

**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(c)(2)
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK:**

TITANIUM DIOXIDE (AIRBORNE, UNBOUND PARTICLES OF RESPIRABLE SIZE)

May 10, 2024

Public Availability Date: May 10, 2024

Deadline for Public Comment: June 24, 2024

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt a Proposition 65 No Significant Risk Level (NSRL) for titanium dioxide (airborne, unbound particles of respirable size) by amending Title 27, California Code of Regulations, section 25705(c)(2).¹ OEHHA is proposing an NSRL of 440 micrograms per day for airborne, unbound titanium dioxide particles with diameters of 10 micrometers or less, and an NSRL of 44 micrograms per day for airborne, unbound titanium dioxide particles with diameters of 0.8 micrometers or less. Both parts of the NSRL must be met before it applies.

SUBMISSION OF PUBLIC COMMENTS

All written comments must be submitted to OEHHA by electronic submission, mail, or hand-delivery, by June 24, 2024, 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.

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., is referred to herein as "Proposition 65" or "The Act." All further regulatory references are to sections of Title 27 of the California Code of Regulations 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, 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 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.²

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, or by telephone at: 916-445-6900.

PUBLIC HEARING

A public hearing on these proposed regulatory amendments will only be scheduled upon request. To request a hearing, send an e-mail to Esther Barajas-Ochoa at esther.barajas-ochoa@oehha.ca.gov or letter to the address listed above by no later than **June 10, 2024**. 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 website at least ten days before the public hearing date. The notice will provide the date, time, and instructions for participating in the hearing.

² <https://www.w3.org/WAI/standards-guidelines/wcag/>

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. Corey N. Friedman is a back-up contact person for inquiries concerning processing of this action and is available at (916) 323-2635 or corey.friedman@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.³ The Act also prohibits a business from knowingly discharging a listed chemical into water, or onto land where such chemical passes or probably will pass into any source of drinking water.⁴

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.⁵ 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 states those levels for certain listed chemicals.

Businesses are not required to rely on an NSRL to demonstrate their product does not require a Proposition 65 warning. 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 provides guidance to businesses that choose to rely on the NSRL instead of developing their own analysis. This eases compliance for regulated businesses.

³ Health and Safety Code section 25249.6.

⁴ Health and Safety Code section 25249.5.

⁵ Health and Safety Code sections 25249.9 and 25249.10

Details on the basis for the proposed NSRL for titanium dioxide 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 and is posted on the OEHHA website at www.oehha.ca.gov.

This proposed amendment to section 25705 would add an NSRL for titanium dioxide by amending Section 25705(c)(2) as follows (addition in underline):

...

(c)(2) The following levels based on state or federal risk assessments shall be deemed to pose no significant risk:

<i>Chemical Name</i>	<i>Level (micrograms per day)</i>
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...

Polychlorinated biphenyls (PCBs)	0.09
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Tetrachloroethylene	14
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Titanium dioxide (airborne, unbound particles of respirable size). If daily exposure to this chemical is at or below both of the following levels, it is deemed to pose no significant risk:

<u>Unbound, airborne particles with diameters of 10 micrometers or less</u>	<u>440</u>
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<u>Unbound, airborne particles with diameters of 0.8 micrometers or less</u>	<u>44</u>
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...

When OEHHA has not previously established an NSRL for a listed chemical based on its own risk assessment, then under subsection 25705(c), “levels of exposure deemed to pose no significant risk may be determined by [OEHHA] based on state or federal risk assessments.” OEHHA is proposing to establish an NSRL for the listed form of titanium dioxide based on a federal risk assessment, namely Occupational Exposure to Titanium Dioxide, Current Intelligence Bulletin 63, Publication No. 2011–160 (2011), by the National Institute for Occupational Safety and Health (NIOSH).

Anticipated Benefits of the Proposed Regulation

Regulated businesses that choose to rely on the NSRL will have an easier time determining if their products expose people to a level of titanium dioxide (airborne, unbound particles of respirable size) 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 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.

AUTHORITY

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 titanium dioxide (airborne, unbound particles of respirable size) 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.

The 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. The proposed NSRL will ease compliance and further the right-to-know purposes of the Act, thereby benefiting the health and welfare of California residents and promoting worker safety. Additionally, 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 health benefit to Californians and to the state's environment.

NO 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 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. Use of the NSRL is not mandatory. No costs are anticipated, because no representative person or business must 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.⁶

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 proposal described in this Notice.

⁶ Health and Safety Code section 25249.11(b).

EFFECT ON HOUSING COSTS

OEHHA has determined that the proposed regulatory action 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.

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.⁷

NO IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Because Proposition 65 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.⁸

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 action.⁹

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 action.

⁷ Title 27, Cal. Code of Regs., section 25701(e)

⁸ See Health and Safety Code section 25249.11(b)

⁹ *Ibid.*

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 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.

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.