubMed, 1989).

Previously, DB was an active ingredient in nail-biting and thumb-sucking deterrents. The Food and Drug Administration removed the approval for these products, citing the lack of efficacy data (CPSC, 1992). Recent epidemiology studies in several U.S. states have also demonstrated that adding bitterants to antifreeze did not prevent pediatric ingestions or suicidal ingestions of antifreeze (White et al., 2008, 2009; PLOS One, 2015).

Addition of DB to Nintendo Switch cartridges to deter small children and pets from licking them lead to the unintended consequence of gamers licking the game cartridges in an exact reversal of what Nintendo expected to happen (TechWorm, 2020). While the use of bitterants may look like a promising idea, the available data do not support their usefulness in the real world.

F. Injury

DFE inhalation toxicity, discussed in Tab A, may be enhanced by DB-induced bronchodilation (Perron et al., 2021) and other drugs (*e.g.*, prescription drugs or illegal drugs) taken by the abuser.

G. Summary

The Petitioner requested that CPSC require manufacturers to add an aversive (bitterant other than DB) to all aerosol duster cans at a level of 30 ppm to 40 ppm.

There are many unresolved issues with the proposed use of bitterants for aerosol dusters. The most important of them are the absence of efficacy data for bitterants for inhalation abuse and the lack of data for bitterant-inhalation toxicity, in general.

Staff analyzed the data available for 22 synthetic and natural bitterants. The most potent alternative bitterants were humulone and SOA. Humulone has not been found to be used in aerosol formulations. There is a patented SOA aerosol formulation with a recommended range in the liquid phase from 5 ppm to 50 ppm. It is not demonstrated that the deterrent effect is achievable in the aerosol formulation. A high level of bitterants in an aerosol duster is detrimental to regular users. However, bitterants were not a sufficient deterrent for adults inclined to abuse the product and consume denatured alcohol or for suicidal ingestions and pediatric ingestions of liquids, such as antifreeze.

The Petitioner stated that DB often was not injected into the cans during the manufacturing process, and therefore, requested that CPSC improve the injection technology. Staff could not verify this statement by the Petitioner and did not identify any improvements in the bitterant injection technology during manufacturing.

III. Staff Conclusions and Recommendations

As discussed above, HS staff has concluded that neither DB, nor any other bitterant, should be required for use in aerosol duster products, due to the lack of efficacy data and safety concerns.

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TAB C: ESHF Memorandum - Petition from Families United Against Inhalant Abuse (FUAIA) - CP 21-1

United States
Consumer Product Safety Commission
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Memorandum

TO: Cheryl Scorpio, Ph.D., Project Manager, Aerosol Duster Petition
Division of Pharmacology and Physiology Assessment
Directorate for Health Sciences

DATE: July 20, 2022

THROUGH: Mark Kumagai, P.E., Associate Executive Director
Directorate for Engineering Sciences

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

FROM: Julia Kerns, Engineering Psychologist
Division of Human Factors
Directorate for Engineering Sciences

SUBJECT: ESHF Memorandum - Petition from Families United Against Inhalant Abuse (FUAIA) - CP 21-1

In this memorandum, staff from the Directorate for Engineering Sciences, Division of Human Factors (ESHF) evaluates the Petitioner's request for revisions to the warning label and assesses its effectiveness.

INCIDENT DATA

Based on the 2015 National Survey on Drug Use and Health (NSDUH), a nationally representative survey and a primary source for statistical information on illicit drug use, out of 1.8 million people age 12 and over, around 684,000 adolescents ages 12 to 17 were estimated to have used inhalants in 2015 (Lipari, 2017). This means that about 38 percent of total users of inhalants were younger than 18 years of age. The survey indicates that a variety of household products were used, including aerosol duster products.

In contrast, based on the cases reported through the Consumer Product Safety Risk Management System (CPSRMS) by staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), staff developed the following injury estimates for aerosol duster huffing during the period from 2006 to 2020, by age groups:

- Ages 0-17 totaled 3,600, about 14 percent of injuries;
- Ages 18-34 totaled 11,500, about 45 percent of injuries;
- Ages 35-54 totaled 9,700, about 38 percent of injuries, and
- Ages 55-older, about 2 percent of injuries (NEISS, 2006-2020). Injuries for ages 55 and older are under 500; therefore, staff is unable to report an approximate estimate.

These estimates account for approximately 25,300 of injuries caused by aerosol duster products (Tab D).

DESIGNING OUT THE HAZARD

In general, Human Factors relies on a standard hierarchy of approaches to address product hazards, first, by designing out the dangerous features of the product; second, protecting against the hazards, by guarding or shielding; and lastly, by providing adequate warnings and instructions for proper use and foreseeable misuse (Kalsher et. al., 2008). The purpose of warning labels is to provide awareness to unforeseen hazards and persuade consumers to alter their behavior to avoid those hazards. However, in this case, warning labels may not prevent intentional abuse brought on by the consumer.

Staff notes that while designing out the hazard may address the risk with the aerosol duster products, it does not deter users from abusing other available household products. Data show that a variety of household products have been inhaled, such as felt-tip pens and markers, glue, shoe polish, or toluene, spray paints, gasoline or lighter fluid, computer cleaner/aerosol duster, correction fluid, degreaser, or cleaning fluid, lacquer thinner or other paint solvents, amyl nitrate, poppers, locker room deodorizers, nitrous oxide or whippets, lighter gases (butane, propane), halothane, ether or other anesthetics, or other aerosol sprays (Lipari, 2017).

UNDERSTANDING THE LABELING AND THE EFFECTS ON CONSUMERS

For a warning label to be effective, the consumer must notice, read, understand, and heed the warning (Wogalter, Conzola, & Smith-Jackson, 2002). Research demonstrates that the presence of a warning label does not guarantee that it will be noticed or read by the consumer (Wogalter et al., 1987). Consumers may be eager to use the product and ignore the warning label, particularly if they are familiar with the product. A warning label that is concise, easily comprehensible, and noticeable, due to its format and prominent placement, has a higher likelihood of being effective. However, even the best of warnings is not likely to be 100 percent effective; people at risk may not see or understand the label, or they may show an unwillingness to comply (Laughery et al., 2006).

UNINTENDED CONSEQUENCES OF A WARNING LABEL PROPOSED BY THE PETITIONER

A key concern regarding warnings in this application is that a consumer's motivation would be a driving factor in whether the warning label would curb their actions (Argo & Main, 2004).

Warning labels do not prevent consumer exposure to hazards that a consumers might pursue intentionally (Sanders & McCormick, 1993).

Certain warning statements may affect a consumer's emotions or feelings, which could result in the consumer testing the limits of the warning label. Steinberg (2004) posits that risk taking during adolescence is the product of an interaction between seeking heightened stimulation, and an immature self-regulatory system that is not able to modulate reward-seeking impulses. Steinberg states that the notion of self-regulatory competencies is slow to mature, which is consistent with emerging research on the development of prefrontal cortical systems. This research indicates that certain warning language may not have the same level of effectiveness, depending on the consumer's ability to self-regulate. In addition, social influences and peer pressure can drive adolescent behavior stronger than their independent thought processes (Vredenburgh & Zackowitz, 2006).

ESHF staff notes the possibility that the message delivered by warning label proposed by the Petitioner may inadvertently encourage risky behavior by consumers who may not be able to self-regulate their emotions or actions. In other words, it's possible that the suggested label could have the perverse consequence of prompting those who are inclined to abuse inhalants directly to the products so labeled.

ASSESSMENT OF PRODUCT LABELING

ESHF staff evaluated 12 different aerosol duster products to understand the format, content, and placement of on-product labeling of the products currently in the market. CPSC sets forth labeling requirements for products subject to the requirements of the Federal Hazardous Substances Act (FHSA) and 16 CFR § 1500.121.

The labeling requirements for hazardous substances in 16 CFR § 1500.121 provide, at a minimum, the language that should be on the label. Some examples are: "HARMFUL IF SWALLOWED"; "VAPOR HARMFUL"; or "KEEP OUT OF REACH OF CHILDREN." ESHF staff verified that all the examined aerosol duster products are using one or more of these examples provided in FHSA. Furthermore, ESHF staff's observation of examined aerosol duster products found that the products met the format of the type-size requirements, as listed in 16 CFR § 1500.121.[66]

Although all the aerosol duster products examined used signal words, the signal words did not adhere to the formatting required by ANSI Z535.4, American National Standard for Product Safety Signs and Labels. The ANSI Z535 requirement states: "if DANGER is used, it shall be in safety white letters on safety red background, if WARNING is used, it shall be in safety black letters on safety orange background, and if CAUTION is used, it shall be in safety black letters on a safety yellow background."

[66] One aerosol duster product contained a precautionary statement that just barely met the type-size requirement.

ESHF staff observed that the examined aerosol duster products contained statements to inform of the possible intentional misuse, possibility of inhalation abuse, and the potential consequences of either. Although misuse and abuse are not the same concept, the examined aerosol duster products are observed using messages around both concerns. From the examined aerosol duster products, there was also messaging describing the severity of the unforeseen hazards (*e.g.*, dangerous, and fatal).

Some of the observed aerosol duster product labels were easier to read and easily understood. In addition, the information was placed in a conspicuous location, compared to other labels. However, the "intentional misuse or abuse" language was not found in the same placement across the aerosol duster product labels examined.

Although the statements were not placed uniformly across the products examined, the most commonly used statement reads: "INTENTIONAL MISUSE BY DELIBERATELY CONCENTRATING THE CONTENTS OF THIS CAN AND INHALING MAY BE HARMFUL OR FATAL."[67] Seven of the examined aerosol duster products used signal words to draw greater awareness to the severity of the consequences. Five of the examined aerosol duster products contained statements on the back label addressing misuse and abuse. A few examples of "inhalant abuse" statements used the words: "INHALANT ABUSE CAN BE FATAL!" or "INHALANT ABUSE IS ILLEGAL AND CAN CAUSE PERMANENT INJURY OR BE FATAL."

