

INITIAL STATEMENT OF REASONS
November 2017

**SAFER CONSUMER PRODUCTS REGULATIONS – LISTING PAINT OR VARNISH
STRIPPERS CONTAINING METHYLENE CHLORIDE
AS A PRIORITY PRODUCT**

Department Reference Number: R-2016-05
Office of Administrative Law Notice File Number: Z-2017-1107-10

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I. SUMMARY OF PROPOSED ACTIONS & REGULATORY PROGRAM ACTIVITIES AFFECTED

The Department of Toxic Substances Control (DTSC) proposes to amend section 69511 and add section 69511.3 to Article 11,¹ Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations [Safer Consumer Products (SCP) regulations] to add paint or varnish strippers containing methylene chloride as a Priority Product to the Priority Products List.

Pursuant to section 69503.2(b), DTSC may identify and list as a Priority Product, one or more product-chemical combinations that it determines to be of high priority. DTSC's decision to identify and list a product-chemical combination is based on an evaluation of potential exposures and adverse impacts. DTSC has identified paint or varnish strippers containing methylene chloride as a Priority Product. Paint or varnish strippers containing methylene chloride are designed to break down paint, varnish, or any other surface coating to facilitate its removal from any surface. Methylene chloride is highly volatile and vapors can concentrate in the breathing zone of applicators during the normal use of paint or varnish strippers. Methylene chloride is an acute toxin and inhalation exposure during the use of paint or varnish strippers can result in severe injury or death. Methylene chloride is also recognized as a neurotoxicant and is known to the State of California to cause cancer. The wide use of this product creates potential for significant adverse health effects from exposure to methylene chloride by California workers and consumers.

DTSC is required to establish and update the Priority Products List through rulemaking under the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Division 3 of Title 2 of the California Government Code).

II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE AND RATIONALE

A. Statutory Intent and Requirements

In April 2007, California's Secretary for Environmental Protection launched the California Green Chemistry Initiative, a six-part initiative to develop policy options to

¹ DTSC conducted a separate rulemaking to list and identify children's foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP) as a Priority Product and adopt Article 11, which was approved and filed with the Secretary of State on April 19, 2017, with an effective date of July 1, 2017.

implement a green chemistry program and reduce public and environmental exposures to toxic chemicals through improved knowledge about and regulation of chemicals. In 2008, Assembly Bill 1879 (Chapter 559, Statutes of 2008) was signed into law to implement a key recommendation of the California Green Chemistry Initiative Final Report: accelerate the quest for safer consumer products. These statutory mandates are outlined in Health and Safety Code sections 25252 and 25253.

Specifically, Health and Safety Code section 25252 requires DTSC to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered as being Chemicals of Concern. This process must include consideration of the following factors:

- The volume of a chemical in commerce in California;
- The potential for exposure to a chemical in a consumer product; and
- The potential effects of the Chemical of Concern on sensitive subpopulations.

Health and Safety Code section 25252 also requires DTSC to develop criteria by which chemicals and their alternatives may be evaluated. At a minimum, the criteria must include hazard traits, physicochemical characteristics, and toxicological endpoints identified by the California Office of Health Hazard Assessment (OEHHA) in regulations set forth in Chapter 54 of Division 4.5 of Title 22 of the California Code of Regulations (CCR) adopted pursuant to Health and Safety Code section 25256.1. DTSC is also required to reference and use, to the extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes.

Health and Safety Code section 25253 requires the establishment of a process to evaluate the availability of potential alternatives to the use of Chemical(s) of Concern in a Priority Product, and potential hazards posed by those alternatives, through use of lifecycle assessment tools. Health and Safety Code section 25253 also authorizes DTSC to implement a range of Regulatory Responses following completion of an evaluation and comparison of the Priority Product and alternatives by the manufacturer through an Alternatives Analysis (AA).

B. Safer Consumer Products Regulations

1. Overview

The SCP regulations were adopted in October 2013 to meet the statutory requirements outlined in Health and Safety Code sections 25252 and 25253. The

regulations outline a science-based process for evaluating Chemicals of Concern in consumer products and safer alternatives by:

- Establishing a list of Candidate Chemicals and specifying criteria by which these may be designated a Chemical of Concern;
- Establishing a process to identify and prioritize product and Candidate Chemical combinations that may be listed as Priority Products;
- Requiring manufacturers to notify DTSC when their product is listed as a Priority Product;
- Requiring manufacturers of a Priority Product to perform an AA to determine how best to reduce exposures to, or the level of adverse public health and environmental impacts posed by, the Chemical(s) of Concern in the product;
- Requiring DTSC to identify and require implementation of Regulatory Responses following the completion on an AA; and
- Creating a process for persons to petition DTSC to add or remove chemicals from the Candidate Chemicals list, add or remove Candidate Chemicals lists in their entirety, or to add or remove a product-chemical combination from the Priority Products List.

2. Initial Proposed Priority Products List

The SCP regulations required DTSC to propose an initial list of Priority Products within 180 days from the effective date of the regulations. DTSC was required to consider products only if the Candidate Chemicals that were the basis for listing the products were included in one or more authoritative lists in both subdivisions (a)(1) and (a)(2) of section 69502.2. As a result, each Candidate Chemical identified as the basis for listing each of the initial Priority Products appears in one or more authoritative lists based on hazard traits [section 69502.2(a)(1)], as well as in one or more authoritative lists based on potential exposure concerns [section 69502.2(a)(2)].

DTSC identified specific product-chemical combinations for the initial Priority Products List based on an evaluation of available scientific literature, analysis of known hazard traits for the Candidate Chemicals, and consideration of the potential for exposure to the Candidate Chemicals in the product. DTSC also considered potential adverse impacts posed by the Candidate Chemicals in the product during the life cycle of the product, and the scope of other regulatory programs under which products and/or their Candidate Chemicals are regulated.

DTSC selected the following product-chemical combinations for the initial Priority Products List:

- Children’s foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP);
- Spray Polyurethane Foam (SPF) systems containing methylene diphenyl diisocyanates; and
- Paint or varnish strippers containing methylene chloride.

DTSC published the initial proposed Priority Products List on March 13, 2014, and held public workshops throughout California to solicit stakeholder input. However, to formally identify and list a product-chemical combination as a Priority Product, DTSC is required to establish and update the Priority Products List through rulemaking under the Administrative Procedure Act. DTSC is conducting this rulemaking to adopt paint or varnish strippers containing methylene chloride as a Priority Product.

