

TITLE 22 CALIFORNIA CODE OF REGULATIONS

**30-DAY NOTICE OF MODIFIED TEXT AND AVAILABILITY OF
ADDITIONAL DOCUMENTS AND INFORMATION**

**SAFER CONSUMER PRODUCTS REGULATIONS –
Listing Nail Products Containing Toluene as a Priority Product**

**Department of Toxic Substances Control Reference Number: R-2019-04
Office of Administrative Law Reference Number: 2021-0921-06**

NOTICE IS HEREBY GIVEN that the Department of Toxic Substances Control (DTSC) has made changes to the proposed regulatory text, amending title 22, California Code of Regulations, section 69511 and adopting title 22, California Code of Regulations, section 69511.6. The modification to the proposed regulation would set an Alternatives Analysis Threshold (AAT) for nail products containing toluene at 100 parts per million (ppm) and describe the requirements related to submission of an AAT Notification. DTSC considers these new changes to the rulemaking to be “sufficiently related changes,” as defined in title 1, California Code of Regulations, section 42.

DTSC mailed the initial notice of proposed action for this rulemaking and provided links to these documents for public review and comment on October 1, 2021. Written comments were accepted during the 45-day public comment period.

WRITTEN COMMENT PERIOD

A public comment period for the modified rulemaking has been established commencing on July 8, 2022 and closing on August 8, 2022. Statements, arguments, or contentions regarding the rulemaking and/or supporting documents must be submitted in writing for them to be considered by DTSC before it adopts this regulation. Only comments received in writing at the DTSC office on or before that date will be considered. 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 SCP Information Management System, CalSAFER at: <https://calsafer.dtsc.ca.gov/>. Please direct questions or concerns about CalSAFER to Christine Papagni at 818-717-6541 or Christine.Papagni@dtsc.ca.gov.

While DTSC prefers that comments be submitted through the CalSAFER system, interested persons may also submit their comments in an email to: SaferConsumerProducts@dtsc.ca.gov or through the DTSC regulations email address at regs@dtsc.ca.gov. Written comments in hard-copy format can be directed to the Office of Legislation and Regulatory Review, as specified below:

Office of Legislation and Regulatory Review
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806
Fax Number: (916) 324-1808
Phone Number: (916) 322-4563
TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT PERSONS

Inquiries regarding technical aspects of the proposed regulation may be directed to Christine Papagni as specified above. However, such oral inquiries are not part of the rulemaking record.

AVAILABILITY OF MODIFIED TEXT AND ALL OTHER RULEMAKING DOCUMENTS

Copies of the Notice of Proposed Action, Initial Statement of Reasons, all the information upon which its proposal is based, and the express terms of the proposed regulation (also known as the proposed regulatory text), are posted to DTSC's Internet website at <https://dtsc.ca.gov/regs/> or may be obtained from the Office of Legislation and Regulatory Review, as specified above.

After the close of the comment period, DTSC may adopt the proposed regulation. If substantial changes are made, the modified full text will be made available for comment for at least 15 days prior to adoption. Only persons who request the specific proposed regulation or provide written comments on this specific regulation will be sent a copy of the modified text if substantive changes are made.

DTSC will prepare a Final Statement of Reasons that updates the Initial Statement of Reasons, summarizes how DTSC addressed comments, and includes other materials. A copy of the Final Statement of Reasons will also be posted on DTSC's Internet site at <https://dtsc.ca.gov/regs/> along with the date the rulemaking is filed with the Secretary of State and the effective date of the regulation.

Please direct all written comments, procedural inquiries, and requests for documents by mail, e-mail, or fax to the office of Legislation and Regulatory Review, as specified above. To be included in this regulation package's mailing list and to receive updates of this rulemaking, please visit <https://dtsc.ca.gov/dtsc-e-lists/> and subscribe to the applicable e-list or e-mail: regs@dtsc.ca.gov.

CHANGES TO PROPOSED REGULATIONS MADE AFTER THE 45-DAY COMMENT PERIOD

Modified Regulatory Text

The proposed regulatory text has been modified to add several new subsections to section 69511.6 to set an AAT for toluene in nail products at 100 ppm. A detailed statement of reasons for these changes is provided below. All other sections in the originally proposed regulatory text that are not listed below remain unchanged.