From the examined aerosol duster products, two contained Public Service Announcements (PSAs) about inhalation misuse or abuse. The PSA statement was highlighted with a bold framed box around the message, to stand out from the remainder of the information on the label. In addition, four of the examined aerosol duster products directed the consumer to websites like "inhalants.com" and "inhalants.org," which provide a plethora of information, resources, and education regarding inhalant abuse and recovery.

Lidwell et al., (2003) explain through the Universal Principles of Design that passive redundancy is ideal for noncritical situations. However, if the message is redundant, it can contribute to system failure when used for elements critical to system operation. In simpler terms, Lidwell describes passive redundancy as a way of providing a message one too many times, which may diminish the vital importance of that message. Intentional misuse and abuse are messages that need to reach many, if not all, consumers who use the product. If it is vital for consumers to understand the consequences of intentional misuse and abuse messaging, then the message should be placed once, and in a prominent location.

Staff noted that four of the aerosol duster products examined included a symbol on the label to deter inhalation. These symbols can be seen in Figure 1. Although the inhalation symbols are not a requirement in the CFR regulation, based on research for warning labels, the symbols have been found to assist consumers in understanding the risks of a product in less time than it

[67] One aerosol duster product did not contain any statements pertaining to intentional misuse or abuse, and two aerosol dusters products used a different statement to explain the consequences of misuse or abuse.

would take to read a warning label. ESHF staff acknowledges that well-designed symbols might be useful to convey the inhalation hazard. Pictorial symbols increase the salience and noticeability of warnings (Wogalter, Conzola, & Smith-Jackson, 2002). For example, in a research study, 65 percent of participants found symbol signs easier to understand than word signs (King, 1971). This research supports the conclusion that consumers can comprehend and recognize hazards more quickly in well-designed and concise messaging that uses a symbol sign versus a word sign. Other research also shows that safety symbols increase noticeability of warnings, capture and maintain a user's attention, and facilitate comprehension of safety messages (Young & Wogalter, 1990; Laughery et al., 1993).

Figure 1: Inhalation abuse symbols used on various aerosol dusters

Staff examined the labels for information pertaining to a bitterant. Nine of the aerosol duster products stated that difluoroethane was an ingredient used in the product. However, the placement of the label with this information varied from product to product. Staff also noted that, as described elsewhere in this briefing package, difluoroethane is a propellant, not a bitterant.

Furthermore, there were several aerosol duster products observed online and one from CPSC staff's evaluation that contained the phrase "air in a can," despite a commenter to the petition describing that statement as being discouraged from use in marketing, labeling, and advertising. It is possible that describing the product as just "air" could mislead consumers who might not fully understand how hazardous the product is to breath or inhale.

PETITIONER'S PROPOSED WARNING

The Petitioner proposed placing a "much stronger" warning on the aerosol duster products. The Petitioner suggested using: "DANGER: DEATH – This product can kill you if you breath [sic] it," as an example of wording for a label. The Petitioner also proposed that the warning text be "a full 50% of the front panel in bright red letters with a graphic of a skull and crossbones."

ESHF staff consulted the ANSI Z535.4, American National Standard for Product Safety Signs and Labels, the primary voluntary standard in the United States regarding product safety signs and labels, to assess the adequacy of warning labels (ANSI, 2011). ESHF staff's assessment of the petitioner's recommendation is summarized below:

- Signal word: The Petitioner proposes to use the signal word "DANGER." According to ANSI Z535.4, "DANGER indicates a hazardous situation that, if not avoided, will result in death or serious injury." On the other hand, "WARNING indicates a hazardous situation that, if not avoided, could result in death or serious injury"; and "CAUTION indicates a hazardous situation that, if not avoided, could result in minor or moderate injury" (ANSI, 2011). Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), reviewed the CPSRMS database and identified 1,126 incidents resulting in death from aerosol duster products that occurred in the period January 1, 2006 to December 31, 2020 (Tab D). Furthermore, ESHF staff notes that some of the examined duster products currently state: "DANGER," and they provide some level of information to explain the dangers of inhaling the product and offer guidance in the "First Aid" information about what to do after the inhalation has occurred. Therefore, ESHF staff assesses that the signal word "DANGER" is appropriate.
- Hazard: The Petitioner describes the hazard and consequences with the following proposed text: "DEATH – This product can kill you if you breath [sic] it." When used as directed, aerosol duster products do not pose a risk of death. The proposed text should accurately discuss the conditions that may lead to death and that may erroneously create a false alarm to consumers who would use it as intended. However, as discussed by staff of CPSC's Directorate for Health Sciences, Division of Pharmacology and Physiology (HSPP), at Tab A, if the product is abused, human injuries and death can occur.
- Label Size and Location: The Petitioner suggests covering half of the front panel of the aerosol duster product with the proposed warning label. The ANSI Z535.4 requires that product safety signs and labels be placed in a location so that the label or sign is readily visible to the intended viewer. ESHF staff is unaware of such a large label placed on a consumer product with similar hazard scenarios (*i.e.*, potential abuse). Staff is aware of upcoming regulations for cigarette packaging that will require a warning label to comprise at least the top 50 percent of the front and rear panels of the cigarette package.[68] Staff cautions that the awareness of the hazard and intention of the users in this instance are draw different inferences.
- Color: The Petitioner suggests using red color for the proposed label. As discussed earlier in the assessment of current labeling section, the ANSI Z535.4 requires different colors for different signal word panels: if the word "DANGER is used, it shall be in safety white letter on safety red background"; if the word "WARNING is used, it shall be in safety black letters on safety orange background"; and if the word "CAUTION is used, it shall be in safety black letters on a safety yellow background" (ANSI, 2011). Based on the severity of the outcome discussed above, the signal word panel containing the word "DANGER" must have letters in safety white on a safety red background. In addition, although the Petitioner did not specifically propose this, ANSI Z535.4 recommends the safety alert symbol (exclamation mark in a triangle) to be the same color as the signal word lettering. The same standard provides that the message panel must be in safety

[68] https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements#b

black lettering on a safety white background or be in safety white lettering on a safety black background.

- Graphic containing skull and crossbones: The skull and crossbones are required for certain materials, as stated in 16 CFR § 1500.14. Based on HS staff's analysis, the ingredients in the aerosol duster products do not contain highly toxic hazardous substances listed in 16 CFR § 1500.14 (Tab A). Based on HS staff analysis, ESHF staff concludes that the graphic of a skull and crossbones does not apply to the aerosol duster products.

CONCLUSION

The petition discusses the abuse of aerosol duster products when an individual uses the product in a manner, not recommended by the manufacturer, to satisfy a desired state of feeling. The Petitioner proposes various remedies to address the hazard of aerosol duster abuse. ESHF staff's evaluation of several aerosol duster products provides a baseline level of understanding of the labeling used on aerosol duster products currently in the market.

Bitterants do not prove to be effective, based on analysis by HS staff (Tab B). Many of the aerosol duster products that ESHF staff observed contain labeling with information and messaging about inhalant abuse, albeit in various locations and formats.

Aerosol duster products pose a difficult challenge. Although aerosol duster products provide consumers the ability to clean tiny spaces with ease, the product's design may be susceptible to misuse or abuse for various reasons (*e.g.*, product contents, readily available, or even design). Staff notes that although designing out the hazard may address the risk with the subject aerosol duster products, it does not deter users from abusing other household products.[69]

ESHF staff notes the possibility that the message delivered by the petition's proposed warning label may inadvertently encourage risky behavior by consumers who may not be able to self-regulate their emotions or actions. In other words, it's possible that the suggested label could have the perverse consequence of prompting those inclined to abuse inhalants, directly to the products so labeled. Based on available information, it is unknown whether warning labels will deter misuse or abuse of aerosol duster products or encourage some consumers who may be struggling with addiction or a panoply of other emotions to misuse or abuse aerosol duster products. It would require extensive CPSC research to understand whether abusers would be attracted to the proposed label. However, ESHF staff is uncertain if such research would result in a solution to address intentional misuse or abuse. Nevertheless, even if action were taken to discourage abuse of aerosol duster products, abusers may shift to a variety of other similar products to abuse and misuse intentionally.

ESHF staff also notes that parents who are unaware of the intentional abuse and misuse associated with aerosol duster products may benefit from a noticeable, easy-to-understand, and

[69] Refers to the multitude of other household products that have been abused, as listed in Lipari's data, 2017.

concise, on-product warning label that aims to increase consumers' awareness of the hazard and influence their behavior, such as keeping the product away from not only children, but also teenagers' reach. However, most of the incidents (86% of NEISS injuries and 97% of CPSRMS incidents) analyzed in Tab D involved adult consumers.

Based on the analysis by staff of CPSC's Directorate for Economic Analysis (EC), retailers employ incentive pricing to sell aerosol duster products in cases of 12 to consumers (Tab E). However, if parents knew of the hazard and were concerned about their children's access to the product, parents may avoid buying in bulk, despite the cheaper pricing. ESHF staff also concludes that, based on warning research, having a clear symbol on the product could help alert people to the inhalation hazard.

An effective warning label alerting consumers to the hazard of intentionally abusing aerosol duster products must be balanced with the potential for such a label to encourage risky behavior by consumers struggling with addiction. Hence, such a warning label could lead to the very behavior the label is intended to protect against.

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TAB D: Review of Incidents, Injuries, and Fatalities Associated with Aerosol Duster Products

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Cheryl Scorpio, Ph.D.
Project Manager, Aerosol Duster Petition
Directorate for Health Sciences

DATE: July 20, 2022

THROUGH: Risana Chowdhury
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM: Chao Zhang
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT: Review of Incidents, Injuries and Fatalities Associated with Aerosol Duster Products

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I. INTRODUCTION

Staff from the Hazard Analysis Division of the Directorate for Epidemiology (EPHA) prepared this review of data involving misuse or intentional abuse of aerosol duster products. This review presents information on deaths, injuries, and non-injury incidents from misusing or intentionally abusing (commonly known as sniffing, spraying or huffing, but referred to here as *inhaling or inhalation*) of aerosol duster products.