3. Prioritization Criteria for Listing a Priority Product

DTSC is required to use the identification and prioritization criteria and process specified in CCR, title 22, sections 69503.2, 69503.3, and 69503.5 to identify and add a Priority Product to the Priority Products List.

Section 69503.2 requires that any product-chemical combination listed as a Priority Product meet two key prioritization criteria:

- There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

The first key prioritization principle requires DTSC to evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product by considering routes of exposure to the product and the Candidate Chemical(s) in the product throughout its full life cycle. This evaluation considers available information regarding one or more exposure scenarios, assesses the extent and quality of the relevant available information, and includes consideration of one or more of the exposure potential factors listed in section 69503.3(b).

The second key prioritization principle requires DTSC to evaluate whether one or more exposures to a Candidate Chemical in the product have a potential to contribute to or cause significant or widespread adverse public health and/or

environmental impacts. Evaluating the potential for significant adverse impacts may include consideration of the Candidate Chemical's toxicity, and impacts on sensitive subpopulations or sensitive environmental receptors. Similarly, the evaluation of the potential for widespread adverse impacts could include consideration of the Candidate Chemical's mobility in different types of environmental media or how widely products containing that chemical are sold or used.

In the context of the SCP regulations, the ability of a chemical to cause an adverse impact depends on the hazard trait(s) of that chemical. The potential for an exposure to that chemical to result in an adverse impact depends on particular exposure factors, such as the route or pathway of exposure under evaluation. The term "potential" is a critical term because the regulations incorporate not only experienced harm, but also address the possibility that a chemical could contribute to or cause harm. Section 69501.1(a)(51)(A) defines "potential" as "the phenomenon described is reasonably foreseeable based on reliable information." "Reasonably foreseeable" is a term of art in law that means a reasonable person would be able to predict or expect a given outcome. This ensures that assessment of adverse impacts is based on both reasonable grounds and evidence. Another criterion for the determination of "potential" is that consideration must be based on reliable information, which is defined in section 69501.1 of the SCP regulations to mean scientific studies or scientific information that meets certain specified criteria.

Section 69503.3 describes the factors DTSC is required to consider in its evaluation of adverse impacts and exposure to the Candidate Chemical(s) in the product. DTSC's evaluation must include consideration of one or more adverse impact factors listed in section 69503.3(a) and one or more exposure factors listed in section 69503.3(b). Following this evaluation, DTSC uses procedures specified in section 69503.5 to identify and list product-chemical combinations as Priority Products.

4. Requirement to Conduct Alternatives Analysis

Following the adoption of a Priority Product in regulation, manufacturers are required to submit a Priority Product Notification and determine whether they will conduct an AA. An AA is a systematic process for evaluating the life cycle impacts of a Priority Product and any alternatives considered. In lieu of submitting an AA Report, a manufacturer could also remove the Chemical of Concern from the Priority Product, replace it with a safer chemical, or stop selling the product in California. Section 69505.1(a) and section 69505.4(b), (c), and (d) identify the options a manufacturer has to comply with SCP requirements in lieu of conducting

an AA. The duty to comply with the regulation falls first to the manufacturer. If a manufacturer fails to submit a Priority Product Notification, this responsibility shifts to the importer of the product, if applicable, and then to the retailers or assemblers of the product. Once a manufacturer has failed to comply with the regulation and DTSC provides notice of this noncompliance, the requirements for importers, retailers, or assemblers, as applicable, call for importers to cease placing the product into the stream of commerce in California, and for retailers and assemblers to cease ordering the product.

The AA is a two-stage process that considers many facets of product manufacturing, including process engineering, environmental management, financial analysis, and research and development. In the first stage of the AA process, manufacturers are required to identify the legal, functional, and performance requirements of the Priority Product and the Chemical of Concern, and use this information to identify an array of alternatives to consider. When the first stage is completed, the manufacturer documents the findings in a Preliminary AA Report and submits this report to DTSC. During the second stage of the AA, the manufacturer compares the Priority Product with possible alternatives using a more in-depth analysis and considers additional factors, including additional life cycle and economic impacts. This information is then submitted to DTSC in the Final AA Report.

If, after completing the first five steps of the first stage of the AA, a manufacturer determines there are no functionally acceptable or technically feasible alternatives to the use of the Chemical of Concern in the Priority Product, it may submit an Abridged AA Report in lieu of submitting the Preliminary and Final AA Reports required by the two-stage process. The Abridged AA process requires the manufacturer to document the screening of potential alternatives. Because the Abridged AA process allows for the continued sales and use of the Priority Product, the Abridged AA Report must include an implementation plan to carry out the following required Regulatory Responses:

- providing product safety information to consumers, including information on chemical hazards, safe handling and disposal procedures, and other information needed to protect public health and the environment; and
- advancing green chemistry and green engineering principles, including initiating research and development projects or funding challenge grants to design safer alternatives or to improve performance, lower cost, or increase market penetration of existing safer alternatives.

Following submission of an Abridged AA Report or Final AA Report, DTSC will post the report using the Safer Consumer Products Information Management System (CalSAFER) located on the DTSC website and provide the public with an opportunity to submit comments. DTSC is required to review the public comments and may require the manufacturer to address all substantive comments before initiating departmental review. DTSC must evaluate each report on its own merits, taking into consideration unique conclusions and proposals. Because the reports and proposed Regulatory Responses address specific business situations, DTSC cannot predetermine the actions that manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advancing green chemistry or green engineering principles. DTSC's response to these submissions from manufacturers will maximize the use of alternatives of least concern industry-wide and give preference to Regulatory Responses that provide the greatest level of inherent protection to people and the environment.

C. Rationale for Proposing Paint or Varnish Strippers with Methylene Chloride as a Priority Product

This section describes the Candidate Chemical and the product that comprise the proposed Priority Product, and DTSC's rationale for proposing to list this Priority Product. This section also discusses products that are not included in the product-chemical description and describes the responsible entities impacted by this proposed regulation.

The information presented in this section was taken from the peer-reviewed report titled "Summary of Technical Information and Scientific Conclusions for Designating Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product." That report is one of the documents relied upon for this rulemaking proposal.

