

FINAL STATEMENT OF REASONS

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 Notice Reference Number: Z2021-0921-06

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UPDATED INFORMATIVE DIGEST

Changes to Existing Statutes or Regulations

There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Notice of Proposed Action dated October 1, 2021, or the 30-Day Notice Modified Text and Availability of Additional Documents and Information dated July 8, 2022.

DTSC made the following substantive changes to the proposed regulatory text:

Section 69511.6(a). Revised the definition of nail products containing toluene and added the language “that contain toluene as an added ingredient, contaminant, or residual” to the definition of “nail products containing toluene.”

Section 69511.6(f). Revised the definition of nail products containing toluene and added language regarding when a Priority Product Notification and an Alternatives Analysis Threshold (AAT) Notification must be submitted to DTSC.

Section 69511.6(g). This section revised the definition of nail products containing toluene and indicates that an AAT is set at 100 parts per million (ppm) for toluene in nail products.

Section 69511(h). Revised definition of nail products containing toluene and added language in this section to specify 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.

GENERAL INFORMATION

Update to the Initial Statement of Reasons

As authorized by Government Code section 11346.9, subsection (d), the Department of Toxic Substances Control (DTSC) incorporates by reference the Initial Statement of Reasons (ISOR) prepared for this rulemaking. DTSC published the proposed regulatory text, ISOR, and Economic and Fiscal Impact Analysis (STD 399), and supporting documents for public review and comment on October 1, 2021. This public review and comment period concluded on November 18, 2021.

Changes to the Proposed Regulatory Text

Changes to the proposed regulatory text, along with the modified ISOR, modified STD 399, modified Attachment to STD 399, and modified Product-Chemical Profile for Nail

Products Containing Toluene, were released for public comment from July 8, 2022, through August 8, 2022.

Mandates on Local Governments and School Districts

DTSC has determined that this regulatory action will not result in mandates to any local agencies or school districts.

Alternatives Considered

For the reasons set forth in the ISOR, the responses to comments received, and in this Final Statement of Reasons, DTSC determined that no alternative considered by the agency would be more effective in carrying out the purpose for which the regulatory action was proposed, or would be as effective and less burdensome to affected private persons, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law than the action taken by DTSC.

Alternative 1: List nail products containing toluene, including nail coatings and nail polish thinner, as the Priority Product.

This option was selected because it allows DTSC to quickly and effectively reduce significant exposure to toluene from nail products.

Alternative 2: List nail polish remover containing toluene, among other products, as the Priority Product.

This option was dismissed because toluene is not used in nail polish removers in California. Historically, toluene was used as a solvent in nail polish removers, but this use is now effectively banned by the California Air Resources Board Consumer Products regulations, which limit the total concentration of volatile organic compounds in polish removers to one percent by weight.

Alternative 3: List nail products containing all Candidate Chemicals that are volatile organic solvents (VOCs) used in nail products.

This was considered as an alternative but dismissed as an option due to differences in hazard traits and endpoints of various volatile organic solvents. Further, this alternative would significantly increase the scope and scale of the product-chemical combinations evaluated, greatly expand DTSC's workload, and include compounds in which their exposure does not cause or contribute to significant or widespread adverse impacts.

Small Business Alternatives Considered

DTSC has not identified reasonable alternatives that would lessen any adverse impact

on small business.

CHANGES MADE TO THE ORIGINAL PROPOSAL

Proposed Regulatory Text

Substantive Changes

DTSC made the following substantive changes to the proposed regulatory text:

Section 69511.6(a). Revised the definition of nail products containing toluene and added the language “that contain toluene as an added ingredient, contaminant, or residual” to the definition of “nail products containing toluene.” This change was made to clarify what nail products are included in the definition of the Priority Product.

