

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

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
PROPOSITION 65**

**NOTICE OF PROPOSED RULEMAKING  
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

**AMENDMENT TO SECTION 25705  
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK:**

**ANTIMONY TRIOXIDE**

**August 26, 2022**

Public Availability Date: August 26, 2022

Deadline for Public Comment: October 11, 2022

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt a Proposition 65<sup>1</sup> No Significant Risk Level (NSRL) for antimony trioxide by amending Title 27, California Code of Regulations, section 25705(b)<sup>2</sup>. The proposed NSRL for antimony trioxide is 0.13 micrograms per day.

**SUBMISSION OF PUBLIC COMMENTS**

All written comments must be submitted to OEHHA by electronic submission, mail, or hand-delivery, by October 11, 2022, as indicated below. OEHHA strongly recommends that comments be submitted electronically through our website at <https://oehha.ca.gov/comments> rather than in paper form. Alternatively, comments can be submitted in paper form, by either mail or delivered in person.

Electronic Submission (preferred):

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

Mailed Submission:

Esther Barajas-Ochoa

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<sup>1</sup> The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., referred to herein as "Proposition 65" or "The Act."

<sup>2</sup> All further regulatory references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated.

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 commenters to submit their comments in a format compliant with Section 508 of the federal Rehabilitation Act, Web Content Accessibility Guidelines 2.0<sup>3</sup> and California Government Code sections 7405 and 11135, so that they can be read using screen reader technology and those with visual impairments are able to listen to them.

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

Inquiries concerning the action described in this notice may be directed to Esther Barajas-Ochoa, in writing at the address given above, by email at [esther.barajas-ochoa@oehha.ca.gov](mailto:esther.barajas-ochoa@oehha.ca.gov), or by telephone at: 916-445-6900

## **PUBLIC HEARING**

A public hearing on these proposed regulatory amendments will only be scheduled upon request. The hearing would be virtual due to the COVID-19 emergency<sup>4</sup>. To request a hearing, send an e-mail to Esther Barajas-Ochoa at [esther.barajas-ochoa@oehha.ca.gov](mailto:esther.barajas-ochoa@oehha.ca.gov) or letter to the address listed above by no later than **September 26, 2022**. If one is scheduled, OEHHA will mail a notice of the hearing to the requester and interested parties on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days before the public hearing date. The notice will provide the date, time, and instructions for participating in the hearing.

## **CONTACT**

Please direct inquiries concerning the proposed regulatory action described in this notice to Esther Barajas-Ochoa at (916) 445-6900, or by e-mail to [esther.barajas-ochoa@oehha.ca.gov](mailto:esther.barajas-ochoa@oehha.ca.gov)

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<sup>3</sup> <https://www.w3.org/WAI/standards-guidelines/wcag/>

<sup>4</sup> Executive Orders [N-25-20](#) and [N-29-20](#).

[ochoa@oehha.ca.gov](mailto:ochoa@oehha.ca.gov). Kristi Morioka is a back-up contact person for inquiries concerning processing of this action and is available at (916) 322-5624 or [kristi.morioka@oehha.ca.gov](mailto:kristi.morioka@oehha.ca.gov).

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Proposition 65 prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual<sup>5</sup>. The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water<sup>6</sup>.

For carcinogens, an exemption from the warning requirement is provided by the Act when the exposure for which the person is responsible can be demonstrated to produce no significant risk, or when a discharge which otherwise complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water<sup>7</sup>. A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by OEHHA (Sections 25701-25721). Section 25701 describes alternative methods for making such a determination. Section 25705 sets forth the process for determining “no significant risk” levels for purposes of Proposition 65 and establishes those levels for certain listed chemicals.

Details on the basis for the proposed NSRL for antimony trioxide are provided in the Initial Statement of Reasons for this regulatory amendment, which is available on request from Esther Barajas-Ochoa at [esther.barajas-ochoa@oehha.ca.gov](mailto:esther.barajas-ochoa@oehha.ca.gov) and is posted on the OEHHA website at [www.oehha.ca.gov](http://www.oehha.ca.gov).

