# 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, DIVISION 4, CHAPTER 1, ARTICLE 7

# AMENDMENT TO SECTION 25705(b) SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK:

# 1-BROMOPROPANE AND DIETHANOLAMINE (DERMAL)

August 22, 2025

Public Availability Date: August 22, 2025 Deadline for Public Comment: October 6, 2025

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 1-bromopropane, as well as a dermal NSRL for diethanolamine, by amending Title 27, California Code of Regulations, section 25705(b). OEHHA is proposing an NSRL of 54 micrograms per day for 1-bromopropane and an NSRL of 6.4 micrograms per day for diethanolamine (dermal). The latter does not apply to non-dermal routes of exposure.

## SUBMISSION OF PUBLIC COMMENTS

All written comments must be submitted to OEHHA by electronic submission, mail, or hand-delivery, on or before **October 6, 2025**, as indicated below. OEHHA strongly recommends that comments be submitted electronically through our website at <a href="https://oehha.ca.gov/comments">https://oehha.ca.gov/comments</a> rather than in paper form. Alternatively, comments can be submitted in paper form by mail or delivered in person, using the instructions below.

<sup>&</sup>lt;sup>1</sup> The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et. seq., commonly known as Proposition 65, is hereafter referred to as "Proposition 65" or "The Act." All further regulatory references are to sections of Title 27 of the Cal. Code of Regs., unless otherwise indicated.

Electronic Submission (preferred):

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

Mailed Submission:

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
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 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.<sup>2</sup>

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 with your name and any contact information, please be aware that information may be available to third parties.

Although OEHHA requests that you provide your name and affiliation (if any) when making comments, you may still comment anonymously. OEHHA will accept and consider anonymous comments to the same extent as any other comments.

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 <a href="mailto:esther.barajas-ochoa@oehha.ca.gov">esther.barajas-ochoa@oehha.ca.gov</a>, or by telephone at: 916-445-6900.

### **PUBLIC HEARING**

A public hearing on these proposed regulatory amendments will only be scheduled upon request. Any interested person or their authorized representative may request a public hearing. To request a hearing, send an e-mail to Esther Barajas-Ochoa at <a href="mailto:esther.barajas-ochoa@oehha.ca.gov">esther.barajas-ochoa@oehha.ca.gov</a> or letter to the address listed above by no later

<sup>&</sup>lt;sup>2</sup> See https://www.w3.org/WAI/standards-guidelines/wcag/.

than **September 22, 2025**. If one is scheduled, OEHHA will mail a notice of the hearing to the requester, interested parties on the Proposition 65 mailing list for regulatory public hearings, and anyone who has commented on this rulemaking. The notice will also be posted on the OEHHA website 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 actions described in this notice to Esther Barajas-Ochoa at (916) 445-6900, or by e-mail to <a href="mailto:esther.barajas-ochoa@oehha.ca.gov">esther.barajas-ochoa@oehha.ca.gov</a>. Corey N. Friedman is a back-up contact person for inquiries concerning this action and is available at (916) 323-2635 or <a href="mailto:corey.friedman@oehha.ca.gov">corey.friedman@oehha.ca.gov</a>.

### **INFORMATIVE DIGEST**

# Summary of Existing Laws and Regulations, Effect of Proposed Action, and Policy Statement

Proposition 65 prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been added to the Proposition 65 list for cancer or reproductive toxicity, without first giving clear and reasonable warning to such individual.<sup>3</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>4</sup>

Diethanolamine was added to the Proposition 65 list as a carcinogen on June 22, 2012. 1-Bromopropane<sup>5</sup> was added to the Proposition 65 list as a carcinogen on August 5, 2016.

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.<sup>6</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

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<sup>&</sup>lt;sup>3</sup> Health and Safety Code section 25249.6.

<sup>&</sup>lt;sup>4</sup> Health and Safety Code section 25249.5.

<sup>&</sup>lt;sup>5</sup> The chemical is also listed under Proposition 65 for reproductive toxicity. It was listed for developmental toxicity, male reproductive toxicity, and female reproductive toxicity on December 7, 2004.

<sup>&</sup>lt;sup>6</sup> Health and Safety Code section 25249.10(c).

a determination. Section 25705 states the "no significant risk" levels for certain listed chemicals. Daily exposure to a chemical at or below those levels "shall be deemed to pose no significant risk…."<sup>7</sup>

As the lead agency for Proposition 65, OEHHA may determine an NSRL based on its own risk assessment, conducted according to Section 25703 [Quantitative Risk Assessment], or a risk assessment reviewed by OEHHA and determined to be consistent with that section.<sup>8</sup>

Businesses are not required to rely on an NSRL to demonstrate that a product does not require a Proposition 65 warning, however. As stated in existing section 25701(a), "Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk." Thus, an NSRL does not create a requirement or a mandatory threshold; rather, it allows businesses to rely on the NSRL instead of developing their own analysis. This eases compliance for regulated businesses.

This proposed amendment would add NSRLs for 1-bromopropane and diethanolamine (dermal) by amending Section 25705(b) as follows (additions in <u>underline</u>):

. . .

# **Section 25705(b)**

(1) The following levels based on risk assessments conducted or reviewed by the lead agency shall be deemed to pose no significant risk:

Chemical name	Level (micrograms per day)
Acrylonitrile	0.7
1-Bromopropane	<u>54</u>
<u>Diethanolamine</u>	6.4 (dermal)

. . .

The proposed NSRL for 1-bromopropane is 54 micrograms per day (µg/day). This proposed NSRL is based on the cancer potency value developed by OEHHA in "1-Bromopropane Cancer Inhalation Unit Risk Factor. Technical Support Document for

<sup>&</sup>lt;sup>7</sup> Section 25705(a).