The National Electronic Injury Surveillance System (NEISS)–based injury estimates are from January 1, 2006 to December 31, 2020; finalized NEISS data and estimates will be available in spring 2022. The reported incidents from CPSC's Consumer Product Safety Risk Management System (CPSRMS) are from January 1, 2006 through December 31, 2020. Data collection is ongoing in CPSRMS, and reporting should be considered incomplete for 2020.[70]

[70] The most recent search of the CPSC databases for incidents involving misuse or intentional abuse of aerosol duster products was conducted on January 7, 2022. Product codes searched were 1133 (Aerosol containers), 0921 (Chemicals not elsewhere classified) and 0954 (General-purpose household cleaners). Aerosol duster products are included as a sub-category of product code 0954 but may occasionally be sorted into product codes 1133 and 0921.

II. RESULTS

The CPSC databases do not contain an exclusive product code for aerosol duster products. Rather, the available relevant product codes are also used to categorize other aerosol containers, general-purpose household cleaners, other chemical products, and any other general products that may be classified within the categories. Aerosol duster products were identified in incident narratives or CPSRMS product descriptions as dusters, aerosol dusters, computer/keyboard/electronics dusters or cleaners, canned/compressed air, or specific brand names. Other volatile substances that appear frequently in huffing or inhaling incidents, but are not in the scope of this review, include paint products, general household cleaning solutions, refrigerants from appliances, air fresheners, and other aerosol can products like spray paint, or whipped cream, for example. This review also excludes aerosol duster incidents that were exclusively associated with common non-huffing/inhaling hazards, such as explosions, fires, and chemical burns.

CPSRMS Incident Data (2006–2020)

Only incidents that specifically mention an aerosol duster product are included in this analysis. Many incidents found in CPSRMS reported deaths due to difluoroethane toxicity, but they did not always identify the product used by the victim. This is most prevalent in death certificate data, where often, the cause of death is only described as difluoroethane toxicity due to inhalant abuse. Although 1,1-difluoroethane is commonly used as an aerosol propellant in duster products, the compound is less frequently used in other products, such as pesticides and air fresheners. As such, the number of CPSRMS incidents included in this analysis is almost certainly an underrepresentation of the true number of aerosol duster huffing incidents that have been recorded in CPSRMS.

Between 2006 and 2020, CPSC received reports for 1,133 unique incidents involving inhalation hazards from aerosol duster products. Table 1 provides an overview of the severity of these 1,133 incidents.

Table 1: Severity of Aerosol Duster Huffing Incidents

Incident Severity	Total Incidents
Death	1,126
Emergency Department Treatment Received	2
Seen by Medical Professional	1
Level of care not known	2
No Injury Reported	2
Total	1,133

Source: CPSRMS (2006-2020)

An overwhelming majority (99.4%) of the aerosol duster inhalation incidents in CPSRMS between 2006 and 2020 resulted in deaths. Most of the CPSRMS incident data were comprised of death certificates (947 of 1,133) from the states and medical examiners and coroners (165 of 1,133). The remaining incident data were received from consumers, manufacturers/retailers, online news, health care professionals, or unspecified sources.

Table 2 provides an overview of the distribution of aerosol duster inhalation victims by age group and gender. Around 70 percent of the victims were male, and 92 percent of the victims were between the ages of 18 to 54. The age of all victims ranged from 13 to 70 years old.

Of the 498 victims in the 18 to 34 age group, 121 were between the ages of 18 to 24 (50 female, 71 female); 176 were between 25 to 29 (68 female, 108 male); and 201 were between 30-34 (55 female, 146 male). Of the 551 victims in the 35-54 age group, 339 were between the ages of 35 to 44 (90 female, 249 male); and 212 were between the ages of 45 to 54 (60 female, 152 male).

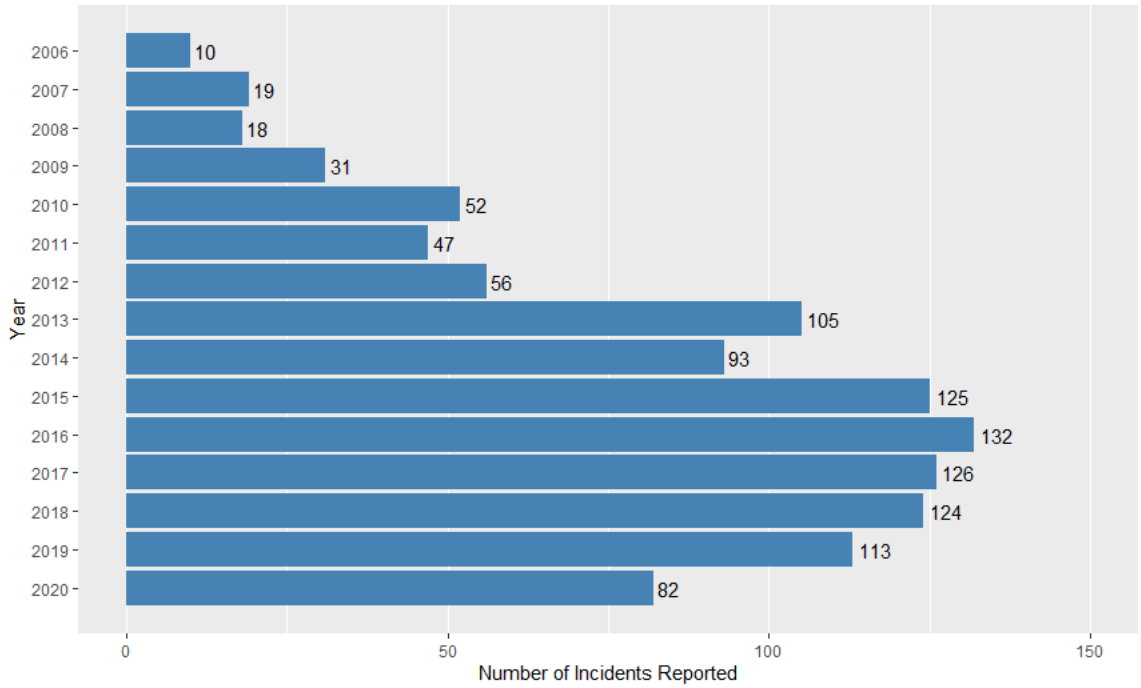
Table 2: Distribution of Aerosol Duster Inhalation Victims by Age Group and Gender

Age Group (Years)	Male	Female	Total
0–17*	12	15	**27**
18–34	325	173	**498**
35–54	401	150	**551**
55 or older*	40	13	**53**
Unknown/Unspecified	4	0	**4**
Total	**782**	**351**	**1,133**

*The minimum victim age in the data was 13 years, while the maximum age was 70 years.
Source: CPSRMS (2006-2020).

Figure 1 provides an overview of the distribution of the number of aerosol duster inhalation incidents in CPSRMS per year. Data in CPSRMS is anecdotal in nature and does not necessarily represent all incidents that have *occurred*. Furthermore, because data collection is ongoing, the numbers may change, especially for the later years.

Figure 1: Number of Aerosol Duster Inhalation Incidents Reported by Year



Source: CPSRMS (2006-2020).

Table 3 and Figure 2 provide an overview of the distribution of aerosol duster inhalation incidents in CPSRMS by U.S. state. CPSRMS contains reports for aerosol duster inhalation incidents from all 50 states, except for West Virginia. No incidents were reported from the District of Columbia.

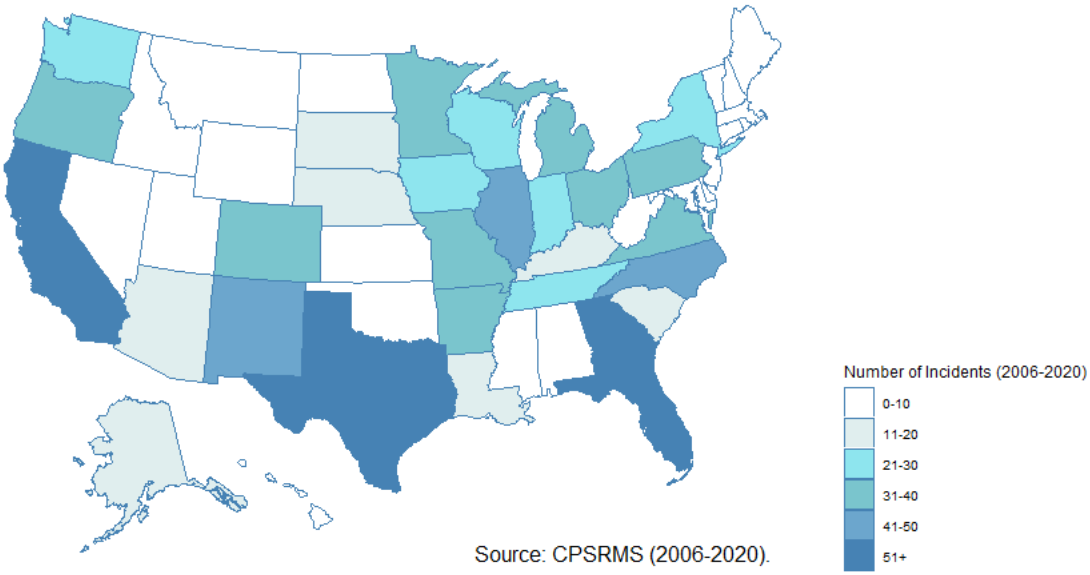
Table 3: Number of Aerosol Duster Inhalation Incidents Reported by State

State	Incidents	State	Incidents
Texas	80	South Dakota	13
Florida	79	Arizona	12
California	68	Kentucky	12
Georgia	57	Maryland	10
Illinois	50	Massachusetts	10
New Mexico	41	Nevada	10
North Carolina	41	Oklahoma	9
Minnesota	37	Alabama	7
Oregon	37	Delaware	7
Colorado	36	Mississippi	7
Pennsylvania	36	Montana	7
Michigan	33	New Hampshire	6
Ohio	33	New Jersey	6
Missouri	32	Maine	5
Arkansas	31	North Dakota	5
Virginia	31	Utah	5
Tennessee	29	Connecticut	4
Wisconsin	27	Hawaii	4
Indiana	25	Kansas	4

New York	25	Vermont	3
Iowa	23	Idaho	2
Washington	21	Rhode Island	2
South Carolina	20	Wyoming	1
Louisiana	15	D.C.	0
Nebraska	15	West Virginia	0
Alaska	13	*Unspecified*	47
		TOTAL	**1,133**

Source: CPSRMS (2006-2020).

