

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

**NOTICE OF MODIFICATION TO PROPOSED REGULATION AND ADDITION
OF DOCUMENTS TO RULEMAKING FILE**

TITLE 27, CALIFORNIA CODE OF REGULATIONS

ARTICLE 7 NO SIGNIFICANT RISK LEVELS

ANTIMONY TRIOXIDE

July 12, 2023

Public Availability Date: July 12, 2023

Deadline for Public Comment: July 27, 2023

The Office of Environmental Health Hazard Assessment (OEHHA) is providing notice of modifications made to a previously proposed regulation, namely the Proposition 65 No Significant Risk Level (NSRL) for antimony trioxide in Title 27, California Code of Regulations, section 25705(b)(1) and addition of documents to the rulemaking file. It is providing this notice pursuant to Government Code sections 11346.8(c) and 11347.1(b), and Title 1, California Code of Regulations, section 44.

OEHHA first proposed the regulation by publishing a Notice of Proposed Rulemaking in the California Regulatory Notice Register (CRNR) on August 26, 2022. In parallel, OEHHA issued an Initial Statement of Reasons for the proposal.

OEHHA provided a 45-day comment period on the original proposal, from August 26, to October 11, 2022.

After reviewing the comments received on this proposed regulation, OEHHA has determined that a modification to the original regulatory text is needed. In addition, OEHHA is relying upon additional documents in this rulemaking and is adding these documents to the rulemaking file. The purpose of this notice is: (1) to provide the public with notice of the modified proposed regulatory text and the additional documents included in the rulemaking file, and (2) to open a 15-day

public comment period, running from July 12, 2023, through July 27, 2023. Consistent with the Administrative Procedure Act, OEHHA will only address comments received during this comment period that address the modifications to the text of the proposed regulation or documents added to the record. Details on how to submit comments are provided below.

Summary of Proposed Modification

OEHHA is modifying proposed Section 25705(b)(1) as shown below. Additions to the proposed text are shown in double-underline (example). There are no proposed deletions.

...

<i>Chemical name</i>	<i>Level (micrograms per day)</i>
Acrylonitrile	0.7
Aldrin	0.04
<u>Antimony Oxide (Antimony Trioxide)</u>	<u>0.13 (inhalation)</u>
Arsenic	0.06 (inhalation)

...

A copy of the full updated proposed regulatory text (amendments to Section 25705(b)(1)), reflecting the modification, is provided as Attachment 1.

Rationale for the Proposed Modification

During the comment period on the original proposal, OEHHA received comments regarding the route of exposure to antimony trioxide. Specifically, comments pointed out that the absorption rate by the oral and inhalation exposure routes appears to differ. As stated in the Initial Statement of Reasons, the animal carcinogenicity studies that were used to determine the cancer potency exposed the animals to aerosols of antimony trioxide (particles) via the inhalation route. The carcinogenicity of antimony trioxide in inhalation studies reflects effects from both the inhaled particles and, subsequent to inhalation, the dissolved form. After careful review of available scientific literature reviews such as those by the European Commission (2008), ATSDR (2019), WHO (2003), IARC (1989), and

Boreiko and Rossman (2020) and toxicokinetic data from studies such as Gross et al. (1955), Groth et al. (1986), Hiraoka (1986), Newton et al. (1994), Sunagawa (1981), and Westrick (1953), OEHHA determined there are not enough data to assess the relative contributions of particulate and dissolved forms of antimony trioxide to the carcinogenic effects observed in the inhalation studies to confidently inform quantitative route-to-route extrapolation. With this uncertainty, and the apparent differences in absorption between the oral and inhalation routes, OEHHA determined that it could not confidently derive an NSRL of this chemical for exposures via the oral route. Therefore, OEHHA is limiting the NSRL to exposure via inhalation by adding “(inhalation)” to the proposed NSRL. This does not preclude the possibility of the development of an NSRL for the oral route in the future when sufficient information becomes available.