This proposed amendment to section 25705 would add an NSRL for antimony trioxide by amending Section 25705(b) as follows (addition in underline):

(b) Chemical name	Level (micrograms per day)
Acrylonitrile	0.7
...	
<u>Antimony oxide (Antimony trioxide)</u>	<u>0.13</u>
...	

<sup>5</sup> Health and Safety Code section 25249.6.

<sup>6</sup> Health and Safety Code section 25249.5.

<sup>7</sup> Health and Safety Code sections 25249.9 and 25249.10

To develop the proposed NSRL for antimony trioxide, OEHHA relied on the 2017 National Toxicology Program (NTP) technical report entitled “Toxicology and Carcinogenesis Studies of Antimony Trioxide (CAS No. 1309-64-4) in Wistar Han [CrI:WI (Han)] Rats and B6C3F<sub>1</sub>/N Mice (Inhalation Studies)”<sup>8</sup> and the NTP Report on Carcinogens “Monograph on Antimony Trioxide”<sup>9</sup>. The NTP technical report and the NTP Report on Carcinogens (RoC) monograph summarize the available data from rodent carcinogenicity studies, as well as other information relevant to the carcinogenic activity of antimony trioxide.

The NSRL for antimony trioxide is based upon the results of the most sensitive scientific study deemed to be of sufficient quality<sup>10</sup>.

### **Anticipated Benefits of the Proposed Regulation**

Some businesses may not be able to afford the expense of establishing an NSRL and therefore may be exposed to litigation for a failure to warn or for a prohibited discharge of the listed chemical. By providing an NSRL, this regulatory proposal spares businesses the expense of calculating their own NSRL and may also enable them to reduce or avoid litigation costs. In addition, the NSRL does not require, but may encourage, businesses to reduce exposures to the listed chemical to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians. This in turn may reduce resident, worker and environmental exposures to antimony trioxide.

### **No Inconsistency or Incompatibility with Existing Regulations**

After conducting an evaluation on any related regulations in this area, OEHHA has found that these are the only regulations dealing with Proposition 65 No Significant Risk Levels for this specific chemical. Therefore, OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations. The proposed regulation does not impose any mandatory requirements on businesses, state or local agencies and does not address compliance with any other law or regulation.

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<sup>8</sup> National Toxicology Program (NTP 2017). Toxicology and Carcinogenesis Studies of Antimony Trioxide (CAS No. 1309-64-4) in Wistar Han [CrI:WI (Han)] Rats and B6C3F<sub>1</sub>/N Mice (Inhalation Studies). NTP Technical Report Series No. 590. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from <https://ntp.niehs.nih.gov/go/tr590>.

<sup>9</sup> National Toxicology Program (NTP 2018). Report on Carcinogens Monograph on Antimony Trioxide. RoC Monograph 13. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from [https://ntp.niehs.nih.gov/ntp/roc/monographs/antimony\\_final20181019\\_508.pdf](https://ntp.niehs.nih.gov/ntp/roc/monographs/antimony_final20181019_508.pdf).

<sup>10</sup> Section 25703(a)(4).

**RESULTS OF ECONOMIC IMPACT ANALYSIS**  
**(Gov. Code section 11346.3(b))**

**Impact on the Creation, Elimination, or Expansion of Jobs/Businesses in California**

This regulatory proposal will not affect the creation or elimination of jobs within the State of California. Proposition 65 requires businesses with ten or more employees to provide warnings prior to exposing people to chemicals that are known to cause cancer. The law also prohibits the discharge of listed chemicals into sources of drinking water. Antimony trioxide is listed under Proposition 65; therefore, businesses must provide a warning if their product or activity exposes the public or employees to significant amounts of antimony trioxide. The regulatory proposal does not create additional compliance requirements, but instead provides a “safe harbor” value that aids businesses in determining whether a warning is required for a given exposure.

The proposed NSRL provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses. Therefore, OEHHA has determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Benefits of this regulation include sparing businesses the expense of calculating their own NSRL and possibly enabling them to reduce or avoid litigation costs. By providing an NSRL, it may encourage businesses to reduce exposures to the listed chemical to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians. This in turn may reduce resident, worker and environmental exposures to antimony trioxide.

