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TITLE 22, CALIFORNIA CODE OF REGULATIONS

45-DAY PUBLIC NOTICE AND COMMENT PERIOD

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

NOTICE IS HEREBY GIVEN that the Department of Toxic Substances Control (DTSC) proposes to amend the California Code of Regulations, Title 22 (22 CCR), Division 4.5, Chapter 55, article 11 to amend section 69511 and add section 69511.3. This proposed amendment pertains to identification of a Priority Product under the Safer Consumer Products (SCP) regulations, approved by the Office of Administrative Law (OAL) and filed with the Secretary of State on August 28, 2013 (effective date: 10/01/2013; OAL reference number: Z-2012-07170-04).

PUBLIC HEARING

DTSC will hold a public hearing on the proposed regulation on January 8, 2018, at the CalEPA Building, located at 1001 "I" Street, Sacramento, California. The hearing will convene in the Sierra Hearing Room at which time any person(s) may present statements or arguments, orally or in writing, relevant to this proposal described in the Informative Digest. The public hearing will begin at 1:00 PM and will remain open until 5:00 PM or until no attendees present testimony, whichever occurs first.

Representatives of DTSC will preside at the hearing. DTSC requests persons who wish to speak to please register before the hearing. Pre-hearing registration is conducted at the location of the hearing from 12:30 PM until the hearing commences. Registered persons will be heard in the order of their registration. Anyone else wishing to speak at the hearing will have an opportunity after all registered persons have been heard.

All visitors are required to sign in prior to attending any meeting at the Visitor and Environmental Services Center, located just inside main entrance of the building, to the left of the security guard post. Please allow adequate time to sign in and receive a visitor badge before the public hearing begins.

NOTICE PERTAINING TO ACCESSIBILITY & REASONABLE ACCOMMODATION

All documents related to this regulation can be made available in alternate format (i.e., Braille, large print, etc.) or in another language, as requested, in accordance with State and Federal law. Further, to ensure the public has equal access to all available services and information, DTSC will provide disability-related reasonable accommodations and/or translator/interpreter services, upon request. For assistance, please contact the staff person below as soon as possible, no later than 10 business days prior to the scheduled hearing:

Dr. Julia Gress
Safer Products and Workplaces Program
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806
Email: Julia.Gress@dtsc.ca.gov
Phone number: (916) 322-4062
TTY/TDD Speech-to-Speech users may dial 711 for the California Relay Service

WRITTEN COMMENT PERIOD

Any interested person(s) or their authorized representative(s) may submit written comments relevant to the proposed regulatory action to DTSC in either electronic or hard-copy formats.

Written comments may be submitted electronically through the Safer Consumer Products information management system (CalSAFER) at: <https://calsafer.dtsc.ca.gov/>.

Please direct hard-copy written comments to:

Proposed Regulations
Office of Legal Affairs
Department of Toxic Substances Control
1001 "I" Street
Sacramento, California 95812-0806

Fax Number: (916) 323-5542
Phone Number: (916) 323-7811

The written comment period for mailed and electronically submitted comments will close at 11:59 p.m. PST on January 18, 2018. Only comments submitted through CalSAFER and letters that are postmarked on or before that date and time will be considered. Written comments that are hand-delivered to the above address must be delivered by 5:00 p.m. PST on January 18, 2018.

AUTHORITY & REFERENCE

Authority

This regulation is being adopted under the following authorities:

Health and Safety Code (HSC) section 25252 authorizes and requires DTSC to adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered a Chemical of Concern. This section also directs DTSC to reference and use available information from various sources, but does not limit DTSC to use only this information.

HSC section 25253 authorizes and requires DTSC to adopt regulations that establish a process for evaluating Chemicals of Concern in consumer products, and their potential alternatives, to determine how best to limit exposure to or to reduce the level of hazard posed by a Chemical of Concern.

HSC section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991) grants DTSC authority to adopt regulations to execute its duties.

Reference

This regulation implements, interprets, or makes specific the following statutes: HSC sections 25252 and 25253.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Policy Statement Overview

DTSC proposes to amend the SCP regulations (Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (commencing with sections 69501)) to amend section 69511 and add one Priority Product to the Priority Products list (section 69511.3).