Figure 2: Aerosol Duster Inhalation Incidents Reported by State



Around 66 percent of aerosol duster inhalation incidents in CPSRMS occurred at a home, apartment, or condominium, while around 12 percent of inhalation incidents occurred on public property, in an office, or other public space. The location of the remaining 22 percent of inhalation incidents was recorded as unknown or unspecified. Although most incident narratives did not provide detailed information on the victim or the incident circumstances, the following observations were made, based on keywords in the more descriptive incident narratives:

- In 67 of the incident narratives, the aerosol duster inhalation victim was using, or had a history of using, inhalants, drugs, or alcohol. In 11 other incidents, the victim had a previous history of depression or other underlying mental condition, and in 12 additional incidents, the victim was noted to suffer from substance abuse and mental health problems. All these were fatal incidents.

- In 58 incidents, all fatal, the inhalation victim was reported to have died from drowning, or was found fully or partially submerged in water, usually a bathtub or a pool.
- In 17 incidents, the inhalation victim was found in a vehicle, or found operating a vehicle. Sixteen of these 17 incidents resulted in death, while one required emergency-department treatment of the victim.

Lastly, between 2006 and 2020, there were an additional 1,023 CPSRMS incidents that mentioned either difluoroethane toxicity from an unspecified product, or difluoroethane, freon, or hydrocarbon inhalation from unspecified aerosol products. All these incidents resulted in deaths. As the scope of the analyses was determined to include only incidents explicitly mentioning an aerosol duster product, these additional incidents are not included among the 1,133 incidents in the analyses above, and they are mentioned only to provide information on, and context for, the excluded incidents.

NEISS-Based National Injury Estimates (2006–2020)

Between 2006 and 2020, it is estimated that there were 25,300 emergency department-(ED) treated injuries in the United States resulting from the inhalation aerosol duster products. This estimate is based on a sample of 562 NEISS injury cases.

Cases were only included in the sample if the product being used could reasonably be classified as an aerosol duster. [71] Although CPSRMS incidents typically report product-identifying characteristics (*i.e.,* manufacturer, brand, model, retailer, product description), NEISS narratives, which are drawn from hospital emergency department health records, rarely provide such detailed information on the products involved. As such, the NEISS statistic is very likely an underestimate of the number of injuries resulting from inhaling aerosol dusters. An additional 3,200 estimated ED-treated injuries resulted from inhaling products described as “aerosol cans,” “aerosol cleaners,” or simply “aerosols”; but these injuries are excluded from this analysis because of the non-specificity of the product description.

Table 4 presents yearly estimates of ED-treated injuries in the United States from inhaling aerosol dusters, based on NEISS. Due to estimates in the early years of the data’s time frame being either too small or too unstable to report (see footnote 61), a separate year-by-year trend analysis is not feasible, and thus, was not conducted.

Table 4: NEISS Estimates for Aerosol Duster Inhalation Injuries by Year

Year	Estimate[72]	Sample Size
2006	**	8
2007	**	10
2008	**	17
2009	**	15

[71] Keywords used to identify products in CPSRMS and NEISS include huffing, inhaling, sniffing, duster, aerosol duster, computer cleaner, keyboard cleaner, computer duster, keyboard duster, electronic duster, compressed air, canned air, and specific brands (Endust, Dust Off). Variations and combinations of these keywords were also used to capture misspellings or variations in how the product was identified.

[72] According to the NEISS publication criteria, an estimate must be 1,200 or greater; the sample size must be 20 or greater; and the coefficient of variation must be 33 percent or smaller.

2010	**	25
2011	1,800	42
2012	**	25
2013	2,000	46
2014	1,500	35
2015	2,600	47
2016	3,100	67
2017	2,700	67
2018	2,100	53
2019	2,000	50
2020	**	55
2006 – 2020	25,300	562

Source: NEISS (2006-2020). Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **. Rows may not add to total due to rounding.

Table 5 presents a breakdown of the disposition of the injured patients.

Table 5: NEISS Estimates for Aerosol Duster Inhalation Injuries by Disposition

Disposition	Estimate	Sample Size
Treated and released, or Examined and released without treatment	18,000 (71%)	398
Treated and admitted for hospitalization, or Held for observation	4,800 (19%)	114
Left without being seen, or Left without treatment	2,200 (9%)	46
Death	** (<1%)	4
All Severities	**25,300 (100%)**	**562**

Source: NEISS (2006-2020). Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **. Rows may not add to total due to rounding.

Table 6 presents an overview of the injuries based on age and gender.

Table 6: NEISS Estimates for Aerosol Duster Inhalation Injuries by Age & Gender

Age Group (Years)	Male	Female	Total
0 – 17	2,000	1,600	3,600 (14%)
18 – 34	7,800	3,700	11,500 (45%)
35 - 54	6,400	3,400	9,700 (38%)
55 or older	**	**	** (2%)
Total	16,400 (65%)	9,000 (36%)	**25,300 (100%)**

Source: NEISS (2006-2020). Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **. Rows may not add to total due to rounding.

Of the approximately 11,500 aerosol duster inhalation injuries for patients between the ages of 18 to 34; around 4,100 occurred to patients between the ages of 18 to 24; around 3,600 occurred to patients between the ages of 25 to 29; and around 3,800 occurred to patients between the ages of 30 to 34. Of the approximately 9,700 estimated injuries for patients between the ages of 35 to 54, around 6,700 occurred to patients between the ages of 35 to 44; and 3,000 occurred to patients between the ages of 45 to 54.

Approximately 7,100 of the ED-treated estimated injuries (28%) occurred at a home. Another 6,500 estimated injuries (26%) took place at some public property; and 2,300 estimated injuries (9%) took place on a street or highway, at a school, or at a place of recreation. The location for the remaining injuries was either unknown or not recorded.

Approximately 21,800 of the ED-treated estimated injuries (86%) were diagnosed primarily as poisonings, while the remaining 3,500 estimated injuries were diagnosed mostly as burns (chemical, thermal or unspecified), anoxia, contusions/abrasions, lacerations, or internal organ injuries.

Approximately 22,100 of the ED-treated estimated injuries (87%) were considered “whole body” injuries (*i.e.*, no specific individual body part injured from of inhaling). Another 1,900 estimated injuries (8%) were classified as head, face, or mouth injuries, while the remaining 1,300 estimated injuries (5%) were mostly classified as hand, lower arm, or upper trunk injuries.

III. CONCLUSION

Staff reviewed aerosol duster data from CPSC’s CPSRMS and NEISS databases covering the 15-year timeframe between 2006 and 2020. For this data review, staff focused only on incidents involving the intentional inhalation of aerosol duster products.

The analysis included only incidents, injuries, and fatalities that were clearly caused by, or that clearly involved, aerosol duster products. Although compounds like 1,1-difluoroethane are most often found in aerosol dusters, incident narratives that did not identify the direct source of difluoroethane toxicity were excluded from the analysis. As such, both the CPSRMS counts and NEISS estimates should be considered as possible underestimates of the total amount of injuries and fatalities resulting from aerosol duster inhalation.

Staff identified:

- 1,133 incidents in CPSRMS related to aerosol duster inhalation, including 1,126 deaths, 5 nonfatal injuries, and 2 non-injury cases. The majority of CPSRMS incident data were sourced from death certificates and medical examiner and coroner reports. Of these 1,133 incidents, 900 took place between 2013 and 2020.
- Approximately 70 percent of the incident victims in CPSRMS were male, and more than 92 percent were between the ages of 18 to 54.

- An estimated 25,300 emergency department-treated injuries resulted from aerosol duster inhalation, based on a sample of 562 NEISS records. An estimated 16,000 of these injuries (63%) occurred between 2013 and 2020.
- An estimated 16,400 of the injuries (65%) occurred in males, and an estimated 21,200 of the injuries (83%) occurred among individuals ages 18 to 54 years.

According to data published in 2019 by SAMHSA (Substance Abuse and Mental Health Services Administration),[73] in comparison to other commonly abused inhalants, difluoroethane from computer cleaners or air dusters is relatively popular, but is less frequently abused than some other inhalants, such as nitrous oxide, amyl nitrite, and felt-tip pens/markers. More than half of the 25 million estimated lifetime inhalant-use cases among persons ages 12 and older involved nitrous oxide. The same study estimated 2.9 million lifetime uses of computer cleaners or air dusters, and 1.4 million lifetime uses of other aerosol sprays.

[73] Source: SAMHSA (2019). https://www.samhsa.gov/data/sites/default/files/reports/rpt29394/NSDUHDetailedTabs2019/NSDUHDetTabsSect1pe2019.htm?msclkid=8cc4960bb12611eca2d540e0507affc1

TAB E: Market and Economic Considerations for Petition Requesting the Commission Initiate Rulemaking to Adopt a Mandatory CPSC Safety Standard to Address the Hazards Associated with "Duster" Aerosol Products

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Cheryl Scorpio, Ph.D.,
Project Manager, Aerosol Duster Petition
Directorate of Health Sciences

DATE: July 20, 2022

THROUGH: Alex Moscoso
Associate Executive Director
Directorate for Economic Analysis

FROM: Cynthia Gillham and Susan Proper
Economists
Directorate for Economic Analysis

SUBJECT: Market and Economic Considerations for Petition Requesting the Commission Initiate Rulemaking to Adopt a Mandatory CPSC Safety Standard to Address the Hazards Associated with "Duster" Aerosol Products

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I. Introduction and Summary of Findings

The Commission Directive Implementing Procedure 302 for Petitions requires the Directorate of Economics to provide preliminary information on the following:

- **A brief discussion of market information.** Using readily available information from government, industry, or other sources, staff will provide data on sales, product use, the number and size of firms, an estimate of product life, and the number of products in use.
- **A preliminary estimate of the annual cost to society of the hazard if accurate information is readily available.** Estimates of the annual societal cost include estimates on injuries from the CPSC Injury Cost Model (ICM) and other sources, property damage, and an assumed Value Per Statistical Life (VSL).