1. Description of Methylene Chloride

DTSC has identified methylene chloride as the Candidate Chemical and the basis for listing paint or varnish strippers containing methylene chloride as a Priority Product. Methylene chloride is identified by the chemical abstract service (CAS) registry number 75-09-2, and common synonyms or trade names include methylene chloride, dichloromethane, and methylene dichloride.

Methylene chloride is a solvent that is commonly used in paint or varnish strippers at concentrations ranging from 16-100% (weight by volume). Most paint or varnish stripping formulations sold in California contain methylene chloride. It is estimated

that nearly 33% of all methylene chloride manufactured worldwide is used as a solvent in paint or varnish strippers. The United States Environmental Protection Agency (U.S. EPA) estimated U.S. production and imports of methylene chloride totaled 261.5 million pounds in 2012, with 25% of that used in the production of paint or varnish strippers. In 2008, U.S. EPA estimated that approximately 3,000 commercial paint stripping shops operated in the U.S., including those engaged in automotive, furniture, marine, and wall paint removal. Of these, approximately 2,000 paint stripping shops used less than 2,000 pounds of methylene chloride per year in their operations, while 1,000 businesses used more than 2,000 pounds annually.²

Consistent with section 69503.6(a) of the SCP regulations, DTSC identified methylene chloride as a Candidate Chemical because it is included on certain authoritative lists or has been identified as a certain type of chemical. Those authoritative lists and chemical types are specified in section 69502.2(a)(1) & (2), respectively, and for methylene chloride they include:

- Methylene chloride is known to the State of California to cause cancer (under the Safe Drinking Water and Toxic Enforcement Act of 1986).
- Methylene chloride is classified as “possibly carcinogenic to humans” (i.e., a group 2B carcinogen) by the International Agency for Research on Cancer (IARC).
- Methylene chloride is classified as “reasonably anticipated to be a human carcinogen” in the Twelfth Edition of the Report on Carcinogens published by the U.S. Department of Health and Human Services, National Toxicology Program.
- Methylene chloride is classified as “likely to be carcinogenic to humans” in the U.S. EPA’s Integrated Risk Information System.
- Methylene chloride is recognized as a neurotoxicant by the Agency for Toxic Substances and Disease Registry’s Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, and Nervous System.
- Methylene chloride is identified by California Water Quality Control Plans under section 303(c) of the federal Clean Water Act and as a pollutant by California for one or more water bodies under section 303(d) of the federal Clean Water Act.

² U.S. EPA (2014) *Methylene Chloride: Paint Stripping Use*. Office of Chemical Safety and Pollution Prevention. Accessed online at https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf on 4/06/2017.

- Methylene chloride is classified as a Toxic Air Contaminant by the State of California under sections 93000 and 93001 of title 17 of the CCR.
- Methylene chloride is identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by the California Office of Environmental Health Hazard Assessment under Health and Safety Code section 44360(b)(2).

Methylene chloride is highly volatile and can rapidly accumulate in the breathing zone of the user. The major route of exposure is via inhalation, although methylene chloride can also be absorbed through the skin.

Methylene chloride is associated with the following hazard traits:

- Carcinogenicity,
- Neurotoxicity
- Dermatotoxicity, and
- Ocular toxicity.

Exposure to methylene chloride is associated with the following toxicological endpoints:

- Cancer of the brain, liver, and biliary tract,
- Skin irritation, and
- Central nervous system depression, intoxication, and unconsciousness.

Methylene chloride depresses central nervous system function by inhibiting the function of nerve cells. This acute effect is generally reversible, however, chronic high-level exposure can lead to a debilitating degenerative condition known as chronic solvent encephalopathy. The recognized effects of methylene chloride exposure on the central nervous system clearly meet the definition of neurotoxicity in California Code of Regulations, title 22, section 69403.12(a).

Exposure to methylene chloride has been associated with various acute toxic effects. High-level acute exposures can be fatal and there are numerous worker and consumer deaths associated with the use of paint or varnish stripping products containing methylene chloride. The primary cause of death from acute methylene chloride exposure is related to the aforementioned central nervous system depression, which leads to decreased respiratory rate and heart function. This in turn leads to decreased oxygen uptake and availability to tissues (hypoxia). Very high concentrations of methylene chloride, as with other organic solvents, can also

induce cardiac arrhythmias by sensitizing the heart muscle to catecholamines such as epinephrine and the severity of cardiac dysfunction is then further exacerbated by hypoxia. Methylene chloride is metabolized to carbon monoxide in the human body and may cause symptoms of carbon monoxide poisoning, including asphyxiation, respiratory distress, and chest pain. The accumulation of carbon monoxide further decreases oxygen availability by forming carboxy hemoglobin, which further exacerbates the depressive effect of methylene chloride on the central nervous system. In summary, acute poisoning may cause central nervous system depression, which leads to decreased respiratory and cardiac output, which may disrupt the regular beating of the heart, resulting in hypoxia. At the same time, methylene chloride metabolism produces carbon monoxide, which further increases hypoxia by inhibiting the ability of hemoglobin to carry oxygen. The overall effect is a starving of tissues for oxygen, a depression of central nervous system and cardiac function, and ultimately death by asphyxiation.

The central nervous system and cardiovascular effects of methylene chloride may be exacerbated in fetuses and infants because methylene chloride may be more rapidly metabolized to carbon monoxide in children, and fetal hemoglobin has a higher affinity for carbon monoxide than adult hemoglobin. Moreover, an increase in the spontaneous abortion rate was observed for female workers exposed to organic solvents, and women exposed to methylene chloride may have increased risk of miscarriage. As documented in the Technical Summary, DTSC assumes that the fetus, infants, and children have increased susceptibility to carcinogens relative to adults.³

In addition to central nervous system depression, acute exposures may also result in dizziness, loss of coordination, memory loss, personality changes, unconsciousness, and respiratory distress. According to the California Department of Public Health, methylene chloride can cause chest pain (angina) and other cardiac symptoms in people with heart disease. Other groups of people who may be at increased risk of adverse health effects when exposed to methylene chloride include elderly people, people taking medications that depress the central nervous system, and those with respiratory problems such as asthma or emphysema.

Once a Candidate Chemical is identified as the basis for a product being listed as a Priority Product, that chemical is then designated the “Chemical of Concern” for

³ DTSC (Revised October 2016), *Summary of Technical Information and Scientific Conclusions for Designating Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product.*

that product pursuant to the SCP regulations. For clarity and consistency, the term “Chemical of Concern” will be used throughout the remainder of this document when referring to methylene chloride in paint or varnish strippers.