Summary of Existing Requirements

The SCP regulations were adopted in October 2013 to meet the statutory requirements outlined in HSC 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 Chemicals 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 Alternatives Analysis (AA) to determine how best to reduce exposures to, or the level of adverse public health or environmental impacts posed by, the Chemical(s) of Concern in the product;
- Requiring DTSC to identify and require implementation of Regulatory Responses following completion of an AA; and
- Creating a process for persons to petition DTSC to add chemicals to 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.

Proposed Regulation

DTSC proposes to amend section 69511 and add section 69511.3 to Article 11 of the SCP regulations. The proposed action will add paint or varnish strippers containing methylene chloride as a Priority Product on the Priority Products List.

This listing applies to 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.

Following extensive review of the scientific literature and analysis of the known hazard traits of methylene chloride, DTSC determined there is potential for workers and consumers to be exposed to methylene chloride during the use of paint or varnish strippers and there is potential for one or more exposures to contribute to or cause significant adverse health impacts. Potential health effects include acute toxicity and death, carcinogenicity, skin irritation, and central nervous system depression. DTSC

based this determination on an evaluation of available, reliable scientific information pertinent to the regulatory criteria.

Benefits

A primary goal of the SCP program is to significantly reduce adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of these impacts to the state's society. By listing paint or varnish strippers containing methylene chloride as a Priority Product, DTSC asks manufacturers to evaluate whether methylene chloride is necessary in paint or varnish strippers or whether there are safer alternatives that would reduce human exposure to methylene chloride during normal use of paint or varnish strippers. A reduction in airborne methylene chloride means healthier air quality and safer workplaces and homes. Reducing exposure to methylene chloride could reduce the incidence of work-related adverse health effects and the number of workdays lost to occupational illness or injury. The development of safer alternatives benefits California workers, consumers, and the businesses that employ workers who use paint or varnish strippers.

Determination of Inconsistency/Incompatibility with Existing State and 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 and whether there is a safer alternative, with the goal of protecting consumers and the environment from adverse effects associated with a product throughout its lifetime.

Methylene chloride is regulated by the United States Environmental Protection Agency (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.

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 some 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.

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 a 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.

DISCLOSURE REGARDING THE PROPOSED ACTION

DTSC made the following initial determinations:

Mandates on Local Agencies or School Districts

DTSC determined that adoption of this regulation will not impose a local mandate or result in costs subject to reimbursement pursuant to Part 7 of Division 4, commencing with section 17500, of the Government Code or other nondiscretionary costs or savings to local agencies.

Costs or Savings to Any State Agency

DTSC will absorb additional costs associated with reviewing Notifications, Abridged AA Reports, or two-stage AA Reports submitted by manufacturers of paint or varnish strippers containing methylene chloride by reallocating staff to this new task. DTSC estimates that the total fiscal costs to state government for reviewing all Notifications, Abridged AA Reports, and two-stage AA reports submitted by manufacturers will range from \$735,798 to \$2,608,242.

Costs or Savings to Local Agencies or School Districts Subject to Reimbursement

DTSC determined that adoption of this regulation would not result in costs or savings for any local agency or school district required to be reimbursed pursuant to Part 7 of Division 4, commencing with section 17500 of the Government Code, or other nondiscretionary costs or savings imposed on local agencies.

Cost or Savings in Federal Funding to the State

DTSC determined that adoption of this regulation will not result in any decrease or increase in federal funds to California.

Effect on Housing Costs

The proposed regulation does not change or impact current building codes or standards included in the Health and Safety Code; therefore, DTSC determined that housing costs would not be impacted.

Determination of Adverse Statewide Economic Impact

DTSC made an initial determination that the adoption of this regulation may have a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. DTSC has not considered proposed alternatives that would lessen any adverse economic impact on businesses and invites the public to submit proposals. Submissions may include the following considerations:

- Establishment of differing compliance or reporting requirements or timetables that take into account the resources available to businesses;

- Consolidation or simplification of compliance and reporting requirements for businesses;
- Use of performance standards rather than the prescriptive standards; and
- Exemption or partial exemption from the regulatory requirements for businesses.