This memorandum analyzes the market for aerosol dusters, and the societal cost of the actions requested by the Petitioner. There are dozens of manufacturers and importers of aerosol duster products in the U.S. market, many of which are small, U.S.-based businesses. Two of the commenters that could potentially be impacted by the petitioned rulemaking are small firms, according to U.S. Small Business Administration guidelines.

Aerosol duster products are widely available online and in brick-and-mortar general retail, office supply, and home improvement stores. The total market for aerosol duster products is approximately 20 million units sold per year, at a typical price range of $5 to $20 per 10-ounce

can. Some specialty products exceed $50 per can. Other small, battery-powered air compressors are available, some marketed specifically as “keyboard dusters” that provide similar functionality and compete with these products.

The potential cost of implementing the suggested warning on the duster product may be minimal to most suppliers, with the revisions as described in the HF memo. However, the cost of implementing the suggested warning on the duster product potentially could be significant for two of the small firms that commented on the *Federal Register* notice (86 FR 34171). As for the performance standard proposed by the Petitioner, we cannot estimate its cost precisely, unless additional information is provided on redesigning can injection technology, third party testing, and additional detail on the types and amounts needed for an effective bitterant.

The benefits to consumers of implementing the warning and performance standard would be the reduced cost to society (*i.e*., avoided injuries and deaths) from mitigating the hazard of inhalant abuse. The estimated total cost to society of the hazard for injuries, which staff generated using CPSC’s ICM, exceeds $140 million per year. This estimate includes medical costs, productivity losses, and pain and suffering from inhalant abuse. The EPI memo shows approximately 75 deaths per year for aerosol duster abuse over the past 15 years. At an estimated current VSL of $10.5 million, that would represent a cost to society of $787.5 million per year.

The product defined by the Petitioner is “duster” aerosol products “used for cleaning electronics and other items and containing the chemical 1,1-Difluorethane, or any derivative thereof.” Staff assumed for the purposes of this memorandum that products in-scope would include aerosol products using the same propellant marketed for cleaning. These estimates are preliminary, and if a future rulemaking involved a different scope, the estimates could be impacted by the scope change.

II. Market – The Products: Products, Prices, Consumer Uses, and Competing Substitutes

a. Products In-Scope as Defined by the Petitioner

The Petitioner defines the product as follows: “For the purpose of this Petition, ‘Duster’ products will refer to any hydrofluorocarbon propellant cleaner containing 1,1-Difluorethane or similar derivative. This product is sold directly to the public (in any quantity) both in person and online for the purpose of cleaning electronic devices, photographic equipment, and any other item having areas where dust resides and is inaccessible by hand.” The Petitioner lists several general retail stores, office supply stores, drugstores, and home improvement stores where aerosol dusters might be sold. The Petitioner also states: “The list of retailers of this product is endless and the price varies from $2.95 to $6.95 per can with discounts for multipack purchases.”

Staff’s analysis finds that there are dozens of brands of aerosol “duster” products sold at the types of retailers identified by the Petitioner, as well as by auto parts suppliers, industrial shop suppliers, and medical supply retailers. Generally, suppliers tend to offer discounts for purchasing the product in bulk. Only a few of these items are within the price range specified by the Petitioner for a 10-ounce can. Most are priced higher, some much higher; however, the lower-priced items may be readily available and relatively easy to acquire in bulk. The in-store brand of a major office supply chain sells a 10-ounce can of duster for $10.29 from their online

store. However, the retailer provides a discount for purchasing in bulk, and charges $62.39 for a case of 12 cans ($5.20 per can, excluding tax). The market-leading brand on that same site sells for more $7 a can, when purchased in a 12-can case, or at $17.80 per can when purchased in a pack of two, excluding tax. At a large, discount-retail chain store, prices online for a single can start around $8, or $3 per can in a case of 12. At a major home-improvement chain store, prices online and in-store for a single can range from $5 to more than $28. On a major internet retailer, with many third-party sellers, prices can range from $3 for a 3.5 ounce can to more than $30 for a 10-ounce can.

According to the Substance Abuse and Mental Health Services Administration (SAMHSA), inhalant abuse of household products, paint thinner, gasoline, and similar items is appealing to adolescents because inhalants are legal, relatively cheap, and easy to acquire.[74] In general, prices are higher than the Petitioner claimed; although prices may vary across geographic regions in brick-and-mortar stores, which staff could not readily observe.

On June 29, 2021, CPSC posted a request for comment on the petition. Multiple public commenters pointed out that inhalant abuse involves more than 1,400 other common household products; however, staff was unable to confirm this assertion. Regardless, there are aerosol consumer products, at prices lower than "dusters," which can be misused as inhalants. For example, body sprays, spray paints, sunscreens, and air fresheners may use the same propellant as "dusters," are also easily available at a variety of retailers, and often sell for less than $10 per can. However, aerosol dusters might also be considered significantly different from body sprays, spray paints, sunscreens, and air fresheners by abusers who would inhale them. One of the ways that aerosol dusters are different from body sprays, spray paints, sunscreens, and air fresheners is that they can be inhaled directly from the product container, by mouth, or through the nose. (See Tab B.)

Some aerosol duster products sold at office supply stores, chain drug stores, and general retailers contain a bitterant. Most aerosol duster products containing a bitterant do not specify, either on the can or the Safety Data Sheet, which bitterant is used. However, several widely available brands advertise specifically that they do not contain any bitterant, supposedly because the bitterant can damage sensitive electronics. Aerosol dusters are used for a variety of purposes, and those sold at medical and industrial supply retailers and home improvement stores, as well as auto parts stores, may not contain a bitterant.

b. Marketed Uses of the Products, Consumer Uses of the Products

There are dozens of products advertised as keyboard cleaners, computer dusters, electronic equipment dusters, and camera cleaners that are within the Petitioner's defined scope of "aerosol dusters." Some of these products are advertised or labeled as "canned air."

As noted in the HS memorandum, although aerosol duster products have been referred to as "air dusters," they do not contain "air." (See Tab A) Regardless, staff is currently aware of nine aerosol duster products that use the term "air" directly on the product.[75] In addition, online

[74] https://www.samhsa.gov/data/sites/default/files/report_3095/ShortReport-3095.html
[75] This is based on staff's review of information available on the internet. The review was completed in February 2022. Since the original review, staff have identified two additional aerosol duster products that

retailers sell aerosol duster products within the product category of “compressed air dusters” and describe products as “canned air.”

The Petitioner indicates that when retailers advertise dusters as “air” it misleads young individuals who may believe that the product is air or contains air, and that it is perhaps not very hazardous to inhale. In this way, aerosol dusters are different from other widely available and low-cost inhalants currently available on the market. According to comments we received, at least one member of industry agrees, to some extent, that it could be misleading to label an aerosol duster product as “air,” and the also indicates that they never use the term “air in a can” to describe their product. This commenter notes that they actively discourage their retail partners and others from using the term “air” to describe their product. However, staff identified that this firm’s products are currently available online for sale and are described as “compressed air duster” by an online retailer, despite the commenting firm’s attempts to discourage their partners from using the term “air” to describe their product.

There are other products that would fit within the Petitioner’s scope (same active ingredients and propellant), such as gun cleaner, auto detailer, medical equipment cleaner, and industrial equipment cleaner. These are also consumer products because they may be purchased in quantities of one to 12 cans and are readily available online and at select brick-and-mortar retailers.

Product reviews indicate that consumers use aerosol duster products for many purposes other than the marketed duster use. These uses include blowing air into a cast, making edible bakery decorations, freezing or cooling body parts, quickly drying paint or finishes on small parts, and deterring cats from undesirable activities or locations. Product reviews also indicate that some customers believe that the bittering agent leaves a residue or indicate that the bitterant can damage electronics. These customers prefer non-bitterant duster for cleaning or for other non-abusive uses, such as drying paint. This is anecdotal evidence that adding a bitterant reduces demand, by discouraging legitimate users from buying the product. At least one large manufacturing company, and several smaller suppliers, in the past 3 years have stopped supplying aerosol duster products that contain a bitterant.

c. Annual Sales, Size of Market

Approximately 20 million aerosol duster cans are sold each year. Staff derived this estimate by analyzing revenues of market-leading firms with information from the Household & Commercial Products Association (HCPA) annual survey of aerosol pressurized products. With a typical price of $8 per can, 20 million units sold would make this approximately a $160 million per-year industry. HCPA estimates that 3.75 billion aerosol cans were filled in the United States in 2020, for use by commercial and industrial facilities, as well as by households.[76] Twenty million cans would represent less than 1 percent of that total.

use the term ”air” directly on the product, bringing the total to 11 aerosol duster products that use the term ”air”.

[76] https://www.thehcpa.org/wp-content/uploads/2021/06/2020-Aerosol-Pressurized-Products-Survey-Press-Release.pdf.

d. Similar Products that Could Be In-Scope, But Are Marketed for Other Uses or Contain a Different Propellant

Similar aerosol duster products that use a different propellant, particularly HFC-134a (1,1,1,2-Tetrafluoroethane), are widely available. These products are generally more expensive, and some are advertised for industrial (shop) or medical use. These products are also marketed for use on sensitive home electronics and called "canned air" or "aerosol dusters." Several commenters noted that 1,3,3,3-Tetrafluoropropene (HFO-1234ze) is commonly used when non-flammability is needed, or as a more environmentally friendly choice.