A copy of the revised text is posted to DTSC's Internet website at <https://dtsc.ca.gov/regs/>. Changes to the regulatory text after the start of the rulemaking process contain the following formatting features:

- New language in the original regulations text is indicated by single underlining the text.
- Deleted language in the original regulations text is indicated by ~~striking-out the text~~.
- Language that has been added since publishing the original notice of this proposed action is indicated by double-underlining text.
- Language that has been deleted since publishing the original notice of this proposed action is indicated by ~~double-striking-out the text~~.

General Overview and Background of the Modifications

Pursuant to section 69503.2(b) of the Safer Consumer Products regulations, 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 proposes to identify nail products containing toluene – including nail coatings and nail polish thinners – as a Priority Product and set an AAT of 100 ppm for toluene in the Priority Product in accordance with section 69503.5(c).

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 Alternatives Analysis (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 may also remove the Chemical of Concern from the Priority Product, replace it with a safer alternative, or stop selling the product in California. Section 69505.1(a) and section 69505.4, subdivisions (b), (c), and (d) identify the options a manufacturer must comply with in lieu of conducting an AA. Alternatively, if the concentration of the Chemical of Concern in the Priority Product does not exceed a set AAT level, the manufacturer may submit an AAT Notification in lieu of an AA, in accordance with section 69505.3.

This proposal has been modified to allow the manufacturer to submit an AAT Notification in lieu of an AA if the concentration of toluene in the Priority Product does not exceed the AAT level of 100 ppm.

DTSC is proposing to set an AAT for toluene in nail products at 100 ppm based on the following:

- DTSC's goal in listing this Priority Product is to reduce the potential for nail salon workers and nail product consumers to be exposed to, and harmed by, toluene that is intentionally added in nail products as an ingredient.
- Data received in 2020 from nail product manufacturers and other entities indicated that toluene was present in nail products as a contaminant, residual, or as an intentionally added ingredient.
- DTSC recently conducted analytical laboratory testing of 157 nail products and detected toluene in 27 nail products at concentrations ranging from 31.4 ppm to 187,000 ppm. These findings were consistent with the information from manufacturers reporting that toluene is in some products as an intentionally added ingredient where it was found at high concentrations, and present in other products as a contaminant where it was found at much lower concentrations.
- During the regulatory 45-day public comment period, industry stakeholders requested that DTSC set an AAT above contaminant levels. When toluene is present as a contaminant in nail products, the concentration is generally 100 ppm or lower, according to these commenters.
- Several other states have enacted laws requiring that manufacturers report products marketed to children that contain toluene and other specified chemicals above a contamination threshold of 100 ppm, including:
 - Oregon Toxic Free Kids Act;
 - Washington Children's Safe Products Act; and
 - Vermont Chemicals of High Concern to Children Law.

DTSC is proposing to allow manufacturers of the Priority Product the option of demonstrating that their products qualify for the AAT Notification by providing testing data from ingredient suppliers. During adoption of the SCP framework regulations in 2012, DTSC stated, in responses to public comments related to the AAT, that it would not accept supplier declarations or certification of material content as a demonstration of a Priority Product meeting the AAT. However, DTSC has determined that it is appropriate to allow manufacturers, in this instance, to use information from suppliers if the manufacturer determines and certifies that the supplier meets specified reporting and analytical requirements to measure the concentration of toluene in the supplied ingredients. DTSC believes it is appropriate to allow manufacturers to use information from suppliers for toluene in nail products due to toluene's likely presence in nail product supply chain ingredients at low concentration levels.

Section 69511.6(a).

This section has been modified to update the definition "nail products containing toluene" to mean nail products containing toluene, including nail coatings and nail polish thinners that contain toluene as an added ingredient, a residual, or a contaminant. This change is necessary because any responsible entity that manufacturers, sells, imports, or assembles a nail product containing toluene as an added ingredient or as a known or suspected contaminant or residual is required to submit a Priority Product Notification.

Section 69511.6(f).

This section has been modified to clarify that a manufacturer submitting an AAT Notification to request an exemption from the Alternatives Analysis requirements must do so no later than the due date for the Preliminary AA Report, as indicated in section 69505.3(a).

This change is necessary to provide responsible entities with a time frame for complying with the notification and reporting requirements included in the SCP regulations.

Section 69511.6(g).