Section 69511.6(f). Revised the definition of nail products containing toluene and added language regarding when a Priority Product Notification and an Alternatives Analysis Threshold (AAT) Notification must be submitted to DTSC. This language was added to ensure that Responsible Entities know that they must submit a Priority Product Notification even if the concentration of toluene does not exceed the AAT. Further, language was added to state that an AAT Notification must be submitted concurrently with the Priority Product Notification or must be submitted no later than the due date for the Preliminary Alternatives Analysis Report (AA Report) for the Priority Product. This language informs manufacturers of when to submit an AAT Notification to DTSC to request an exemption from the Alternative Analysis requirements.

Section 69511.6(g). This section revised the definition of nail products containing toluene and indicates that an AAT is set at 100 parts per million (ppm) for toluene in nail products. 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.

Section 69511(h). Revised definition of nail products containing toluene and added language in this section to specify 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.

Changes made to section 69511 in OAL Matter No. 2022-0128-02s were also included.

Non-Substantive Changes

The following changes constitute non-substantive changes to the regulatory text because they do not materially alter the requirements or conditions of the proposed rulemaking action.

Section 69511. Added the authority and reference note to the end of section 69511.

Section 69511(b)(4). Changed the capitalization from upper case to lower case, added a semi-colon, and removed “and.”

Section 69511(b)(5). Changed from “[Reserved]” to “Treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles.”

Section 69511.6(a)(1)(A). Corrected the numbering of “solvent-based coatings” definitions 1-5.

Section 69511.6(a)(1)(B). Corrected the numbering of “UV gel nail coatings” definitions 1-5.

Revised Initial Statement of Reasons

Substantive Changes

The ISOR was revised to include:

- the rationale for setting an AAT,
- an explanation of when an AAT is due to DTSC,
- the requirements for submitting an AAT and qualifying for an exemption from submitting an Alternatives Analysis,
- the potential economic impacts associated with the AAT,
- editorial changes to clarify and accurately reflect the Safer Consumer Products Program, and
- additional language to describe the requirements of the California Professional Cosmetics Labeling Law.

These changes were made to ensure that manufacturers understand why DTSC is setting an AAT, the potential cost for submitting an AAT, the requirements for submission of an AAT in lieu of conducting an Alternatives Analysis, and to update the list of current laws which pertain to nail products.

DTSC does not believe that additional peer review was required because none of the subsequent changes were scientifically based; instead they were based on factual and policy considerations.

Non-Substantive Changes

Page 1, heading date, changed from “August 2021” to “July 2022.”

Page 2, paragraph 2, sentence 4, changed “has identified” to “proposes to identify.”

Page 3, paragraph 4, bullet 4, added “to decide whether.”

Page 3, paragraph 4, bullet 5, changed “Requiring” to “Allowing” and added “, as needed.”

Page 4, paragraph 2, sentence 1, changed “selected” to “previously placed”, changed “in” to “onto”, and removed “initial.”

Page 4, paragraph 3, bullet 3, deleted “and.”

Page 4, paragraph 3, bullet 4, added “and.”

Page 4, paragraph 3, bullet 5, added “Treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers.”

Page 5, paragraph 3, sentence 4, removed “of 22 CCR.”

Page 6, paragraph 1, sentence 1, removed “s” from “sections” and added “, subdivisions.”

Page 7, paragraph 2, sentence 4, added “information provided by manufacturers in AA”, “are tailored”, and “which Regulatory Response, if any, will be proposed by DTSC after the AA process is complete” and removed “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 (Section 69506(b)).”

Page 8, paragraph 3, sentence 2, changed “7” to “6.”

Page 10, paragraph 5, sentence 3, added “personal protective equipment” and “).”

Page 11, paragraph 6, sentence 2, added “that contain toluene as an added ingredient, a residual, or a contaminant.”

Page 17, paragraph 4, sentence 1, changed “Alternatives Analysis (AA)” to “AA.”

Page 17, paragraph 5, sentence 3, changed “Alternatives Analysis (AA)” to “AA.”

Page 21, paragraph 3, sentence 1 and sentence 2, added “has”, removed “paint or varnish strippers containing methylene chloride in a”, added “Priority Products, who estimated”, removed “DTSC regulatory action for their expected costs of

submitting an AA. Those interviewed indicated that they expect”, added “the cost to prepare and submit”, removed “to cost their businesses”, and added “to range.”