Additionally, there are physically similar products marketed as "cold" or "freeze" spray that use the same propellant as in the petition. There are also aerosol products that are not advertised as cleaners–such as silicone lubricant spray for food pans, air fresheners, and body sprays–that use the same propellant and include other ingredients. One public commenter provided information that the same propellant could be used in metered-dose medical inhalers.

e. Competing Products

Aerosol duster products compete with other consumer products that perform a similar blown-air cleaning function. For example, some products advertised as "keyboard dusters" are small, battery- or USB-powered items that blow or vacuum air. This type of item sells for as high as $80, but generally falls within the $20 to $35 range. There are also "keyboard dusters" that sell for less than $10 that are simply a squeezable plastic bulb that pushes air through a narrow tube. In a home woodshop or garage setting, the aerosol duster products may compete with expensive air compressors. These products also compete with small, battery-powered or corded-tire inflators that some consumers may own already. Most consumers may not purchase aerosol duster products or other consumer products that perform a similar blown-air function and may simply use a vacuum cleaner to clean their keyboard and other home electronics.

As noted by multiple public commenters, there are many other products that are misused as inhalants. The U.S. Department of Health and Human Services' (HHS) national survey on drug use and health found that the inhalants most abused by adolescents are (in descending frequency of use) markers and pens; glue, shoe polish, or toluene; spray paint; gasoline or lighter fluid; and computer cleaner/aerosol dusters.[77] The HHS national survey shows "dusters" are the fifth most abused consumer product inhalant used by adolescents.

f. Summary of Product Prices, Availability, and Competing Substitutes

"Aerosol dusters," as defined by the Petitioner are available from a wide variety of brick-and-mortar and internet retailers. Prices range from $3 to more $50 a can, but they generally cost $5 to $20 per can for products advertised for general consumer use. Competing products for the intended cleaning purpose include aerosol products that use a different propellant, small, battery-powered blowers, vacuums, and air compressors marketed for other purposes.

The competing powered air compressor products are generally more expensive but have a much longer product lifespan and can be used for other purposes. More than a thousand household products in aerosol cans can be misused, many that sell for much less per can than

[77] https://www.samhsa.gov/data/sites/default/files/report_3095/ShortReport-3095.html.

dusters. However, these products include different ingredients and may be abused in a different manner.

According to information available from the Consumer Product Information Database, 1,1-Difluoroethane (DFE) can be found in many consumer products that are not used for electronics dusting, and in a variety of concentrations.[78] These products include pesticides, like insect repellent, which uses DFE as a propellent in a concentration of 1.0 to 5.0 percent, and ant and roach killer aerosols in a concentration of 89.65 percent. DFE is also found in oven-grill cleaning aerosols in a concentration of 4.25 percent. DFE is found in consumer auto products, like tire glaze, in a concentration ranging from 40 to 60 percent. The chemical DFE is used as a propellent in a range of concentrations for a variety of personal care items, such as hair spray and hair-styling mousse.

If the Commission decides to proceed to rulemaking, it will be necessary to define the in-scope products. The product defined by the Petitioner is "duster" aerosol products "used for cleaning electronics and other items and containing the chemical 1,1-Difluorethane, or any derivative thereof." Staff assumed, for the purposes of this memorandum, that in-scope products would include aerosol products using the same propellant marketed for cleaning. If products with a different propellant, or not marketed for cleaning, were excluded from the scope of a future rulemaking, any hazard-reduction benefits of the rule would be limited, because manufacturers could change the formulation of the product, or its marketed use, to be outside the scope of the rule.

III. Preliminary Estimate of the Societal Costs of Aerosol Dusters

Based on the results of the CPSC's ICM, staff estimates there were more than 4,275 medically treated, aerosol duster-inhalation injuries per year from 2006 through 2020. This included emergency room treatments, hospital admissions, and doctor's office visits. The value of the societal costs of these injuries (in 2018 dollars) amounted to about $141 million per year, using the average number of cases per year for the past 15 years. Overall, medical costs and work losses accounted for about 20 percent of the total costs, or about $32 million per year; the intangible costs associated with pain and suffering accounted for the remaining 80 percent, or $109 million. Medical costs alone are estimated to exceed $13 million per year.

The average cost per case is about $3,000 for medical treatment only, but aerosol duster inhalation injuries requiring only a doctor visit cost much less, around $475, while injuries requiring hospitalization exceed $20,000 per case. Considering lost productivity and long-term pain and suffering, the average cost per case exceeds $32,000.

The ICM estimates a greater number of cases than in the EPI memorandum because NEISS data include only a representative sample of hospital emergency department visits, while the ICM extrapolates the number of cases for the entire United States. This includes visits to urgent care centers and doctor's offices, in addition to hospital in-patient treatments. Many product-related injuries are treated in other medical settings, such as physicians' offices, clinics, and ambulatory surgery centers. Some injuries also result in direct hospital admissions, bypassing the hospital ED entirely. CPSC's ICM uses empirical relationships between the characteristics

[78] https://www.whatsinproducts.com/chemicals/index/1.

of injuries (diagnosis and body part) and victims (age and sex) initially treated in hospital EDs and the characteristics of those initially treated in other settings. The ICM estimate of injuries treated outside of hospitals or hospital EDs (*e.g.*, in doctors' offices, clinics) is based on data from the U.S. Department of Health and Human Services'(HHS) Medical Expenditure Panel Survey (MEPS). The ICM uses MEPS data, in combination with a classification tree analysis technique, to project the number and characteristics of injuries initially treated outside of hospitals. To project the number of direct hospital admissions that bypass hospital EDs, the ICM uses data from HHS' Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project (HCUP-NIS).

The VSL is a measure of society's willingness to pay for small reductions in mortality risks. It is commonly used in cost/benefit analyses of federal regulations, particularly those by EPA and DOT, and in economic analyses of proposed health policies and safety measures. CPSC uses EPA's estimate for VSL, but adjusts for inflation, so that the current value in CPSC's ICM is $10.5 million, in 2021 dollars. According to CPSC's epidemiology data collected from the CPSRMS,[79] from 2006 through 2020, there were 1,126 deaths related to aerosol duster products, or on average, roughly 75 deaths per year over the period. (See Tab D.) Based on the HF memorandum, it is unclear whether product labeling would prevent deaths or injuries. (See Tab C.)

V. Conclusions

The Commission's Directive Implementing procedure requires the Directorate of Economics to provide a brief discussion of market information and a preliminary estimate of the annual cost to society of the hazard. As defined by the Petitioner, the products in-scope of this petition are aerosol duster products. Using data from the HCPA, staff derived that there are approximately 20 million aerosol duster cans sold each year. Aerosol duster products compete with other consumer products that perform a similar blown-air cleaning function, such as small, battery-powered products called "keyboard dusters" that blow air. If the Commission decides to proceed to rulemaking, it will be necessary to define clearly what are the in-scope products.

The benefit to consumers and society of successful rulemaking would be the reduced cost of medical treatment associated with injury and death from the abuse of this product. Currently, staff estimates the annual societal cost of the hazard to be $831 million in injuries and deaths.

[79] Data from the CPSRMS are anecdotal in nature, and therefore, they do not necessarily represent all incidents that have occurred.

TAB F: Public Comment Responses

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Cheryl Scorpio, Ph.D.,
Project Manager, Aerosol Duster Petition, HSPP

DATE: July 20, 2022

FROM: Adrienne Layton, Ph.D. Pharmacologist, HSPP
Andrei Komarov, Ph.D. Physiologist, HSPP
Julia Kerns, Engineering Psychologist, HF
Matthew Brookman, Mechanical Engineer, LSM

SUBJECT: Response to Comments – Petition from Families United Against Inhalant Abuse (FUAIA) - CP 21-1

The CPSC received 17 comments (two identical comments were from the same commenter) in response to the *Federal Register* notice requesting public comment on the Aerosol Duster Petition. Two additional comments came from the same commenter after the comment period ended; they were docketed by the CPSC and are referred to as "Additional Commenter." The Petitioner twice submitted additional data outside of the comment period and the data are addressed at the end of this memo. The data are docketed with the other comments.

Table 1: Names of Commenters

Number	Commenter
3	Jeffrey Oxarart
4	Mark Strauch
5	Blake Webber
6	Anonymous
7	Valeria Benard
9	Iza Rosario
10	Shannon Yowell
11	Koura
12	Falcon Safety Products, Inc.
13	National Aerosol Association
14	Stoner Incorporated
15	Techspray
16	Alliance for Consumer Education
17	Household & Commercial Products Association

GENERAL COMMENTS: Many commenters support granting the petition for various reasons that include the belief that duster aerosol products are dangerous and in need of regulation. These commenters state that these products have been overlooked for too long and are taking lives every year. Huffing duster aerosol products has become a chronic problem in the United States and is affecting individuals of all ages. Some commenters felt that 1,1-difluoroethane was harmful and that a warning and a bitterant would reduce the risk of harm from the chemical.

1. TOXICITY

COMMENT: Commenter 3 states that aerosol duster products are dangerous and in need of regulation, and that the potential for abusing aerosol dusters is substantial. The commenter asserts that many children and young adults are dying from abuse of aerosol duster products.

STAFF RESPONSE: We agree that aerosol duster products are being abused. CPSC staff has found data showing that there are deaths from the abuse of aerosol duster products in children and adults. According to data from CPSC's Consumer Product Safety Risk Management System (CPSRMS), from 2006 through 2020, CPSC received reports of 1,133 incidents involving hazards from aerosol duster products. Most aerosol duster huffing incidents in the CPSRMS from 2006 to 2020, resulted in death. The minimum age of the victim was 13 years, while the maximum age was 70 years.

COMMENT: Commenter 5 states that aerosol duster products are dangerous and in need of regulation, and thus, regulation should be swift. This commenter states that age is not a factor and that abuse of this product affects everyone. The commenter asserts that children and adults are dying from abuse of aerosol duster products.

STAFF RESPONSE: CPSC staff has found evidence that children and adults are dying from abuse of aerosol duster products. The CPSRMS data provide a distribution of aerosol duster victims by age and gender. According to data from 2006 to 2020, 92 percent of victims were between the ages of 18 to 54.

COMMENT: Commenter 6 states the inhalation of aerosol duster products has become a chronic problem in the United States.