Documents Added to the Record

In the interest of completeness and in accordance with Government Code section 11347.1, subdivision (a), OEHHA has also added to the rulemaking record the following documents to those it relies in this rulemaking:

- Agency for Toxic Substances Disease Registry (ATSDR 2019). Toxicological profile for antimony and compounds. Atlanta, GA. Available from: <https://www.atsdr.cdc.gov/toxprofiles/tp23.pdf>
- Boreiko CJ and Rossman TG (2020). Antimony and its compounds: Health impacts related to pulmonary toxicity, cancer and genotoxicity. *Toxicol. Appl. Pharmacol.* 403:115156.
- European Commission (2008). European Union risk assessment report. Diantimony trioxide. CAS No: 1309-64-4. EINECS No: 215-175-0. Risk Assessment. Luxembourg, Luxembourg: Office for Official Publications of the European Communities. Available from: <https://echa.europa.eu/documents/10162/553c71a9-5b5c-488b-9666-adc3af5cdf5f>
- Gross P, Brown JH, Westrick ML, Srsic RP, Butler NL, Hatch TF (1955). Toxicologic study of calcium halophosphate phosphors and antimony trioxide. I. Acute and chronic toxicity and some pharmacologic aspects. *AMA Arch Ind Health* 11(6):473-478.
- Groth DH, Stettler LE, Burg JR, Busey WM, Grant GC, Wong L (1986). Carcinogenic effects of antimony trioxide and antimony ore concentrate in rats. *J Toxicol Environ Health* 18(4):607-626.

- Hiraoka N (1986). The toxicity and organ-distribution of antimony after chronic administration to rats. Journal of Kyoto Prefectural University of Medicine 95: 997-1017.
- International Agency for Research on Cancer (IARC 1989). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol 47, Some Organic Solvents, Resin Monomers and Related Compounds, Pigments and Occupational Exposures in Paint Manufacture and Painting. IARC, World Health Organization, Lyon, France. Available from: <https://publications.iarc.fr/65>
- Newton PE, Bolte HF, Daly IW, Pillsbury BD, Terrill JB, Drew RT, Bendyke R, Sheldon AW, Rubin LF (1994). Subchronic and chronic inhalation toxicity of antimony trioxide in the rat. Fundam Appl Toxicol. 22(4):561-576.
- Sunagawa S (1981). Experimental studies on antimony poisoning. Igaku Kenkyu 51(3):1-14.
- Westrick ML (1953). Physiologic responses attending administration of antimony, alone or with simultaneous injections of thyroxin. Proc Soc Exp Biol Med 82(1):56-60.
- WHO. 2003. Antimony in drinking-water – background document for development WHO Guidelines for Drinking-water Quality. Geneva. Available from: <https://cdn.who.int/media/docs/default-source/wash-documents/wash-chemicals/antimony.pdf>

Copies of these materials are available through links provided above or on request as provided below.

Submission of Public Comments

OEHHA is requesting comments on the modification to the regulatory text, shown below. To be considered, **OEHHA must receive comments by 11:59 p.m. on July 27, 2023, which is the designated close of the comment period.**

OEHHA strongly recommends that comments be submitted electronically through our website at <https://oehha.ca.gov/comments>, rather than in paper form.

Alternatively, the submission can be in paper form, either by mail or delivered in person.

Electronic Submission (preferred):

Through OEHHA website at: <https://oehha.ca.gov/comments>

Mailed Submission:

Attention: Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
P. O. Box 4010 Sacramento, California 95812-4010

In-person delivery submission:

Attention: Esther Barajas-Ochoa
Office of Environmental Health Hazard Assessment
1001 I Street, 23rd Floor
Sacramento, California 95814

OEHHA encourages all submissions to be in a format compliant with Section 508 of the federal Rehabilitation Act, Web Content Accessibility Guidelines (WCAG) 2.1 (see [the World Wide Web Consortium \[W3C\] WCAG 2 Overview](#)), and California Government Code sections 7405 and 11135, so that they can be read using screen reader technology.

OEHHA is subject to the California Public Records Act and other laws that require the release of certain information upon request. If you provide a submission, please be aware that your name, address and e-mail may be available to third parties.

If you have any questions, please contact Esther Barajas-Ochoa at Esther.Barajas-Ochoa@oehha.ca.gov or at (916) 445-6900.