Page 21, paragraph 3, sentence 3 and sentence 4, removed “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.”

Page 21, paragraph 3, sentence 5, added “In the same survey,”, changed “M” to “m”, removed “of these other products”, added “the cost to prepare”, removed “they would incur”, added “an Abridged AA Report”, removed “costs”, added “to range”, removed “to prepare an Abridged AA Report”, added “and the cost to prepare a two-stage AA Report to range from”, removed “or”, and removed “to prepare a two stage AA Report.”

Page 21, paragraph 4, sentence 3, changed “separate” to “previous.”

Page 22, paragraph 4, sentence 1, added “.”

Page 23, paragraph 1, sentence 3, added “.”

Page 23, paragraph 2, sentence 3, deleted “the actions that nail product 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.”

Page 23, paragraph 2, sentence 4, changed “it” to “the preparation of AA Reports.”

Page 24, paragraph 1, sentence 4, added “and adoption”

Page 25, paragraph 4, sentence 2, changed “polish remover” to “nail products” and changed “among other products” to “including nail coatings, nail polish thinner, as well as nail polish remover.”

Page 29, Heading 4, deleted “Appendices”

Page 29, paragraph 8, point A, deleted “A. Proposed Regulatory Text.”

Page 29, paragraph 8, point B, deleted “B. Documents Relied On.”

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

Substantive Changes

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 and \$20,748.

DTSC estimates the maximum combined total costs to manufacturers for engaging in the development of Priority Product Notifications, Alternatives Analyses, and AAT Notifications will not exceed \$3,376,000. These changes were made to the economic impact analysis to reflect the addition of AAT Notification submitting manufacturers to the list of responsible entities for this regulation. Additionally, the inclusion of AAT Notifications affected the estimated fiscal cost impacts to state government. The estimated fiscal impacts rose to a range of \$1,375,864 to \$4,928,500 due to added review workloads for DTSC staff.

Non-Substantive Changes

STD 399 - Economic Impact Statement

A.4. Changed Attachment page number reference from 4 to 5.

B.5. Changed Attachment page number reference from 7 to 8.

D.1. Changed Attachment page number reference from pages 8-9 to pages 9-10.

STD 399 - Fiscal Impact Statement

B.4. Changed Attachment page number reference from 10 to 12.

STD 399 Attachment

Page 1, heading date, changed from "August 2021" to "May 2022" and added "Office of Administrative Law Reference Number: 2021-0921-06."

Page 1, paragraph 2, sentence 1, added "Note: This document only includes sections of

the Form 399 for which an explanation could not fit in the space provided. As such, the section headings and titles are intentionally written to match the corresponding sections of the form and may not be in consecutive order.”

Page 1, paragraph 3, sentence 1, deleted an “s” from “sections 69501.”

Page 1, paragraph 3, sentence 2, add “as an added ingredient, contaminant, or residual” at the end of the sentence.

Page 2, paragraph 1, sentence 3, deleted “to submit a Priority Product Notifications and Alternatives Analyses (AA)” from the end of the sentence.

Page 2, paragraph 2, Sentence 3, added footnote number 3 “³See California Code of Regulations, title 22, section 69505.2.”

Revised Product-Chemical Profile for Nail Products Containing Toluene.

Substantive Changes

The Product-Chemical Profile for Nail Products Containing Toluene was updated by adding:

- information about DTSC setting an AAT for nail products containing toluene,
- data from DTSC's analytical lab study of nail products and DTSC's information call-in effort,
- three new appendices:
 - Appendix 2 - Alternatives Analysis Threshold Rationale,
 - Appendix 3 – DTSC's Information Call-In Data of Nail Products, and
 - Appendix 4 – Measured Toluene Concentrations in Nail Products from DTSC's Analytical Laboratory Study, and
- language to describe the requirements of the California Professional Cosmetics Labeling Law.