STAFF RESPONSE: CPSC staff has seen that huffing/inhalation is an ongoing problem in the United States. CPSRMS data are used to provide an overview of the distribution of the number of aerosol duster huffing incidents per year, with certain data limitations. The largest number of aerosol duster huffing incidents were reported in 2016. However, because data collection is ongoing, the numbers of incidents for later years may change. Anecdotally, the number of aerosol duster huffing incidents reported annually appears to be increasing.

COMMENT: Commenter 7 notes that difluoroethane is a colorless, odorless gas, shipped as a liquefied gas under its vapor pressure, and it is mainly used as an aerosol propellant. The commenter identifies that when there is human exposure to difluoroethane, a consumer may be harmed in several ways, and the commenter listed the ways in the comment. The commenter states that abuse of this substance is on the rise among teens and that it is important to keep children safe from these products.

STAFF RESPONSE: Staff agrees that some aerosol dusters are propellant cleaners that may use an active ingredient called difluoroethane, a colorless, liquefied hydrofluorocarbon gas. Staff agrees that when an aerosol duster product is abused, a consumer may be harmed in several ways. Tab A describes the toxicity of 1,1-difluoroethane (DFE), or similar derivatives contained in computer aerosol products, based upon the medical literature and a MECAP search. Due to a lack of readily available information, staff cannot confirm that abuse of this substance is on the rise among teens. However, literature reviewed indicates that inhalant abuse may be a hidden epidemic.

COMMENT: Commenter 11 notes that the Petitioner misquoted a paper (Mathias, 2002) to support their notion of brain damage by inhalant abuse.

STAFF RESPONSE: The paper authored by Mathias (2002) and cited by the Petitioner, describes brain damage by solvents, such as toluene, which can be called an inhalant (Howard et al., 2011) but is not directly related to DFE used in aerosol duster products.

COMMENT: Commenter 12 states that there is no evidence supporting the Petitioner's comment on difluoroethane that "It is this mechanism that makes Duster extremely addictive. Individuals attempting to quit inhalation of Duster go through severe withdrawal symptoms similar to those experienced with other drugs."

STAFF RESPONSE: Staff disagrees with the commenter regarding withdrawal symptoms and aerosol duster inhalant abuse. Volatile inhalant withdrawal has been observed and defined as "a clinically significant cluster of symptoms, behaviors and/or physiological features, varying in degree of severity and duration, that occurs upon cessation or reduction of use of volatile inhalants in individuals who have developed volatile inhalant dependence or have used volatile inhalants for a prolonged period or in large amounts." Signs of inhalant withdrawal include insomnia, anxiety, irritability, dysphoric mood, shakiness, perspiration, nausea, and transient illusions (https://icd.who.int/browse11/l-m/en)(Perron et al., 2009). Prolonged or excessive use of the central nervous system depressant, difluoroethane, which is an easily acquired and inexpensive volatile substance that can be inhaled recreationally, is associated with toxicity, and abrupt cessation can induce withdrawal (Custer, 2020).

COMMENT: Commenter 12 is concerned that the Petitioner states: "when you know a product you sell is going to be used extensively as a deadly drug of choice and you do nothing to stop

the practice, you're as much to blame as the user." When consulting with experts in the addiction field, they have confirmed that individuals with substance abuse disorders will abuse other products, such as a duster, when their "drug of choice" is not available.

STAFF RESPONSE: Staff agrees that it is possible that a person will abuse aerosol duster products when their drug of choice is unavailable. Adolescents who initially used inhalants were less likely to use a new drug, compared with adolescents who initially used marijuana. After 2 years, the probability of using a new drug was approximately 10 percent for abusers who initially used inhalants. By the eighth year, the probability of using a new drug for an abuser who initially used inhalants is 50 percent, and it is 70 percent to 80 percent for other drug users (Zhang, 2021).

COMMENT: Commenter 6 proposes that component parts (chemical) of aerosol duster products must be changed to address the hazard.

STAFF RESPONSE: CPSC staff concludes that changing the components of this product (other than the bitterant) is outside the scope of this Petitioner's request; but that if the petition were granted, various approaches might be considered.

2. BITTERANTS

COMMENT: Commenters 7 and 17 recommend that an aversive agent be added to the can to reduce the risk associated with difluoroethane.

STAFF RESPONSE: CPSC staff concluded that an aversive agent is not recommended for use in aerosol dusters, due to lack of efficacy and safety concerns of the bitterant (Tab B).

COMMENT: Commenter 12 notes, referring to the Petitioner's statement about the bitterant denatonium benzoate, "Recent product testing documents from two manufacturers of Dusters (under several different names) demonstrates that most often the denatonium benzoate was never injected into the cans at all, and if it was it didn't appear in the spray." The commenter requests that the Petitioner disclose the names of the several dusters that were tested and the full test results and the testing protocols. The commenter notes that, to their knowledge, this was an issue among manufacturers at the start of using the bitterant, has never been the case with a manufacturer, and is no longer the case among the other manufacturers.

STAFF RESPONSE: Neither the Petitioner, nor commenter provided any testing data or any references to support their statements, and therefore, staff could not verify the statements.

COMMENT: Commenter 12 contradicts the Petitioner's statement, "Denatonium Benzoate (DB) is a known bronchial dilator which would only enhance the absorption of the 1,1,-difluoroethane when delivered through inhalation." Commenter 12 asserts that there is no credible research that supports the finding that DB is a bronchodilator in humans.

STAFF RESPONSE: We disagree with the commenter. Staff concludes that denatonium benzoate is a bronchodilator. Molecules that bind to bitter taste receptors (TAS2R), such as denatonium benzoate, have produced strong, smooth muscle relaxation and are potential bronchodilators in man (see Tab B, section B). It is unknown if this bronchodilation potentiates the toxic effect of huffing in humans (Perron, 2021).

COMMENT: Commenter 12 states that bitterants are least likely to be effective among young children. Despite their rejection of bitter substances when tested, children frequently in home settings ingest unpalatable substances, such as gasoline, cleanser, toilet bowl cleaner, and ammonia (*e.g.*, Mowry, Spyker, Cantilena, Jr., Bailey, & Ford, 2012).

STAFF RESPONSE: Staff concludes that adding bitterants are unlikely to be effective to reduce the intentional hazard of misuse and abuse. None of the bitterants studied (See Tab B) have demonstrated efficacy as an aversive agent for inhalants. Information on the human inhalation toxicity of bitterants is lacking. Between 15 percent to 30 percent of the adults do not detect the taste of bitter compounds (CPSC, 1992; NIDCD, 2010; NIDCD, 2019). HS staff does not recommend bitterants, regardless of age.

COMMENT: Several commenters (13, 14, and 15) were concerned with the Petitioner's proposed addition of a bitterant and its potential negative health effects on industrial users, who use aerosol duster products much more frequently than household consumers.

STAFF RESPONSE: Staff agrees with the commenter's concerns regarding the addition of a bitterant and its effect on industrial users. Health effects of denatonium benzoate (DB) include asthma and skin reaction (Bjorkner, 1980; Chen et al., 2019; Youakim, 2007). DB may potentiate the propellant toxicity, lead to nasal polyps, and chronic inflammation of the sinuses surrounding the nasal cavity after chronic exposure (Perron et al., 2021).

COMMENT: Commenter 17 (HCPA) supports voluntary efforts by manufacturers to incorporate a bitterant agent into their products but does not think mandating a bitterant is advised. HCPA questions the feasibility and effectiveness of the petition's approach without offering other bitterant agents that would be technically feasible. HCPA was concerned that the petition proposed to replace denatonium benzoate (DB) in duster aerosols with some other unidentified bitterant. The commenter stated that other bitterants, including sucrose octaacetate (SOA), flavonoids, and quassinoids present formulation challenges; due to insolubility, they are not as bitter as DB, and would require a higher concentration.

HCPA commented that the consumer will inhale some of the product before the bitterness can be detected, which leads to the ineffectiveness of the aversive agent for the initial use of the product.

STAFF RESPONSE: In a previous study, CPSC ruled out flavonoids and quassinoids due to their low bitterness or high toxicity (CPSC, 1992). HSPP staff identified synthetic bitterant SOA and natural bitterant humulone as the most potent alternative bitterants (CPSC, 1992; DuBois,

2008). However, humulone has not been used in aerosol formulations.[80] SOA is readily soluble in organic solvents. It has a solubility of 12 percent (volume/volume) at 95 percent ethanol at room temperature (Stagner et al., 2019). Thus, SOA solubility should not be an issue for aerosol preparation. U.S. patent describes aerosol formulation for SOA from 5 ppm to 1175 ppm in the liquid phase (Patent, 2014). However, the recommended range of liquid-phase concentrations was from 5 ppm to 50 ppm (corresponding SOA levels in the aerosol were from 0.05 ppm to 0.5 ppm). Higher concentrations can interfere with the use of this product (Patent, 2014). The applicants stated that SOA aerosol was bitter in the SOA range from 0.05 ppm to 0.5 ppm. However, it is unclear if aerosol was sufficiently bitter to prevent the abuse. Concentrations stated for SOA (liquid-phase concentrations were from 5 ppm to 50 ppm and corresponding SOA levels in the aerosol were from 0.05 ppm to 0.5 ppm; Patent, 2014) were the same as in the earlier patent application for DB (Patent, 2010). Yet, SOA is 500-fold less bitter than DB. HS staff has concluded that there is no viable option to replace denatonium in duster aerosol products.

Staff concludes that aversive agents are not effective, in general, and not only for the initial use of the product, as stated by the commenter.

COMMENT: The Additional Commenter states the bitterant is not a deterrent because the abuser gets "used to" the taste.

STAFF RESPONSE: CPSC staff said it has been demonstrated that mice acquired tolerance to a broad array of bitter compounds, including denatonium benzoate, after long-term exposure (PLoS One, 2018). However, it is not known if humans develop tolerance to the bitterant.

3. ECONOMIC CONSIDERATIONS

COMMENT: Commenter 12 states that there is absolutely no evidence presented to support the Petitioner's claim that "A buyer for one of the major retailers claims his company earns $14.5 million annually on this product alone. It is likely that a large portion of the income from Duster purchases are for inhalant use rather than the intended dust removal."