2. Description of Paint or Varnish Strippers with Methylene Chloride

DTSC proposes to list paint or varnish strippers containing methylene chloride as a Priority Product. The product category of paint or varnish strippers containing methylene chloride is defined as:

Any product that is placed into commerce in California that contains methylene chloride (dichloromethane), and that may be marketed, sold, or offered for sale as a chemical substance designed to break down paint, varnish, or any other surface coating to facilitate its removal from any surface. Such products may be designed for indoor or outdoor use.

This definition was developed following input from stakeholders at public workshops held throughout the state, and to be consistent with the California Air Resources Board’s (CARB) existing regulatory definition⁴ of “paint remover or stripper.”

3. Products not Included in the Product-Chemical Description

Following DTSC’s publication of the initial proposed Priority Products List in March 2014 and during subsequent public workshops held throughout California, stakeholders expressed concern regarding what specific products would be subject to this proposed regulation. To address stakeholders’ concerns, provide clarity, and avoid conflicts with existing laws, DTSC is providing the following explanation that describes products that are not defined as “Paint or Varnish Strippers Containing Methylene Chloride” and would not be subject to the proposed regulation.

CARB’s Consumer Product Regulations already prohibit the use of methylene chloride in the following products:⁵

- Adhesive Removers
- Bathroom and Tile Cleaners

⁴ See California Code of Regulations, title 17, section 94508(a)(98).

⁵ See California Code of Regulations, title 17, section 94509(m) and Table 94509(m)(1).

- Carpet and Upholstery Cleaners
- Electrical and Electronics Cleaners
- General Purpose Cleaners and Degreasers
- Graffiti Removers
- Metal Cleaners
- Oven or Grill Cleaners
- Paint Thinners
- Spot Removers

Each of these product categories is clearly defined in CARB's Consumer Product Regulations.⁶ Any product marketed or sold for use in California that meets CARB's definition for any one of the above product categories is not subject to the proposed regulation.

4. Rationale for Listing Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product

DTSC proposes to adopt paint or varnish strippers containing methylene chloride as a Priority Product because this product-chemical combination meets the criteria in section 69503.2(a), which requires that:

- There must be potential public and/or aquatic, avian, or terrestrial animal, or plant organism exposure to the Candidate Chemical(s) in the product; and
- There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

Following an extensive review of the scientific literature and analysis of the known hazard traits of methylene chloride, DTSC concluded that there is a potential for workers and consumers to be exposed to methylene chloride during normal use of paint or varnish strippers. These exposures could potentially contribute to or cause significant adverse health impacts.

A 2013 survey by the California Department of Public Health reported that the majority of paint or varnish stripping formulations sold in California contained methylene chloride. In addition, DTSC was informed by specific manufacturers that paint or varnish strippers containing methylene chloride comprise approximately 85% of the domestic paint stripper market. This information indicates that paint or

⁶ See California Code of Regulations, title 17, section 94508.

varnish strippers containing methylene chloride are more widely available than paint or varnish strippers containing other active ingredients.

As of 2006, there were at least six industrial facilities in California using relatively large quantities (more than 1,200 gallons per year) of paint or varnish strippers containing methylene chloride, and as many as 490 smaller businesses (e.g., antique stores) using paint or varnish strippers containing methylene chloride in smaller quantities (ranging from less than 5 gallons per year up to 1200 gallons per year). Many furniture stripping firms that use methylene chloride-based paint or varnish strippers in California have been characterized as having poor ventilation, with workers in such facilities at an increased risk of exposure to airborne methylene chloride. The federal Occupational Safety and Health Administration (OSHA) and the California Division of Occupational Safety and Health (known as Cal/OSHA) have established a permissible exposure limit (PEL) of 25 parts per million and an action level of 12.5 parts per million for methylene chloride in air. According to a 2006 study, most furniture stripping firms routinely exceeded both the action level and the PEL for methylene chloride.

Because methylene chloride is highly volatile, it readily enters the vapor phase and can accumulate in the breathing zone of consumers and workers during normal use of paint or varnish strippers. Inhalation is the predominant mode of exposure, although methylene chloride can also be absorbed through the skin. It has been shown that the use of methylene chloride-based products in home settings can result in high concentrations of methylene chloride in air, often exceeding OSHA PELs. In a home simulation study of furniture stripping, methylene chloride concentrations in air exceeded 2,000 parts per million when paint or varnish strippers were used indoors without local exhaust ventilation. According to the National Institute for Occupational Safety and Health, an air concentration of 2,300 parts per million is considered “Immediately Dangerous to Life and Health.”

There have been numerous worker and consumer deaths associated with the use of paint or varnish strippers containing methylene chloride in enclosed spaces or without adequate ventilation. In 2012, the European Parliament concluded that the potential human health threat from using paint or varnish strippers containing methylene chloride was of sufficient concern that the sale of paint strippers containing methylene chloride to general consumers in the European Union was prohibited. In contrast, methylene chloride-based paint or varnish strippers are still widely available in the United States.

Recognition of health hazards associated with the use of paint or varnish strippers containing methylene chloride prompted the U.S. Consumer Product Safety

Commission to require warning labels on paint or varnish strippers.

Methylene Chloride



WARNING

Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation. May cause drowsiness or dizziness. Suspected of causing cancer. Suspected of damaging fertility or the unborn child. May cause damage to the central nervous system through prolonged or repeated inhalation. May cause damage to the liver or blood through prolonged or repeated ingestion.

PREVENTION

Wash hands and any other contaminated skin thoroughly after handling. Wear protective gloves, eye protection, and respirator. Do not eat, drink or smoke when using this product. Do not breathe vapors. Use only outdoors or in a well-ventilated area.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

RESPONSE

If inhaled: Remove person to fresh air and keep comfortable for breathing. **If in eyes:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. **If on skin:** Take off immediately all contaminated clothing. Wash with plenty of water, and soap if available. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention. **If exposed or concerned:** Get medical advice. Call a poison center or doctor if you feel unwell.

STORAGE: Store in a well-ventilated place. Keep container tightly closed.

WARNING: This product contains a chemical known to the State of California to cause cancer.