These changes provide the basis for DTSC's rationale for setting an AAT and describe the requirements for submitting an AAT Notification, demonstrate concentration data for toluene in nail products, and update the list of current laws that pertain to nail products.

Non-Substantive Changes

Page 5, paragraph 3, sentence 3, added “literature on”, changed “impact” to “impacts”, changed exposure literature on toluene or nail products” to “exposure for toluene or nail products.”

Page 6, paragraph 1, bullet 2, sentence 1, changed “March 2020” to “January 2022”, added “pre-regulatory” before “comment period”, added “, and the regulatory comment period, which ended on November 18, 2021” at the end of the sentence.

Page 6, paragraph 1, bullet 3, sub-bullet 5, added “,”.

Page 6, paragraph 1, bullet 4, added “All substantive changes are unlined or struck out and in red font.”

Page 9, paragraph 4, sentence 1, added “exposure to”.

Page 11, section 3.2, paragraph 1, added “nail coatings and nail polish thinners that contain toluene as an added ingredient, a residual, or a contaminant.”, deleted bullet 1, “nail coatings, and”, and removed bullet 2, nail polish thinner.”

Page 33, paragraph 4, sentence 1, added “Multiple studies and databases report the presence of toluene in nail products.”

Page 55, added paragraph 3 which states, “As illustrated by the data and information described in this Profile, DTSC has determined that there is exposure to toluene from nail product use and this exposure may contribute to or cause significant or widespread adverse impacts.”

Page 62, paragraph 2, sentence 3, added “Toluene must be reported to CSCP if it is an ingredient in a cosmetic product (CDPH 2020).”

Page 63, section 1, added “AA”, added “Alternatives Analysis”, added “AAT”, and added “Alternatives Analysis Threshold”.

Page 64, section 1, added “PPN”, added “Priority Product Notification”, added “PQL”, and added “Practical Quantitation Limit”.

Page 64, section 2, changed “Microgram” to “microgram”, added “ug/mL”, and added “microgram to milliliter”.

SUMMARY OF COMMENTS AND AGENCY RESPONSE

Government Code section 11346.9(a)(3) requires DTSC to include in the FSOR a summary of each objection or recommendation made regarding the proposed regulation and an explanation of how the proposal or procedures for adopting the regulation was changed or not changed in response.

Written comments were received during the October 1 through November 18, 2021, comment period and the July 8 through August 8, 2022, comment period.

List of Commenters and their Affiliations

The tables below provide a complete list of commenters, their affiliations, and the number DTSC assigned to their correspondence or oral comment for both comment periods, beginning with the first comment period. Most of the comment letters cover

more than one theme. To organize the comments, DTSC numbered individual letters as shown and assigned a number to each individual comment. For example, the number “CL4-2” refers to the second comment in the comment letter numbered 4.

Table 1: List of Commenters during the 45-Day Comment Period (October 1, 2021 – November 18, 2021)

#	Commenter	Affiliation
CL1	Dianne Woelke	Retired Advanced Practice and Public Health Nurse
CL2	Thomas F. Myers	Personal Care Products Council
CL3	Paul Bryson	Wella Company
CL4	Swati Sharma	California Healthy Nail Salon Collaborative
CL4	Janet Nudelman	Breast Cancer Prevention Partners
CL4	Andria Ventura	Clean Water Action
CL4	Bill Allayaud	Environmental Working Group

Table 2: Index of Comment Letters and Individual Comments Made During the 45-Day Comment Period (October 1 – November 18, 2021)

Comment #	Location in Comment Letter	Page # in FSOR
CL1-1	Entire letter	13
CL2-1	Page 1, paragraph 2, sentence 2	13
CL2-2	Page 1, paragraph 3, sentences 1-2 through Page 2, paragraph 1, sentences 1-2	13
CL2-3	Page 2, paragraph 2, sentence 1	13
Comment #	Location in Comment Letter	Page # in FSOR
CL2-4	Page 2, paragraph 6, sentences 1-3 Page 2, paragraph 7, sentence 1 Page 3, paragraph 1, bullets 1-2 Page 3, paragraph 2, bullets 1-2, sentences 1-3 Page 3, paragraph 3, bullet 1, sentences 1-2	13

