

**INITIAL STATEMENT OF REASONS  
TITLE 27, CALIFORNIA CODE OF REGULATIONS**

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

**BROMOETHANE**

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

**PURPOSE AND BACKGROUND OF PROPOSED AMENDMENTS OF REGULATION**

This proposed regulatory amendment would adopt a No Significant Risk Level (NSRL) for bromoethane under Proposition 65<sup>1</sup> in Title 27, California Code of Regulations, section 25705(b)<sup>2</sup>. The proposed NSRL of 96 micrograms per day ( $\mu\text{g}/\text{day}$ ) is based on a carcinogenicity study in rodents and was derived using the methods described in Section 25703.

Proposition 65 was enacted as a voters' initiative on November 4, 1986. The Office of Environmental Health Hazard Assessment (OEHHA) is the lead entity responsible for the implementation of Proposition 65<sup>3</sup>. OEHHA has the authority to adopt and amend regulations to further the purposes of the Act<sup>4</sup>. The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to cause cancer or reproductive toxicity<sup>5</sup>. The Act also prohibits the discharge of listed chemicals to sources of drinking water<sup>6</sup>. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant. The NSRL provides guidance for determining when this is the case.

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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., commonly known as Proposition 65, hereinafter referred to as "Proposition 65" or "The Act."

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

<sup>3</sup> Health and Safety Code section 25249.12(a), Title 27, Cal. Code of Regs., section 25102(o).

<sup>4</sup> Health and Safety Code, section 25249.12(a).

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

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

Bromoethane was listed as known to the State to cause cancer under Proposition 65 on December 22, 2000.

#### DEVELOPMENT OF PROPOSED NSRL

Details on the basis for this proposed NSRL are provided in the OEHHA 2012 document<sup>7</sup> which is available on the Office of Environmental Health Hazard Assessment (OEHHA) website at [www.oehha.ca.gov](http://www.oehha.ca.gov) and is included in the rulemaking record. The cited document is a risk assessment prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below.

#### PROPOSED REGULATORY AMENDMENT

##### **Section 25705(b)**

The proposed change to Section 25705(b) is provided below in underline.

- (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                        |
| ...                |                            |
| <u>Bromoethane</u> | <u>96</u>                  |
| ...                |                            |

#### **PROBLEM BEING ADDRESSED BY THIS PROPOSED RULEMAKING**

Proposition 65 does not provide guidance regarding how to determine whether a warning is required or a discharge is prohibited for a listed chemical. OEHHA is the implementing agency for Proposition 65 and has the resources and expertise to examine the scientific literature and calculate a level of exposure, in this case an NSRL, that does not require a warning or for which a discharge is not prohibited.

<sup>7</sup> Office of Environmental Health Hazard Assessment (OEHHA, 2012). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Bromoethane. OEHHA, Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Oakland, July 2012.

**NECESSITY**

The proposed regulatory amendment would adopt an NSRL that conforms to the Proposition 65 implementing regulations and reflects the currently available scientific knowledge about bromoethane. The NSRL provides assurance to the regulated community that exposures or discharges at or below them are considered not to pose a significant risk of cancer. Exposures at or below the NSRL are exempt from the warning and discharge requirements of Proposition 65<sup>8</sup>.

**BENEFITS OF THE PROPOSED REGULATION**

The NSRL provides a safe harbor level that aids businesses in determining if they are complying with the law. 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. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. By providing an NSRL, this regulatory proposal does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

**TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS**

The 2012 OEHHA document<sup>9</sup> provides details on the potency calculation and mechanism of carcinogenesis that is relevant to evaluating the most appropriate method for deriving the NSRL in the context of Section 25703. The 2012 OEHHA document is included in the rulemaking record for this proposed action. It is available on the OEHHA website at [www.oehha.ca.gov](http://www.oehha.ca.gov), and from OEHHA upon request. OEHHA relied on data from the female mouse carcinogenicity study by the National Toxicology Program (NTP)<sup>10</sup> and the NTP report is also included in the regulatory record for this proposed action and is available from OEHHA upon request.

OEHHA also relied on the attached Economic Impact Assessment in developing this proposed regulation.

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<sup>8</sup> Health and Safety Code sections 25249.9(b) and 25249.10(c).

<sup>9</sup> Office of Environmental Health Hazard Assessment (OEHHA, 2012). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Bromoethane. OEHHA, Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Oakland, July 2012.

<sup>10</sup> National Toxicology Program (NTP, 1989). Toxicology and Carcinogenesis Studies of Bromoethane (Ethyl Bromide) (CAS NO. 74-96-4) in F344 Rats and B6C3F1 Mice (Inhalation Studies). Technical Report Series No. 363. NIH Publication No. 90-2818. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health.

**REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES**

The proposed NSRL provides a safe harbor level that aids businesses in determining if they are complying with the law. The alternative to the proposed amendment to Section 25705(b) would be to not adopt an NSRL for the chemical. Failure to adopt an NSRL would leave the business community without a "safe harbor" level to assist them in determining compliance with Proposition 65.

**REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES**

OEHHA is not aware of significant cost impacts that small businesses would incur due to the proposed action. Use of the proposed NSRL by businesses is voluntary and therefore does not impose any costs on small businesses. In addition, Proposition 65 is limited by its terms to businesses with 10 or more employees<sup>11</sup> so it has no effect on very small businesses.

**EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS**

Because the proposed NSRL simply provides a safe harbor level for businesses to use when determining compliance with Proposition 65, OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

**DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS**

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and, thus, there is no duplication or conflict with federal regulations.

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<sup>11</sup> Health and Safety Code, section 25249.11(b)

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

It is not possible to quantify any monetary values for this proposed regulation given that its use is entirely voluntary and it only provides compliance assistance for businesses subject to the Act.

**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 when they expose people to chemicals that are known to cause cancer or developmental or reproductive harm. The law also prohibits the discharge of listed chemicals into sources of drinking water. Bromoethane is listed under Proposition 65; therefore, businesses that manufacture, distribute or sell products with bromoethane in the state, or otherwise operate in the state, must provide a warning if their product or activity exposes the public or employees to this chemical.

**Benefits of the Proposed Regulation:** The NSRL provides a “safe harbor” level that aids businesses in determining if they are complying with the law. 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 of an exposure to or for a prohibited discharge of the listed chemical. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. By providing a safe harbor level, this regulatory proposal does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

**Problem being addressed by this proposed rulemaking:** Proposition 65 does not provide specific guidance regarding how to determine whether a warning is required or a discharge is prohibited. OEHHA is the implementing agency for Proposition 65 and has the resources and expertise to examine the scientific literature and calculate a level of exposure that does not require a warning or trigger the discharge prohibition.

**How the proposed regulation addresses the problem:** The proposed regulation would adopt an NSRL for a listed chemical to provide compliance assistance for businesses that are subject to the requirements of the Act. While OEHHA is not required to adopt such levels, adopting them provides a “safe harbor” for businesses

and provides certainty that they are complying with the law if the exposures or discharges they cause are below the established level.

**Reasonable alternatives to the proposed regulation:** OEHHA determined that the only alternative to the proposed regulation would be to not adopt an NSRL for this chemical. This alternative was rejected because it would fail to provide businesses with the certainty that the NSRL can provide.