Types of Businesses Affected

Manufacturers of paint or varnish strippers with methylene chloride have the principal duty to comply with the notification and reporting requirements.

Reporting Requirements

In accordance with Government Code sections 11346.3(c) and 11346.5(a)(11), DTSC found that the reporting requirements of the proposed regulatory action, which apply to businesses, are necessary for the health, safety, and welfare of the people of the State of California. The specific reporting requirements and forms are:

- Priority Product Notification [section 69503.7]
- Removal/Replacement Notifications:
 - Chemical of Concern Removal Intent Notification [section 69505.2]
 - Chemical of Concern Removal Confirmation Notification [section 69505.2]
 - Product Removal Intent Notification [section 69505.2]
 - Product Removal Confirmation Notification [section 69505.2]
 - Product-Chemical Replacement Intent Notification [section 69505.2]
 - Product-Chemical Replacement Confirmation Notification [section 69505.2]
 - Product Cease Ordering Notification [section 69501.2(b)(2)(B)]
- AA Notifications and Reports:
 - AA Threshold Notification [section 69505.3]
 - AA Extension [section 69505.1(c)]
 - Preliminary AA Report [section 69505.4(a)(2), section 69505.5, section 69505.1(b)(2)(A), section 69505.7]
 - Final AA Report [section 69505.4(a)(3), section 69505.6, section 69505.1(b)(2)(B), section 69505.7]
 - Abridged AA Report [section 69505.4(b)]
 - Alternate AA Work Plan [section 69505.4(c)]
 - Previously completed AA [section 69505.4(d)]

The reports and forms that will be submitted by a manufacturer depend on several factors including the Priority Products produced, the availability of viable alternatives, and business decisions made by the manufacturer.

The reporting requirements applicable to manufacturers may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf

of, or in lieu of, one or more manufacturer. This does not apply to the Priority Product Notification or AA Threshold Exemption Notification requirements [section 69501.2(a)(2)].

Determination of Effect on Small Business

DTSC made an initial determination that the adoption of this regulation may affect small businesses.

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 relied on a variety of sources to estimate the number of manufacturers potentially impacted by this proposed regulation. DTSC searched manufacturers' websites and Safety Data Sheets (SDS) for paint or varnish strippers containing methylene chloride. DTSC conducted a similar search on the websites of home improvement retail stores. DTSC also analyzed a list of manufacturers that was provided by Dun & Bradstreet (a private data vendor). Finally, DTSC asked two prominent manufacturers of paint or varnish strippers, as well as an industry alliance representative, to provide an estimate of the number of manufacturers of paint or varnish strippers containing methylene chloride based in the United States. From these data sources, DTSC estimates there are 24 or fewer manufacturers of paint or varnish strippers containing methylene chloride that would be impacted by this proposed regulation. Three of the 24 potentially affected manufacturers are headquartered in California.

Results of the Regulatory Economic Impact Analysis

DTSC determined that it is:

- Unlikely that this proposal will eliminate or create businesses or jobs in manufacturing of paint or varnish strippers;
- Possible that this proposal could create an unknown number of businesses to assist manufacturers of paint or varnish strippers containing methylene chloride in meeting regulatory obligations including consulting services, chemical and material science research services, and product development support;
- Possible that this proposal could result in the expansion of businesses currently doing business within the state, particularly those engaged in regulatory 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;

- Possible that this proposal could create an unknown number of public or private sector jobs in consulting services, product research and design, chemical and material science research and support, marketing and the development of consumer product safety information and training materials; and
- Likely that this proposal would affect small businesses. DTSC estimates that 7 of the 24 potentially impacted manufacturers are small businesses. Two of these seven small businesses are headquartered in California. Costs to submit Priority Product Notifications and AA Reports are expected to be the same for all impacted businesses.

Benefits of the Proposed Action

A 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 illnesses, injuries, and deaths, 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.

CONSIDERATION OF ALTERNATIVES

Pursuant to Government Code section 11346.5(a)(13), DTSC must determine that no reasonable alternative considered by DTSC or that has otherwise been identified and brought to the attention of the DTSC would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome

to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

DISCLOSURE REGARDING REASONABLE ALTERNATIVES

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 strippers containing methylene chloride.