CL2-5	Page 3, paragraph 2, sentences 1-4 through Page 4, paragraph 1, sentences 1-2	13
CL2-6	Page 4, paragraph 2, sentences 1-5 through Page 6, paragraph 11, sentence 1	13
CL2-7	Page 6, paragraph 12, sentence 1-2	13
CL3-1	Page 2, paragraph 3, sentence 1	13
CL3-2	Page 2, paragraph 3, sentence 4	13
CL3-3	Page 2, paragraphs 5-6	13
CL3-4	Page 3, paragraph 2, sentences 9-10	13
CL3-5	Page 3, paragraph 3, sentence 1	13
CL3-6	Pages 4, paragraph 2, through Page 5, paragraph 2	13
CL3-7	Page 5, paragraph 2, sentence 1	13
CL3-8	Page 5, paragraph 3, sentences 1-2	13
CL3-9	Page 5, paragraph 4, sentences 1-3	13
Comment #	Location in Comment Letter	Page # in FSOR
CL4-1	Page 1, paragraph 1, sentence 2	13
CL4-2	Page 2, paragraph 1	13
CL4-3	Page 2, paragraph 3, sentences 1-3	13
CL4-4	Page 2, paragraph 4	13

CL4-5	Page 2, paragraph 5, sentence 1	13
CL4-6	Page 3, paragraph 2, sentences 6-7	15

Summary of Objections and Recommendations during the 45-Day Comment Period (October 1 – November 18, 2021)

DTSC received four comment letters during the comment period from October 1 through November 18, 2021. The comments fall into one of the following categories:

- I. support of the rulemaking and comments supporting the proposed Priority Product listing;
- II. concern regarding setting an AAT and comments related to setting an AAT that would be feasible for industry to attain compliance with the proposed regulation; and
- III. request to revise language in the ISOR.

DTSC grouped and summarized the comments according to the listed themes, presenting summaries and responses in each section. Table 1 lists the commenters and Table 2 contains an Index of Comment Letters and Individual Comments.

Comments in Support of the Rulemaking

Comments: CL1-1, CL3-1, CL4-1, CL4-2, CL4-3, CL4-4, CL4-5

Comment Summary: These comments express general support for DTSC's proposal to regulate nail products containing toluene as a Priority Product.

DTSC Response: DTSC acknowledges the support offered by these comments.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comments Regarding Setting an Alternatives Analysis Threshold

Comments: CL2-1, CL2-2, CL2-3, CL2-4, CL2-5, CL2-6, CL2-7, CL3-2, CL3-3, CL3-4, CL3-5, CL3-6, CL3-7, CL3-8, CL3-9.

Comment Summary: These comments request setting an AAT above the Practical Quantitation Limit (PQL), provide rationale for setting the AAT above the PQL, and provide recommendations for the AAT concentration. Specifically, the comments suggest the following:

- Recommend the establishment of an AAT.
- DTSC regulations provide an exemption from requirements to conduct an Alternatives Analysis when the Chemical of Concern does not exceed the applicable AAT. The regulations also note that DTSC may opt to specify an AAT greater than the applicable PQL for any Chemical of Concern that is a contaminant.
- The PQL is a moving target. As analytical methods improve over time, the PQL will also change. This is an impractical requirement for small and medium-sized businesses.
- Setting the AAT for toluene at the PQL could result in several consequences, including:
 - a decrease in compliant raw materials,
 - an increase in price of compliant raw materials,
 - difficulties in feasibility of analyses with too low detection limits and background contamination, and
 - market withdrawal of products by ethical companies.
- DTSC should leverage existing information from other authoritative bodies regarding allowable contaminant concentrations of toluene in nail products. Various authoritative bodies have set toluene contaminant concentration at 100 ppm.
- European Union requirements allow toluene in nail polish up to 25 percent, which can translate to 4 ppm toluene in the air
- Recommendation to set the AAT at 100 ppm or between 50 to 200 ppm for toluene present as a contaminant in nail products.