**PEER REVIEW**

This notice, the proposed regulatory change, and the Initial Statement of Reasons are being provided to the OEHHA Science Advisory Board’s Carcinogen Identification Committee for review and comment<sup>11</sup>.

**AUTHORITY**

Health and Safety Code Section 25249.12.

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<sup>11</sup> Title 27, Cal. Code of Regs., section 25701(e)

## **REFERENCE**

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

## **IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS**

Because Proposition 65 expressly<sup>12</sup> does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

## **COSTS OR SAVINGS TO STATE AGENCIES**

Because Proposition 65 expressly<sup>13</sup> does not apply to any State agency, OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

## **EFFECT ON FEDERAL FUNDING TO THE STATE**

Because Proposition 65 expressly<sup>14</sup> does not apply to any federal agency, OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

## **EFFECT ON HOUSING COSTS**

OEHHA has determined that the proposed regulatory action will have no effect on housing costs because it provides compliance assistance to businesses subject to Proposition 65 but does not impose any mandatory requirements on those businesses.

## **SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE**

Because the proposed regulatory level provides compliance assistance to businesses subject to Proposition 65, but does not impose any mandatory requirements on those businesses, OEHHA has made an initial determination that the adoption of the

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<sup>12</sup> See Health and Safety Code section 25249.11 (b)

<sup>13</sup> See Health and Safety Code section 25249.11 (b)

<sup>14</sup> See Health and Safety Code section 25249.11 (b)

regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

### **COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES**

The proposed NSRL was developed to provide compliance assistance for businesses in determining whether a warning is required, or a discharge is prohibited. The NSRL provides a level of exposure at or below which a warning is not required, and a discharge is not prohibited. Use of the NSRL is not mandatory. The implementing regulations allow a business to calculate its own level and provide guidance in order to assist businesses in doing so<sup>15</sup>. However, conducting such a process can be expensive and time consuming, and the resulting levels may not be defensible in an enforcement action. OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

### **EFFECT ON SMALL BUSINESSES**

OEHHA has determined that the proposed regulation will not impose any mandatory requirements on small business. Rather, the proposed NSRL will provide compliance assistance for small businesses subject to Proposition 65 because they will help businesses determine whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition of Proposition 65.

### **CONSIDERATION OF ALTERNATIVES**

Government Code section 11346(a)(13) requires that a rulemaking agency must determine that no reasonable alternative considered by the agency or that has otherwise been identified and brought to the attention of the agency 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 than the proposal described in this Notice.

### **AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS**

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<sup>15</sup> Title 27, Cal. Code of Regs., section 25701 et seq.

OEHHA has prepared and has made available for public review an Initial Statement of Reasons for the regulation, all the information upon which the regulation is based, and the text of the regulation. A copy of the Initial Statement of Reasons, the text of the regulation and the documents relied on to develop the proposed regulation are available upon request from OEHHA at the address and telephone number indicated above. These documents are also posted on OEHHA's website at [www.oehha.ca.gov](http://www.oehha.ca.gov).

#### **AVAILABILITY OF CHANGED OR MODIFIED TEXT**

The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on changed regulations and the full text will be mailed to individuals who testified or submitted written comments at the public hearing, if held, or whose comments were received by OEHHA during the public comment period, and anyone who requests notification from OEHHA of the availability of such changes. Copies of the notice and the changed regulation will also be available on the OEHHA website at [www.oehha.ca.gov](http://www.oehha.ca.gov).

#### **FINAL STATEMENT OF REASONS**

A copy of the Final Statement of Reasons for this regulatory action may be obtained, when it becomes available, from OEHHA at the address and telephone number indicated above, and on the OEHHA website at [www.oehha.ca.gov](http://www.oehha.ca.gov).

OFFICE OF ENVIRONMENTAL  
HEALTH HAZARD ASSESSMENT

David Edwards, Ph.D.  
Chief Deputy Director

Dated: August 26, 2022