U.S. EPA identified methylene chloride as a work plan chemical for assessment under the Toxic Substances Control Act (TSCA) in 2012, and proposed a rule to regulate certain uses 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 attributed to 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 designated a Priority Product in the future.

Cost Analysis for Alternatives to the Regulation

DTSC was unable to estimate the costs of Alternative 1 since the scope of U.S. EPA's proposed rule may significantly change before it is made final. DTSC did not attempt to quantify costs or benefits associated with Alternative 2 because paint or varnish strippers containing NMP could not be included on the initial Priority Products List pursuant to the SCP regulations.

OTHER APPLICABLE REQUIREMENTS PRESCRIBED BY STATUTE

External Scientific Peer Review

DTSC requested an external scientific peer review of the scientific basis of the proposed regulation pursuant to HSC section 57004. The result of the external scientific peer review is posted to DTSC's website at:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm>.

California Environmental Quality Act (CEQA) Compliance

DTSC determined that this rulemaking project is exempt under CEQA (Public Resources Code Section 21000, et seq.). This rulemaking meets the General Rule Exemption available under 14 CCR section 15061(b)(3). A draft Notice of Exemption (NOE) is available for review during the public comment period upon request and will be filed with the State Clearinghouse when the regulation is adopted.

California Environmental Policy Council Review

Under the provisions of HSC section 25252.5, the California Environmental Policy Council (CEPC) reviewed the framework SCP regulations prior to their adoption in October 2013 (the CEPC Resolution may be viewed at:

<http://www.calepa.ca.gov/cepc/>.) Under HSC Section 25252.5(f), the CEPC determined that the proposed regulations would not have any significant adverse impact on public health or the environment and could be adopted by DTSC without undergoing a multimedia life cycle evaluation.

DTSC determined that further review by the CEPC is not warranted for this rulemaking because the requirements of HSC section 25252.5 apply only to the creation of the SCP program and not regulations that may be required to implement this program.

CONTACTS

Inquiries regarding technical aspects of the proposed regulation or CEQA document may be directed to Dr. Julia Gress of DTSC at 916-322-4062 or via email at Julia.Gress@dtsc.ca.gov. However, oral inquiries are not part of the rulemaking record. If Dr. Julia Gress is unavailable, you may contact Daniel Knight in the Office of Legal Affairs at 916-323-7811.

A 45-day public comment period for this rulemaking file, as described above, will commence on November 17, 2017, and close on January 8, 2018. During this time, DTSC will accept statements, arguments or contentions, and/or supporting documents regarding this rulemaking that can be submitted in writing either through CalSAFER or by mail, or may be presented orally or in writing at the public hearing. Comments must be received by the deadline in order for them to be considered before DTSC adopts, amends, or repeals this regulation.

AVAILABILITY OF TEXT OF PROPOSED REGULATIONS AND INITIAL STATEMENT OF REASONS

Copies of the Notice, Initial Statement of Reasons, the text of the proposed regulation, and all the information upon which the proposal is based are posted to DTSC's website at: <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm>.

Copies of these documents may also be obtained from Mr. Daniel Knight in the Office of Legal Affairs, as specified above.

After the close of the 45-day comment period, DTSC may adopt the proposed regulation. If changes are made to the regulation text, the modified full text will be made available for comment for at least 15 days prior to adoption. Only persons who specifically request copies of the modified text, attend the public hearing, provide written or oral comments at the hearing, or submit written comments will be sent a copy of the modified text if substantive changes are made.

Once DTSC finalizes the regulation text, DTSC will prepare a Final Statement of Reasons, which updates the Initial Statement of Reasons, summarizes how DTSC addressed comments, and includes other materials, as required by Government Code section 11346.9. A copy of the Final Statement of Reasons, along with the date the rulemaking is filed with the Secretary of State and the effective date of the regulation, will be posted to DTSC's website at: <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm>.

To be included in this regulation package's mailing list and to receive updates of this rulemaking, please visit <http://www.dtsc.ca.gov/ContactDTSC/ELists.cfm> and subscribe to the applicable electronic mailing list.