DTSC Response: DTSC evaluated the concept of setting an AAT for nail products containing toluene. As part of this evaluation DTSC considered recently collected information from nail product manufacturers and analytical laboratory testing of nail products, finding 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. Some commenters also suggested that when toluene is present as a contaminant in nail products, the concentration is generally 100 ppm or lower. In addition, DTSC notes that several other states have established contaminant thresholds for reporting toluene in children's products at 100 ppm. DTSC agrees that as analytical methods improve over time, the PQL will most likely also change.

For these reasons, DTSC changed the proposed regulation to establish an AAT for toluene in nail products at 100 ppm. Title 22, section 69503.3 of the California Code of Regulations states that when a Chemical of Concern is present in a Priority Product at or below the AAT, the product's manufacturer is exempt from submitting an Alternatives Analysis and must instead submit an AAT Notification along with the Priority Product Notification at or by the due date for the Preliminary AA Report.

DTSC has amended the proposed regulation to set the AAT at a concentration above the PQL and to provide an option to allow manufacturers of the Priority Product to demonstrate that their products qualify for the AAT Notification by providing testing data from ingredient suppliers. DTSC has amended the proposed regulatory text, the ISOR, the STD 399 and Attachment, and the Product-Chemical Profile for Nails Products Containing Toluene to reflect this proposed change.

Comment Requesting to Update Information in the Initial Statement of Reasons

Comment: CL4-6

Comment Summary: The ISOR for nail products containing toluene should be edited to reflect that, with the enactment of Assembly Bill 2775 in 2018, professional cosmetic products sold in California must meet all labeling requirements for any other cosmetic pursuant to the federal Food, Drug, and Cosmetic Act and the federal Fair Packaging and Labeling Act.

DTSC Response: DTSC updated the ISOR as requested by this comment.

Table 3: List of Commenters during the 30-Day Comment Period (July 8, 2022 – August 8, 2022)

#	Commenter	Affiliation
CL1a	Thomas F. Myers	Personal Care Products Council
CL2a	Catherine Porter	California Healthy Nail Salon Collaborative
CL2a	Janet Nudelman	Breast Cancer Prevention Partners
CL2a	Andria Ventura	Clean Water Action
CL2a	Bill Allayaud	Environmental Working Group
CL3a	Alexandra Scranton	Women’s Voices for the Earth

Table 4: Index of Comment Letters and Individual Comments Made During the 30-Day Comment Period (July 8 – August 8, 2021)

Comment #	Location in Comment Letter	Page # in FSOR
CL1a-1	Entire letter	17
CL2a-1	Page 1, paragraph 1, first half of sentence 2	17
CL2a-2	Page 1, paragraph 1, second half of sentence 2	18
CL2a-3	Page 2, paragraphs 2-4	17
CL2a-4	Page 2, paragraphs 5 and 6	18
CL2a-5	Page 3, paragraphs 3-5	18
CL2a-6	Page 3, paragraph 6 Page 4, paragraph 1	18
CL2a-7	Page 4, paragraph 4	18
CL2a-8	Page 4, paragraph 5, sentences 1-3	18
CL2a-9	Page 5, paragraph 2	19
CL2a-10	Page 6, paragraph 2	19
CL2a-11	Page 6, paragraphs 3 and 4	20
CL2a-12	Page 6, paragraph 5	18

Comment #	Location in Comment Letter	Page # in FSOR
CL3a-1	Page 1, paragraph 2	17
CL3a-2	Page 1, paragraph 3, line 1	18
CL3a-3	Page 1, paragraph 3, line 2	19
CL3a-4	Page 1, paragraphs 4	18
CL3a-5	Page 2, paragraphs 2 and 3	18
CL3a-6	Page 2, paragraph 4 Page 3, paragraph 1	18
CL3a-7	Page 3, paragraph 2 Page 4, paragraph 1 Page 4, paragraph 8, sentence 1	19
CL3a-8	Page 4, paragraph 8, sentence 3	19