The labels must identify health hazards associated with exposure to methylene chloride and recommend actions users may take to prevent exposures. However, these labels do not identify the specialized types of gloves and respirators that are required for adequate protection. For example, OSHA requires that workers wear respirators that are full-face and atmosphere-supplying when air concentrations are above the PEL, as air-purifying respirators with chemical cartridges are insufficient. As well, only gloves made of polyethylene/ethylene vinyl alcohol or other laminate materials can protect from dermal exposures because these are resistant to degradation. OSHA also recommends

that workers wear methylene chloride-resistant aprons, sleeves, and boots, as well as goggles or a face shield, when using paint or varnish strippers containing methylene chloride. A survey conducted by the California Department of Public Health determined that sales people at retail outlets where paint or varnish strippers are sold in California typically failed to recommend appropriate protective equipment to consumers purchasing paint or varnish strippers containing methylene chloride.

Occupational exposures to harmful substances such as methylene chloride in paint or varnish strippers are typically addressed via hazard control methodology widely accepted by the industrial hygiene profession and safety organizations, including Cal/OSHA and federal OSHA. Following this approach, hazards are controlled via a “hierarchy” of potential solutions. This hierarchy, in order of preference, is: 1) elimination of the hazard; 2) substitution with a different chemical; 3) engineering controls, including processes and systems, such as exhaust ventilation, which are designed to remove the hazard at the source, before it comes in contact with the worker; 4) administrative controls, including the implementation of policies, procedures, and employee training; and 5) the use of personal protective equipment (PPE).

Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational exposures to workers. Engineering controls can be effective when implemented in combination with appropriate administrative controls and PPE. The use of administrative controls and PPE, alone or in combination, is the least desirable approach to controlling occupational exposure to chemical hazards because their effectiveness depends almost entirely on employees' ability to comply and employers' ability to supervise. Lack of training, experience, or supervision, as well as a range of physical and environmental variables, can significantly decrease the effectiveness of these methods. Worker exposure that can lead to injuries or illness is often a consequence of failing to use PPE, using it improperly, or failing to follow administrative controls. Workers may not use PPE because it is uncomfortable, particularly under hot conditions. Workers also report that PPE often fits poorly and is bulky, which can reduce mobility and productivity. Additionally, employers may not supply workers with adequate PPE or enforce its use. Even when worn properly, PPE may place workers at risk due to reduced dexterity, visual acuity, and mobility, which could increase the likelihood of trip, slip, and fall accidents or heat-related illnesses. Because the original chemical hazard is still present in the workplace, when employees fail to follow administrative controls or to use PPE properly, they risk exposure to chemical hazards that can lead to injuries or illnesses.

Although DTSC does not know how many workers follow employer-developed safety procedures and use adequate PPE, as stated above, administrative controls and use of PPE are at the bottom of the hierarchy of control methods, and therefore are the least effective in protecting workers from exposures to occupational hazards. DTSC has determined that industry-recommended engineering and administrative controls and use of PPE reduce the likelihood of exposure, but do not eliminate the potential for worker exposure to methylene chloride during use of paint or varnish strippers.

Sole proprietors and consumers using paint or varnish strippers containing methylene chloride at home are of particular concern to DTSC. These groups are exempt from state and federal worker protection standards and, as a result, are unlikely to invest in engineering controls and PPE, utilize industry-recommended administrative controls, or receive adequate safety guidance. Even when workers and consumers use PPE during use of paint or varnish strippers, improper use, imperfect fit, and malfunction of PPE can occur and result in exposure to methylene chloride.

In conclusion, use of paint or varnish strippers containing methylene chloride produces measurable concentrations of airborne methylene chloride in the breathing zone, and any person involved in or near the application risks inhalation exposure to methylene chloride, even when protective measures are used. Exposure to methylene chloride in paint or varnish strippers has the potential to harm workers in commercial operations, sole proprietors, and individual consumers in California. It is a carcinogen, neurotoxicant, and acute toxin, and can have adverse impacts on internal organs, including the heart, lungs, liver, eyes, and skin. As an acute toxicant, exposure during the use of paint or varnish strippers has led to numerous accidental deaths of workers and consumers. In addition, studies have suggested that methylene chloride exposure may increase the risk of spontaneous abortions and may have adverse effects on pregnancy.

Therefore, due to the wide availability of paint or varnish strippers containing methylene chloride, the potential for exposure to methylene chloride during use, and the significant adverse health impacts associated with exposure to methylene chloride, DTSC concluded that paint or varnish strippers containing methylene chloride meet the criteria specified in section 69503.2(a) for listing as a Priority Product.

5. *Responsible Entities with the Principal Duty to Comply with the Safer Consumer Products Regulations*

Pursuant to section 69501.2, manufacturers of paint or varnish strippers with methylene chloride have the principal duty to comply with requirements applicable to a responsible entity. These manufacturers will have the principal duty to submit a Priority Product Notification and prepare an AA. In lieu of preparing an AA, manufacturers may notify DTSC that they intend to remove or replace the Chemical of Concern from the Priority Product or remove the Priority Product from the California marketplace.

If manufacturers do not comply, the duty to comply falls to importers, if any, and then to retailers or assemblers. These entities are required to comply with the requirements applicable to a responsible entity only if the manufacturer has failed to comply and DTSC provides notice of such non-compliance by posting the information on the Failure to Comply List on CalSAFER. Compliance options for importers, retailers, and assemblers differ from those applicable to manufacturers, and seek to remove the product from the stream of commerce in California. End users, such as contractors or consumers, are not responsible entities and do not have a duty to comply with the SCP regulatory requirements.

Only manufacturers who control the product manufacturing process for, or specify the use of chemicals to be included in, the product would be subject to many of the requirements in this proposed regulation. DTSC has learned that some companies may buy pre-formulated paint or varnish stripping products without controlling the manufacturing process or requiring the use of specific chemicals. These companies label the pre-formulated product, and then offer that product for sale in California. In situations where such companies buy the already formulated paint or varnish stripping product from another manufacturer and subsequently make a non-material operation to it (e.g., by labeling it with their brand name), the process of labeling would be considered “assembling” and not manufacturing. Under such circumstances, the company who re-labels the product would be considered an assembler and would not be subject to requirements for manufacturers in the proposed regulations. In this instance, the original manufacturer who sold the formulated product to the second company for relabeling and sale would be the primary responsible entity under the proposed regulation.

D. Additions to Chapter 55. The Safer Consumer Products Regulations

Amend section 69511. General.

Section 69511 describes the scope and purpose of article 11 and establishes a Priority Products List. This section is modified to add subsection (b)(3) to identify Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product on the Priority Products List.