STAFF RESPONSE: Commenter 12 did not provide annual sales data for the Commission to assess, and staff cannot confirm how much the firm earns in sales from inhalant abuse.

4. HUMAN FACTORS CONSIDERATIONS

COMMENT: Commenter 6 indicates placing a stronger warning label on the can is appropriate and asserts that a warning label will help people understand better the severe consequences caused by inhaling the product.

STAFF RESPONSE: Human Factors relies on a standard hierarchy of approaches to address product hazards, first, by designing out the dangerous features of the product, second, protecting against the hazards by guarding or shielding, and lastly, by providing adequate warnings and instructions for proper use and foreseeable misuse. The purpose of warning labels is to provide awareness of the unforeseen hazard and persuade consumers to alter their behavior to avoid unforeseen hazards. However, CPSC staff is unable to verify whether a stronger warning label would deter, or attract, more abusers to the product.

COMMENT: Commenter 12 states that labeling is an important element of education to consumers and the public regarding the issue of inhalant abuse of aerosol duster products and the dangerous consequences. Labeling on aerosol dusters may appear on the back of the product, and Commenter 12 highlights the use of ”very stringent labeling” on their product and further stresses that they have also been working on raising awareness of inhalant abuse and its dangers.

STAFF RESPONSE: Most of the current, on-product labeling and warnings provide information to educate and create awareness to consumers about the unforeseen or unintentional hazards. Consumers inherently believe that products in the market are generally safe. Adding on-product labeling or warning information to address the hazards associated with the product, provides awareness to the consumer who may not have thought of the hazard beforehand. (Woodson, Tillman, and Tillman, 1992)

An effective warning is carefully written, designed, and placed in ways that will increase the likelihood that consumers will notice, read, understand, and heed the warning (Wogalter, Conzola, & Smith-Jackson, 2002). Based on this research, staff concludes that the current aerosol duster products on the market do contain language stating the hazards and the potential consequences. Furthermore, the labeling satisfies the labeling requirements set by FHSA.

COMMENT: Commenter 13 notes that using stronger labeling requirements may go against CPSC’s current labeling requirement for an aerosol duster product. The comment also observes that the Petitioner is requesting a statement that may not be inherently true. When the aerosol duster product is used as directed by the label instructions, the product is safe and effective. The comment states: “only when the product is deliberately concentrated and inhaled is the product dangerous . . .. This deliberate inhalation is an abuse of a legitimate product.” The comment also states that adding this pervasive language could potentially encourage or draw inhalant abusers to the product.

STAFF RESPONSE: As discussed in the ESHF memorandum (Tab C), warning labels provide awareness to the consumer of a potential unforeseen hazard. In this case, since the hazard is brought on by intentional abuse by the consumer, this presents a very difficult challenge. CPSC staff agrees with the commenter because warnings may address unforeseen hazards, warning labels must be scrutinized for pervasive language that may encourage a person at risk to abuse or misuse the product (See ESHF Memorandum) (Tab C).

COMMENT: Commenter 12 notes that the Petitioner states: "Dusters can be purchased at almost any store and online, in any quantity and that all studies discussing inhalant abuse emphasize that the "easy access" and "inexpensive cost" of inhalants like Duster are the main reasons this particular inhalant is so popular."

Commenter 12 notes that more than 1,400 other consumer products can be abused through the inhalation route.

STAFF RESPONSE: CPSC staff agrees with the Petitioner that aerosol duster products can be purchased at brick-and-mortar stores and online, in a variety of quantities, and in cases of 12 cans, "in bulk." Staff agrees with the Petitioner that studies discussing inhalant abuse identify ease of access and inexpensive cost of inhalants as reasons for abuse.

Staff could not confirm the commenter's assertion that there are more than 1,400 consumer products that can be inhaled. Although products other than computer aerosol dusters, such as felt-tip pens and markers, Magic Markers, glue, shoe polish, or toluene, spray paints, gasoline or lighter fluid, computer cleaner/aerosol duster, correction fluid, degreaser, or cleaning fluid, lacquer thinner or other paint solvents, amyl nitrate, poppers, locker room deodorizers, nitrous oxide or whippets, lighter gases (butane, propane), halothane, ether or other anesthetics, or other aerosol sprays have been inhaled (Lipari, 2017), staff did not conclude that these products were abused in the same way, or with the same deadly effect, as aerosol duster products.

5. AIR IN A CAN

COMMENT: Commenter 12 and the Additional Commenter state that several manufacturers advertising Dusters as "air in a can" create a misunderstanding for young individuals who believe this is the case. The commenter states that as a manufacturer, his firm NEVER uses the term "air in a can" and actively discourages other retail partners from doing so.

STAFF RESPONSE: Although the commenter discourages retail partners from marketing air dusters as "air in a can," CPSC has identified several aerosol duster products labelled with the term "air" as a product name or as an advertisement for the aerosol duster product. Staff agrees with the Petitioner and the commenter that advertising dusters as "air in a can" is misleading and may cause confusion. Staff identified eleven aerosol duster products that use the term "air." It is possible that describing the product as "air" could mislead consumers who might not fully understand how hazardous the product is to breathe or inhale.

6. EDUCATION

COMMENT: Commenters 12 and 16 state that education is the best measure to address inhalation abuse. Educational efforts would include elaborating on how misuse can create harmful or lethal consequences if users are misinformed or unaware of the safety hazards that the household products can create for consumers. Commenter 12 states that labeling is an important element of education to consumers and the public on the issue of inhalant abuse of aerosol duster products and the dangerous consequences.

STAFF RESPONSE: CPSC staff concludes that educational programs may play an instrumental part to explain the risks and hazards associated with intentional abuse. While some of the aerosol dusters contain this vital outreach information, additional education and outreach information may improve awareness so consumers can be alerted to the hazards. However, research also states that the more familiar a consumer is with a product, the less likely they are to read or look for the warning. (Dejoy,1999)

7. DATA

COMMENT: Commenter 12, a manufacturer of aerosol duster products, asserts that the levels of inhalant deaths reported by the Petitioner would not necessarily be similar around the country, because the data sample provided by the Petitioner was small and confusing. The charts provided by the Petitioner were referred to as "Difluoroethane Inhalant Deaths" and not necessarily duster aerosol deaths.

STAFF RESPONSE: Although the data presented by the Petitioner may be confusing, we do not agree that they are broadly misleading. CPSC staff were not able to confirm the data provided by the Petitioner. However, data collected from CPSC's National Electronic Injury Surveillance System (NEISS), and the Consumer Product Safety Risk Management System (CPSRM) indicate there were more than 1,120 deaths and an estimated 25,300 emergency department-treated injuries from huffing or inhaling aerosol duster products. Furthermore, staff notes that these data may underestimate the total number of injuries and fatalities from aerosol duster huffing. The largest numbers of incidents reported by state were in Texas (80), Florida (79), California (68), Georgia (57), and Illinois (50). Generally, staff agrees that aerosol duster deaths may be increasing over time. (See EPI memo, Tab D, Figure 1.)

CPSC staff acknowledges that there are other products, such as paint products, general household cleaning solutions, refrigerants from appliances, air fresheners, spray paint, and whipped cream, for example, also contain difluoroethane.

COMMENT: Commenter 12, a manufacturer of duster aerosols, asserts that there are several troubling generalizations from the statement: "If this same trend was mathematically extrapolated across all states in the U.S., you would find several thousand individuals have died from Duster inhaling in just the 2007-2018/19 decades."

The commenter also notes that dusters are not the only consumer products that use difluoroethane. The manufacturer references a website that lists 333 consumer products containing difluoroethane, including auto products, personal care products, and pesticides (CPID whatsinproducts.com). The commenter asks how one can "mathematically extrapolate data for the remainder of the US based on 4 states and 2 regions in California?"

STAFF RESPONSE: CPSC staff agrees it is difficult to find data for huffing-related incidents. However, CPSC data collected from CPSC's NEISS, and the CPSRM indicate that there were more than 1,120 deaths and an estimated 25,300 emergency department-treated injuries from the huffing or inhaling of aerosol duster products. Furthermore, staff notes these data may

underestimate the total number of injuries and fatalities from aerosol duster huffing. The largest numbers of incidents reported by state were in Texas (80), Florida (79), California (68), Georgia (57), and Illinois (50). Generally, staff agrees that aerosol duster deaths may be increasing over time.

There are other products, such as paint products, general household cleaning solutions, refrigerants from appliances, air fresheners, spray paint, and whipped cream, for example, which use contain difluoroethane. CPSC staff searched specifically for aerosol dusters as the cause of the incident.

8. MISCELLANEOUS

COMMENT: Commenter 11 expresses concern that the CPSC's regulation of aerosol duster products would affect 1,1-difluoroethane (DFE) use in medical products, such as pressurized metered-dose inhalers (pMDIs).

STAFF RESPONSE: CPSC does not regulate medical products or devices. Therefore, DFE use in pMDIs will not be affected by any potential rule for aerosol duster products.

COMMENT: The Petitioner submitted additional data after the comment period from the State of Georgia on the deaths due to inhalants from the years 2007 through 2021, and subsequently provided additional data on the deaths due to DFE inhalants in VA, FL, CA, PA, TX, NC, GA, and AL over the time period 2006 through 2021.

STAFF RESPONSE: The Petitioner submitted data on 103 deaths in the State of Georgia due to inhalant abuse from the years 2007 through 2021. The data appear to be generally consistent with ours. There were 74 deaths attributed to products that contain DFE, which was 72 percent of all deaths due to inhalants. The majority (75%) of deaths were in males and most deaths were adults. The petitioner subsequently provided additional data on the deaths due to DFE inhalants in VA, FL, CA, PA, TX, NC, GA, and AL over the time period 2006 through 2021. The data appear to be generally consistent with ours. Staff does not know the definitions or scope used in these data, but the total number of deaths attributed to DFE inhalants in that period was 1003, while CPSC identified reports for 1,133 unique deaths over the period 2006 through 2020 as described in Tab D.

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