Summary of Objections and Recommendations during the 30-Day Comment Period (July 8 – August 8, 2022)

DTSC received three comment letters during the comment period from July 8 through August 8, 2022. The comments fall into one of the following categories:

- I. Support of the rulemaking: comments supporting the proposed Priority Product listing and comments in support of the AAT
- II. Opposition to the AAT and/or opposition to setting the AAT at 100 ppm
- III. Opposition to compliance provisions for the AAT
- IV. Suggestion for regulations regarding mislabeling

DTSC grouped and summarized the comments according to the listed themes, presenting summaries and responses in each section. Table 3 lists the commenters and Table 4 contains an Index of Comment Letters and Individual Comments.

Comments in Support of the Rulemaking

Comments: CL2a-1, CL2a-3, CL3a-1

Comment Summary: This comment expresses general support for DTSC's proposal to regulate nail products containing toluene as a Priority Product.

DTSC Response: DTSC acknowledges the support offered by these comments.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comments in Support of Setting an Alternatives Analysis Threshold at 100 ppm

Comments: CL1a-1

Comment Summary: These comments express general support for DTSC's proposal to set an AAT at 100 ppm for nail products containing toluene as a Priority Product.

DTSC Response: DTSC acknowledges the support offered by this comment.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comments in Opposition of Setting an Alternatives Analysis Threshold or setting an Alternatives Analysis Threshold at 100 ppm

Comments: CL2a-2, CL2a-4, CL2a-5, CL2a-6, CL2a-7, CL2a-8, CL2a-12, CL3a-2, CL3a-4, CL3a-5, CL3a-6,

Comment Summary: These comments focus on opposition both to establishing an AAT and to setting an AAT at 100 ppm. The arguments against this proposal focus on the following:

- An AAT is not appropriate for this Priority Product because toluene contamination can be prevented in nail products, as evidenced by nail products described in DTSC's study that do not contain toluene.
- An AAT of 100 ppm is not protective of salon workers and research shows adverse health effects at concentrations below 100 ppm; there is no evidence that 100 ppm is a safe level of exposure.
- DTSC should set an AAT or PQL for toluene lower than 100 ppm because DTSC has the authority to do so and manufacturers have the ability to comply; the AAT should be set at the lowest concentration that can reliably be measured for toluene.
- The rationale for setting the AAT at 100 ppm was based on other state laws that have established 100 ppm as a reporting threshold, not a safety threshold. None

of the data and research collected by DTSC has established 100 ppm as a safe exposure level.

DTSC Response: DTSC's goal in listing this Priority Product is to reduce the potential for nail salon workers and consumers of nail products to be exposed to and harmed by toluene that is intentionally added to nail products as an ingredient. Data received in 2021 from manufacturers indicated that toluene was present in nail products as an ingredient, as well as a contaminant or residual. DTSC's analytical testing of nail product samples detected toluene concentrations ranging from 31.4 ppm to 187,000 ppm; these results were consistent with information from manufacturers reporting that intentionally added toluene was found at high concentrations, whereas toluene that occurred as a contaminant or residual was found at much lower concentrations. DTSC's focus remains on requiring manufacturers of nail products that contain high concentrations of intentionally added toluene to conduct Alternatives Analyses to identify safer alternatives to use instead of toluene in this Priority Product.

The SCP regulations allow DTSC to set the AAT above the PQL for any Chemical of Concern that is a contaminant. (Cal. Code Regs., tit. 22, § 69505.3.) DTSC acknowledges that the establishment of the AAT for this Priority Product at 100 ppm is not a health-based determination. This determination was made to reflect the tendency that contaminant concentrations of toluene in nail products are typically 100 ppm or less, based on data collected by DTSC and comments submitted by manufacturers. DTSC acknowledges that the 100 ppm threshold for reporting by other states is not a risk-based exposure level and was one of several considerations that led to DTSC's decision to set the AAT at 100 ppm.