Add section 69511.3. Paint or Varnish Strippers Containing Methylene Chloride.

In its entirety, this section identifies Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product. This section is necessary because it describes the product-chemical combination being listed as a Priority Product, therefore informing responsible entities and the public what type of paint or varnish strippers are subject to regulation.

Add section 69511.3(a). This section provides a description of the product-chemical combination. “Paint or Varnish Strippers Containing Methylene Chloride” means any product that is placed into commerce in California that contains methylene chloride (dichloromethane), and that may be marketed, sold, or offered for sale as a chemical substance designed to break down paint, varnish, or any other surface coating to facilitate removal of the surface coating from any surface. Such products may be designed for indoor or outdoor use, and may be used to remove paint, varnish, or other surface coatings from any chosen surface. This description is necessary for a responsible entity to determine whether one or more of its products is a Priority Product, as required by section 69503.5(b)(1)(A).

Add section 69511.3(b). This section identifies methylene chloride (CAS RN 75-09-2) as the Candidate Chemical that is the basis for paint or varnish strippers containing methylene chloride being listed as a Priority Product.

Consistent with section 69503.6(a) of the SCP regulations, DTSC identified methylene chloride as a Candidate Chemical because it is included on authoritative lists as specified in section 69502.2(a) and meets the following criteria:

- Methylene chloride is known to the State of California to cause cancer (under the Safe Drinking Water and Toxic Enforcement Act of 1986).
- Methylene chloride is classified as “possibly carcinogenic to humans” (i.e., a group 2B carcinogen) by the International Agency for Research on Cancer (IARC).

- Methylene chloride is classified as “reasonably anticipated to be a human carcinogen” in the Twelfth Edition of the Report on Carcinogens published by the U.S. Department of Health and Human Services, National Toxicology Program.
- Methylene chloride is classified as “likely to be carcinogenic to humans” in the U.S. EPA’s Integrated Risk Information System.
- Methylene chloride is recognized as a neurotoxicant by the Agency for Toxic Substances and Disease Registry’s Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, and Nervous System.
- Methylene chloride is identified by California Water Quality Control Plans under section 303(c) of the federal Clean Water Act and as a pollutant by California for one or more water bodies under section 303(d) of the federal Clean Water Act.
- Methylene chloride is classified as a Toxic Air Contaminant by the State of California under sections 93000 and 93001 of title 17 of the CCR.
- Methylene chloride is identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by the California Office of Environmental Health Hazard Assessment under Health and Safety Code section 44360(b)(2).

This section is needed to clearly identify to responsible entities and the public that methylene chloride is the Candidate Chemical that is the basis for listing paint or varnish strippers containing methylene chloride as a Priority Product.

Add section 69511.3(c). This section indicates the hazard traits associated with methylene chloride. Section 69503.5(b)(2)(A) specifies that DTSC evaluates, at a minimum, the hazard traits of the Candidate Chemicals that are the basis for the product-chemical combination being listed as a Priority Product following the identification and prioritization criteria and process specified in sections 69503.2 and 69503.3. The hazard traits associated with methylene chloride include carcinogenicity, neurotoxicity, dermatotoxicity, and ocular toxicity. This section is necessary because it identifies why exposure to methylene chloride from the use of paint or varnish strippers has the potential to harm California workers and consumers.

Add section 69511.3(d). This section indicates toxicological endpoints associated with exposure to methylene chloride, in accordance with section 69503.5(b)(2)(A). These toxicological endpoints include the following: cancer of the brain, liver and biliary tract; skin irritation; and central nervous system depression, intoxication, and unconsciousness.

It is necessary to identify toxicological endpoints associated with exposure to methylene chloride so that manufacturers and users of paint or varnish strippers are aware of potential adverse impacts that could occur with normal use.

Add section 69511.3(e). This section designates the Candidate Chemical, referred to as methylene chloride, as the Chemical of Concern for the Priority Product. Section 69503.5(b)(2)(B) states that any Candidate Chemical that has been identified as the basis for a product being listed as a Priority Product is then designated as the Chemical of Concern for that product. This section is necessary to clearly identify to responsible entities and the public that methylene chloride (CAS RN 75-09-2) is the Chemical of Concern in paint or varnish strippers affected by this proposed regulation. Clearly identifying the Chemical of Concern in a Priority Product ensures that responsible entities understand DTSC's concerns with their product and take the appropriate steps to comply with the notification and reporting requirements included in the SCP regulations.

Add section 69511.3(f). This section provides responsible entities a due date for submission of the Preliminary AA Report. This section is necessary to comply with section 69503.5(b)(3) and to provide responsible entities with a time frame for complying with the notification and reporting requirements included in the SCP regulations.

III. ECONOMIC IMPACT ANALYSIS

As required by Government Code section 11346.3, DTSC assessed the potential for this proposed regulation to cause adverse economic impacts to California businesses and individuals. Following a review of available information and survey of affected manufacturers and industry organizations, DTSC determined the proposed regulation is not a major regulation⁷ and is unlikely to have a significant adverse impact on business. This Economic Impact Analysis is also based on the assumption that manufacturers of paint or varnish strippers containing methylene chloride will comply fully with the SCP regulations by submitting Priority Product Notifications and AA Reports to DTSC by the dates specified in regulation.

⁷ Government Code section 11342.548 defines a "major regulation" as any proposed adoption of a regulation that will have an economic impact on California businesses in an amount exceeding \$50 million dollars as estimated by the adopting agency. Section 57005 of the Health and Safety Code further requires DTSC (as part of the California Environmental Protection Agency, "CalEPA") to evaluate alternatives to a "major regulation." Section 57005(b) defines a "major regulation" as any rulemaking that will have an economic impact on business enterprises exceeding \$10 million.

Manufacturers of paint or varnish strippers containing methylene chloride that do not submit AA Reports must: 1) remove methylene chloride from their paint or varnish stripper products; 2) replace methylene chloride with a different chemical that meets certain regulatory requirements for those products; or 3) stop selling paint or varnish strippers containing methylene chloride in California. If a manufacturer fails to comply with the regulation and DTSC provides notice of this noncompliance, the requirements for importers, retailers, or assemblers, as applicable, call for importers to cease placing the product into the stream of commerce in California, and for retailers and assemblers to cease ordering the product.