This section is added to the proposed regulatory text. This section indicates that an AAT is being set at 100 ppm for toluene in nail products.

Toluene may be present in nail products as an intentionally added ingredient, residual, or contaminant. The default AAT for a contaminant is the Practical Quantitation Limit (PQL), which is defined in section 69501.1(a)(52) as "the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures." DTSC may also set the AAT at a higher level, pursuant to section 69503.5(c). DTSC was informed that, when toluene is present as a contaminant in nail products, the concentration is generally 100 ppm or lower.

Further, as noted earlier, several other states with chemical ingredient disclosure laws for children's products have established a reporting threshold for toluene of 100 ppm. Based on these factors, DTSC has chosen to set the AAT for nail products at 100 ppm.

If the concentration of toluene in a product does not exceed the AAT, the manufacturer of that product may submit an AAT Notification instead of an AA Report. The AAT Notification may be submitted concurrently with the Priority Product Notification or afterwards, but not later than the due date for the Preliminary AA Report. If the manufacturer submits an AAT Notification, the manufacturer must also certify that it meets and will continue to meet the criteria and conditions that are the basis for the AA exemption.

Add Section 69511.6(h).

This section is added to the proposed regulatory text. This section specifies the reporting requirements for a manufacturer submitting an AAT to demonstrate and certify that the concentration of toluene in a product does not exceed the AAT. This section also provides the sample preparation, analytical methods, instrumentation, calibration, and quality control criteria that a testing laboratory must follow if a manufacturer chooses to submit laboratory testing results of the formulated Priority Product.

This section is necessary to ensure that manufacturers who assert that they are exempt from AA requirements understand the reporting requirements. To this end, this section specifies that a manufacturer may submit certificates of analyses from ingredient suppliers along with calculations of the concentration of toluene in the formulated Priority Product or they may submit laboratory testing results that demonstrate the concentration of toluene in the Priority Product. This section also specifies the laboratory criteria that must be met for measuring toluene in each Priority Product as well as the data submittal requirements. This section provides the specific quality control requirements and documentation to be submitted with an AAT Notification.

Additional Documents

The following documents are added to the rulemaking file.

Revised Initial Statement of Reasons (ISOR)

This document has been revised to include rationale for setting an AAT, the potential economic impacts associated with the AAT, as well as some editorial changes to clarify some language and accurately reflect the Safer Consumer Products Program. Further, in response to a stakeholder comment provided during the 45-day comment period,

some additional language was added to describe the requirements of the California Professional Cosmetics Labeling Law.

Language that has been added to the ISOR since publishing the previously proposed regulatory text is indicated by double-underlining text. Language that has been deleted from the ISOR since publishing the previously proposed regulatory text is indicated by ~~double-striking out the text.~~)

Revised Economic and Fiscal Impact Statement (STD 399) and Revised Economic and Fiscal Impact Analysis (attachment to STD 399)

Note: Language that has been added to this document since publishing the previously proposed regulatory text is indicated by double-underlining text. Language that has been deleted from this document since publishing the previously proposed regulatory text is indicated by ~~double-striking out the text.~~)

These documents have been revised to include the potential economic impacts associated with the AAT. DTSC estimates that each manufacturer submitting an AAT Notification will invest a maximum of three hours at \$42/hour to complete the notification and respond to questions from DTSC. Each manufacturer may develop AAT Notifications for up to, at most, 20 percent of their products. Some of the larger manufacturers possess product ingredient laboratory results produced and gathered onsite, while most manufacturers will obtain and transmit ingredient certificates of analyses of analyses from their suppliers.

DTSC estimates the cumulative cost for all affected California manufacturers of nail products containing toluene to submit AAT Notifications and to respond to DTSC's reviews of these submittals to be between \$13,486 to \$20,748.

DTSC estimates the maximum combined total costs to manufacturers for engaging in the development of Priority Product Notifications, AAs, and AAT Notifications will not exceed \$3,376,000.

Revised Product-Chemical Profile for Nail Products Containing Toluene.

The Product-Chemical Profiles for Nail Products Containing Toluene has been updated to include technical information about the presence of toluene as a contaminant in nail products. New language is indicated by red, single underlined text. Deleted language is indicated by ~~red, strikethrough text~~. The document is cited as follows: DTSC (2022) Revised Product-Chemical Profile for Nail Products Containing Toluene.