Manufacturers of this Priority Product that invoke the AAT will be required to provide an AAT Notification to DTSC that demonstrates and certifies that the manufacturer meets and will continue to meet the criteria and conditions of the AAT. If the Priority Product no longer meets the criteria for the AAT, the manufacturer must notify DTSC and submit a Preliminary AA Report or other applicable notification to DTSC. (Cal. Code Regs., tit. 22, § 69503.3.)

No changes were made to the proposed regulation or supporting documents based on these comments.

Comments in Opposition to the AAT Compliance Provisions

Comments: CL2a-9, CL2a-10, CL3a-3, CL3a-7, CL3a-8

Comment Summary: These comments focus on requiring manufacturers to demonstrate compliance with the AAT in alternate ways. Specifically, commenters suggest:

- Requiring manufacturers to demonstrate they are making reasonable attempts to eliminate the contaminant; requiring manufacturers to implement a manufacturing control plan to eliminate or reduce the toluene contaminant as much as possible prior being eligible for an exemption from submitting an Alternatives Analysis.
- Requiring manufacturers to certify every two years that the toluene contaminant is at or below the AAT or PQL.
- Manufacturers should be required to demonstrate that their products meet the AAT through validated testing of each product. Allowing manufacturers to determine and certify if their suppliers are providing accurate testing information, or to calculate toluene concentrations based on test results from suppliers, only works if manufacturers can be trusted. DTSC's data shows products labeled as toluene-free contain toluene, so many manufacturers and suppliers have shown they cannot be trusted to provide accurate information to DTSC and the public.

DTSC Response: In the proposed regulation, DTSC determined it is appropriate in this instance for manufacturers 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 supply chain transparency is important for manufacturers and believes this provision will help to improve that transparency between suppliers and manufacturers.

To invoke the AAT, a manufacturer must provide an AAT Notification statement that demonstrates and certifies that the manufacturer meets and will continue to meet the criteria and conditions of the AAT. In providing this certification, manufacturers may reference manufacturing control plans to control the concentration of toluene as a contaminant in the final product, but DTSC does not have the authority to require such plans. Additionally, current regulatory requirements do not provide an option for DTSC to impose additional requirements beyond the AAT Notification and its requisite information. This includes demonstrating reasonable attempts to completely remove the contaminant or requiring ongoing certification that toluene is below the AAT in their product.

If the Priority Product no longer meets the criteria for the AAT, the manufacturer must notify DTSC and submit a Preliminary AA Report or other applicable notification to DTSC. (Cal. Code Regs., tit. 22, § 69503.3.) DTSC can and will verify compliance with the applicable regulations to ensure that manufacturers invoking the AAT are submitting correct notifications.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comments in Support of Regulations Regarding Mislabeling

Comments: CL2a-11

Comment Summary: DTSC should implement an adequate regulatory framework with strict repercussions for mislabeling; DTSCs testing results include examples of products that are labeled as “toluene-free” and that contain toluene.

DTSC Response: The SCP regulations incorporate enforcement provisions for the requirements specified in the regulations. Under these provisions manufacturers have the principal duty to comply with the regulations. If a manufacturer does not comply, DTSC may issue a notice of non-compliance to the manufacturer and importer(s) for the product. This notice of non-compliance includes placement of a manufacturer on the Failure to Comply list on DTSC’s website, whereupon an importer must cease to place the product into the stream of commerce in California and retailers and assemblers must cease ordering the product. (Cal. Code Regs., tit. 22, § 69501.2.)

To request an exemption from conducting an AA, a manufacturer must provide an AAT Notification statement that demonstrates and certifies that the manufacturer meets and will continue to meet the criteria and conditions of the AAT. If the Priority Product no longer meets the criteria for the AAT, the manufacturer must notify DTSC and submit a Preliminary AA Report or other applicable notification to DTSC. (Cal. Code Regs., tit. 22, § 69503.3.) While the SCP regulations do not apply to intentional mislabeling of products, DTSC can and will verify compliance with the applicable regulations.

No changes were made to the proposed regulation or supporting documents based on this comment.