A. Cost Impacts on Representative Private Persons or Businesses

DTSC estimates the cumulative cost for all affected manufacturers of paint or varnish strippers with methylene chloride to submit Priority Product Notifications and AA Reports and to respond to DTSC's reviews of these submittals to be from \$2,371,200 to \$6,403,200. DTSC estimates there are 24 or fewer manufacturers of paint or varnish strippers containing methylene chloride that make or sell their products in California that would be required to comply with this regulation. Three of the 24 potentially affected manufacturers are headquartered in California.

Each manufacturer is required to submit a Priority Product Notification to DTSC online using CalSAFER that includes business contact information and the type, brand name(s), and product name(s) of paint or varnish strippers that contain methylene chloride. This is a one-time requirement. DTSC estimates that manufacturers would require a maximum of 16 hours to prepare a Priority Product Notification at a cost of approximately \$50/hour. DTSC estimates that each manufacturer could spend up to \$800 to complete the required notification.

Manufacturers and an industry alliance representative indicated that at least four manufacturers plan on forming a consortium and submitting a combined AA. This group also indicated they cannot determine whether they will complete an Abridged AA or a two-stage AA until they complete the necessary research for the first stage of the AA process. Given the uncertainty around whether manufacturers will submit an Abridged AA Report or a two-stage AA Report, DTSC modeled both scenarios.

Since there are few precedent regulations of this nature and no previously conducted AAs to use as guides for this economic analysis, DTSC derived the estimated costs of an AA utilizing authoritative sources of information. These included the Interstate Chemicals Clearinghouse (IC2) Alternative Assessment guide, the State of Washington's Alternative Assessment Guide for Small and Medium Businesses, University of California Santa Barbara's Life Cycle Analysis and Pilot AA studies, as well

as guidance from the European Chemicals Agency. DTSC's estimated costs to individual manufacturers based on these sources range from \$48,000 to \$78,000 for an Abridged AA and \$86,000 to \$161,000 for a two-stage AA.

DTSC surveyed manufacturers of paint or varnish strippers containing methylene chloride for their expected costs of submitting an AA. Those interviewed indicated that they expect the first stage of an AA to cost from \$100,000 to \$135,000. This estimate does not include the second stage of a two-stage AA or responses to public comments and DTSC reviews. DTSC also conducted similar interviews with manufacturers for other potential Priority Products. Manufacturers of these other products estimated that it would cost from \$50,000 to \$150,000 to prepare an Abridged AA Report or \$120,000 to \$250,000 to prepare a two-stage AA Report.

Given the high degree of uncertainty in the estimated cost of an AA, DTSC opted to use the higher range of estimates provided by manufacturers of proposed Priority Products (\$100,000 to \$150,000 for an Abridged AA and \$120,000 to \$250,000 for a two-stage AA). For an individual manufacturer, the estimated total cost to comply with the Priority Product Notification and the AA report requirements, including responding to DTSC's review, ranges from \$112,800 to \$182,800 for an Abridged AA and \$139,800 to \$304,800 for a two-stage AA.

Given a lack of data and many uncertainties surrounding the effort required to complete the AA process defined in the SCP regulations, these costs may be underestimated. Likewise, if more than four affected manufacturers form a consortium to submit a combined AA Report, overall costs could be lower.

More information regarding potential costs and benefits of this proposed regulation is provided in an attachment to the Economic and Fiscal Impact Statement (STD 399).

B. Creation or Elimination of Jobs within California

The requirement to submit Priority Product Notifications and Abridged AA Reports or two-stage AA Reports is not likely to result in the creation or elimination of jobs in California. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications and AA Reports are low enough for all potentially impacted manufacturers to comply without impacting the number of jobs at their businesses. Manufacturers can significantly reduce their individual costs of compliance by submitting a combined AA Report through a consortium.

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives exist. DTSC reviews each AA Report on its

own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that paint or varnish manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to additional jobs in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

C. Creation of New Businesses or Elimination of Existing Businesses within California

DTSC determined that this proposal is unlikely to result in the elimination of any paint or varnish stripper manufacturers. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications and AA Reports are low enough for all potentially impacted manufacturers to comply without eliminating their businesses. Manufacturers can significantly reduce their individual costs of compliance by submitting a combined AA Report through a consortium.

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives to the use of the Chemical of Concern in the Priority Product exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that paint or varnish manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to creation of new businesses in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

D. Expansion of Current California Businesses

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business

situation, DTSC cannot predetermine the actions that paint or varnish manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to expanded business opportunities in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

E. Effects on Small Businesses

Under California Rulemaking Law, Government Code section 11342.610, a small business is defined as being both independently owned and operated and not dominant in its field of operation. California Government Code 11346.3(b)(4) adds an additional criterion to the small business definition: a small business must have fewer than 100 employees. Many of the potentially impacted manufacturers are non-public companies and do not publish information about employee size, ownership, or management of their organizations. DTSC relied on Dun & Bradstreet (a private data vendor) to provide estimates of employee size for each potentially impacted manufacturer. Based on this information and the limited information that is available on company websites, DTSC estimates that seven of the 24 potentially impacted manufacturers are small businesses. Two of these seven small businesses are headquartered in California.

DTSC estimates that each Priority Product Notification and AA Report would cost from \$112,800 to \$304,800, regardless of the size of the business. If a manufacturer chooses to submit an AA Report prepared by a consortium, its individual costs may be lower than estimated.

F. Anticipated Benefits of the Regulation

The primary goal of SCP regulations is to protect public health by reducing exposures to potentially harmful chemicals. By listing paint or varnish strippers containing methylene chloride as a Priority Product, DTSC sets in motion a strategy to reduce human exposure to methylene chloride during use of this product. A reduction in airborne methylene chloride means healthier air quality and safer workplaces and homes. A reduction in exposure to methylene chloride could reduce workplace-related illness and injury and the number of work days lost to health effects associated with methylene chloride exposure. The development of safer alternatives benefits California workers, consumers, and employers.

DTSC cannot pre-determine the alternatives that each manufacturer will propose; therefore, it is impossible to accurately predict or quantify the full range of potential benefits associated with their development. DTSC will maximize the use of alternatives of least concern and give preference to those that provide the greatest level of inherent protection. In general, economic benefits to California workers and business owners may include expanded employment opportunities in the fields of consulting, worker and consumer education, and marketing. Additional benefits may accrue because of increased research and product development collaboration between manufacturers and California-based research laboratories. Institutional and corporate financial support of chemical and material science programs focused on developing safer paint or varnish strippers could advance the field. These research initiatives could provide manufacturers with employees that are highly skilled in the research and design of products for newly emerging global markets.