<sup>&</sup>lt;sup>8</sup> Section 25705(b). An NSRL may also be promulgated "based on state or federal risk assessments," under section 25705(c), or "by the lead agency using an expedited method," under section 25705(d).

Cancer Potency Factors, Appendix B" (OEHHA 2022). The cancer potency value was derived based on a carcinogenicity study in rodents using methods consistent with those described in Section 25703.

The proposed NSRL for dermal exposures to diethanolamine is  $6.4 \mu g/day$ . This proposed NSRL is based on a carcinogenicity study in rodents and was derived using the methods described in Section 25703. This NSRL does not apply to non-dermal routes of exposure.

The purpose of the amendment concerning 1-bromopropane is to adopt an NSRL which conforms with the Proposition 65 implementing regulations and reflects the currently available scientific knowledge about the chemical. The same is true for the amendment concerning dermal exposure to diethanolamine.

Both amendments are necessary to assist businesses who would prefer to rely on OEHHA's analysis rather than calculating their own NSRLs for 1-bromopropane and/or diethanolamine. This rulemaking provides assurance to the regulated community that exposures at or below the proposed NSRLs are not considered to pose a significant risk of cancer. This amendment is needed to convey that information to the public and the regulated population. This amendment also eases compliance for business, furthering the right-to-know and public health purposes of Proposition 65.

Details on the basis for the proposed NSRLs are provided in the Initial Statement of Reasons for this regulatory amendment, which is available on request from Esther Barajas-Ochoa, whose contact information is listed above, and will be posted on the OEHHA website at <a href="https://www.oehha.ca.gov">www.oehha.ca.gov</a>.

#### Anticipated Benefits of the Proposed Regulation

Regulated businesses that choose to rely on the NSRLs will have an easier time determining if their products expose people to a level of 1-bromopropane or diethanolamine that poses no significant risk of cancer. This will ease compliance, reducing the likelihood of over-warning and furthering the right-to-know purposes of the statute, which promotes Californians' health and safety. 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 risk, thereby providing a public health benefit to Californians.

### No Inconsistency or Incompatibility with Existing Laws and Regulations

This proposal, if enacted, will be the only provision dealing with Proposition 65 No Significant Risk Levels for these specific chemicals. Therefore, OEHHA has determined

that the proposed regulation is neither inconsistent nor incompatible with existing state regulations or laws. The proposed regulation does not impose any mandatory requirements on businesses or on state or local agencies and does not address compliance with any legal requirements other than Proposition 65 and its implementing regulations.

Proposition 65 is a California state law; there are no comparable federal regulations or statutes.

## <u>AUTHORITY</u>

Section 25249.12, Health and Safety Code.

### **REFERENCE**

Sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11 and 57004, Health and Safety Code.

# RESULTS OF ECONOMIC IMPACT ANALYSIS

(Gov. Code section 11346.3(b))

No monetary costs have been estimated for this proposal. An NSRL is not a mandatory limit and does not create a threshold above which warnings are always mandated. Regardless of this rulemaking package, the standard for when a warning is required for either 1-bromopropane or diethanolamine remains the same: no warning is needed if "the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer..." (Health & Safety Code, §25249.10(c).) Businesses are not required to rely on an NSRL to demonstrate this and are still free to conduct their own analysis.

This regulatory proposal will not affect the creation or elimination of jobs within the State of California. The proposal will also not affect the creation or elimination or expansion of business within the State of California.

Benefits of the proposal are discussed above. By easing compliance with Proposition 65 and furthering the right-to-know purposes of that Act, the proposal will benefit the health and welfare of California residents and worker safety.

# NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

Because the proposed regulatory levels provide compliance assistance to businesses subject to Proposition 65, but do not impose any mandatory requirements on those businesses, OEHHA has made an initial determination that the adoption of the proposal 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 NSRLs were developed to provide compliance assistance for businesses. Use of the NSRLs is not mandatory. No costs are anticipated, because no representative person or business is required to take any action as a result of this proposal.

#### **EFFECT ON SMALL BUSINESSES**

Small businesses will not be required to take any action as a result of this rulemaking. Additionally, Proposition 65 is limited by its terms to businesses with 10 or more employees.<sup>9</sup>

#### **CONSIDERATION OF ALTERNATIVES**

Under Government Code section 11346.5(a)(13), OEHHA 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 proposals described in this Notice.

#### **EFFECT ON HOUSING COSTS**

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

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<sup>&</sup>lt;sup>9</sup> Health and Safety Code section 25249.11(b).

#### **PEER REVIEW**

This notice, the proposed regulatory changes, and the Initial Statement of Reasons are being provided to the OEHHA Science Advisory Board's Carcinogen Identification Committee for review and comment.<sup>10</sup>

#### LOCAL AGENCIES AND SCHOOL DISTRICTS

Because Proposition 65 does not apply to local agencies or school districts, OEHHA has determined the proposed regulatory actions 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. <sup>11</sup>

OEHHA has also determined that no other 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 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 actions.<sup>12</sup>

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

OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory actions.

# AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

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 <a href="https://www.oehha.ca.gov">www.oehha.ca.gov</a>.

<sup>&</sup>lt;sup>10</sup> Section 25701(e); Health and Safety Code section 57004.

<sup>&</sup>lt;sup>11</sup> See Health and Safety Code section 25249.11(b).

<sup>&</sup>lt;sup>12</sup> See Health and Safety Code section 25249.11(b).

### **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 <a href="https://www.oehha.ca.gov">www.oehha.ca.gov</a>.

#### 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.