IV. REPORTS RELIED ON

DTSC relied on the Economic Impact Assessment (STD 399), pursuant to Government Code section 11346.3(b) in proposing this regulatory action.

Assembly Bill 1879 (Feuer, Chapter 559, Stats. 2008) was signed into law on September 29, 2008, laying the critical foundation for the Green Chemistry Program. This bill provides the authority and mandate to adopt proposed SCP regulations.

DTSC (Revised October 2016) Summary of Technical Information and Scientific Conclusions for Designating Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product.

European Chemicals Agency (ECHA). Guidance on the Preparation of an Application for Authorisation. Version 1. January 2011. Accessed online at https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9.

Interstate Chemicals Clearinghouse (IC2) (2013). Interstate Chemicals Clearinghouse Alternatives Assessment Guide, Interstate Chemicals Clearinghouse, November 2013, version 1.0, 176 pages. Accessed online at http://www.newmoa.org/prevention/ic2/IC2_AA_Guide-Version_1.pdf on 4/13/2017.

State of Washington (2015) Alternative Assessment Guide for Small and Medium Businesses, January 2015, Publication number 15-04-002. Accessed online at <https://fortress.wa.gov/ecy/publications/documents/1504002.pdf> on 4/13/2017.

University of California-Santa Barbara (2015) Framework for Initial Life Cycle Screening in Alternatives Analysis.

University of California-Santa Barbara (2016) Pilot Study to Support Alternatives Analysis.

U.S. EPA (2014) Methylene Chloride: Paint Stripping Use. Office of Chemical Safety and Pollution Prevention. Accessed online at https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf on 4/06/2017.

V. REASONABLE ALTERNATIVES CONSIDERED

DTSC considered the following alternatives to the proposed regulatory action:

Regulation: List paint or varnish removers containing methylene chloride as a Priority Product.

Methylene chloride is highly volatile and vapors can concentrate in the breathing zone of applicators during the normal use of paint or varnish strippers. Methylene chloride is an acute toxin and inhalation exposure during the use of paint or varnish strippers can result in severe injury or death. The wide use of this product creates potential for significant adverse health effects from exposure to methylene chloride by California workers and consumers.

Alternative 1: Wait for U.S. EPA to regulate the use of paint stripper containing methylene chloride.

U.S. EPA identified methylene chloride as a work plan chemical for assessment under Toxic Substances Control Act (TSCA) in 2012, and proposed a rule to regulate the use of methylene chloride in paint strippers in January 2017. DTSC decided to move forward with this proposed rulemaking because U.S. EPA's rule has only recently been proposed, and the scope of the rule may change before it is final. DTSC's proposed rule will regulate methylene chloride under a regulatory framework that is fundamentally different from TSCA. For these reasons, and in light of recent deaths attributable to the improper use of methylene chloride-based strippers, DTSC has chosen to move forward with its proposed rulemaking so workers and consumers can benefit from this innovative process.

Alternative 2: List paint or varnish strippers containing methylene chloride or N-methyl pyrrolidone (NMP) as a Priority Product.

NMP is a widely used chemical alternative to methylene chloride in paint strippers (CAS number 872-50-4). NMP is a known reproductive and developmental toxicant and a skin and eye irritant. Moreover, NMP is on DTSC's list of Candidate Chemicals due to reproductive and developmental toxicity. However, since NMP does not meet the condition specified in California Code of Regulations, title 22, section 69503.6(a), DTSC may not name paint or varnish strippers containing NMP as part of the initial Priority Products List. Paint or varnish strippers containing NMP may be listed as a Priority Product in the future.

VI. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

The SCP regulations established a unique approach to regulating Chemicals of Concern in consumer products that grants DTSC authority to take actions to protect people and the environment when such actions are outside the scope of other regulatory programs. There are no equivalent federal regulations that require product manufacturers to determine if the chemical in their product is necessary, if there is a safer alternative, and to take steps to protect human health and the environment.

Methylene chloride is regulated by U.S. EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). The proposed regulation does not duplicate or conflict with any of these agencies' regulations, which are discussed below.

A. Regulation by U.S. EPA

Methylene chloride is designated as a hazardous air pollutant (HAP) under the Clean Air Act and U.S. EPA has issued a National Emission Standards for Hazardous Air Pollutants (NESHAP) for area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations. Methylene chloride is listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) and is listed on the Toxics Release Inventory (TRI) pursuant to the Emergency Planning and Community Right-to-Know Act. U.S. EPA has set the maximum contaminant level (MCL) for methylene chloride at 5 parts per billion under the Safe Drinking Water Act.

U.S. EPA proposed a rule under TSCA section 6(a) on January 19, 2017 that would prohibit the manufacture (including import), processing, and distribution in commerce of

methylene chloride for consumer and most types of commercial paint and coating removal uses. DTSC supports U.S. EPA's efforts to regulate methylene chloride under TSCA. Historically, U.S. EPA has not used its regulatory authority under TSCA to restrict the use of chemicals. Recent changes to TSCA through the Frank R. Lautenberg Chemical Safety for the 21st Century Act have given U.S. EPA expanded authority and guidance to evaluate and regulate chemicals based on a risk-based safety standard. Despite these changes, and in light of recent deaths, DTSC is moving forward with this rulemaking effort. DTSC will remain engaged in U.S. EPA's efforts to regulate methylene chloride and will evaluate any duplication or conflict with that regulation if and when it becomes finalized.

B. Other federal regulations

CPSC requires labels of products containing methylene chloride to state that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels must specify precautions to be taken during use by consumers.

FDA has banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health.

OSHA regulations attempt to limit exposure to methylene chloride in occupational settings. OSHA has set the permissible exposure limit for methylene chloride at an eight-hour time-weighted average of 25 ppm and a 15-minute short-term exposure limit of 125 ppm. OSHA regulations also include provisions for initial exposure monitoring, engineering controls, work practice controls, medical monitoring, employee training, personal protective equipment, and recordkeeping. Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational chemical exposures and is also the primary goal of the SCP regulations. This proposed regulation is an important supplement to current state and federal exposure standards and the ongoing efforts to protect California workers by preventing worker and consumer injuries.