

Proposition 65

Initial Statement of Reasons

Title 27, California Code of Regulations, Division 4, Chapter 1, Article 7

Amendment to Subsection 25705(c)(2)

No Significant Risk Levels

Titanium Dioxide (Airborne, Unbound Particles of Respirable Size)

May 10, 2024

**California Environmental Protection Agency
Office of Environmental Health Hazard Assessment**

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I. Summary

The Safe Drinking Water and Toxic Enforcement Act of 1986, referred to here as “Proposition 65” or “the Act,” requires businesses to provide a clear and reasonable warning before they knowingly and intentionally expose people to a chemical listed as a carcinogen or reproductive toxicant under the Act.¹ Businesses are also prohibited 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.² The Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency that implements Proposition 65 and has the authority to promulgate and amend regulations to implement and further the purposes of the Act.³

OEHHA is proposing to adopt a “No Significant Risk Level” (NSRL), under section 25705(c) for the listed chemical “titanium dioxide (airborne, unbound particles of respirable size).” An NSRL will provide guidance for determining when a warning is not required for exposure to that chemical.

The proposed NSRL would apply when the daily average exposure level is at or below *both* of the following:

- For airborne, unbound particles with diameters of 10 micrometers (µm) or less, the proposed NSRL is 440 micrograms (µg); and
- For airborne, unbound particles with diameters of 0.8 µm or less, the proposed NSRL is 44 µg.

II. Background

As lead agency, OEHHA maintains the Proposition 65 list of carcinogens and reproductive toxicants. Health and Safety Code section 25249.8(a) and Labor Code section 6382(b)(1) together require OEHHA to list chemicals that are “listed as human or animal carcinogens by the International Agency for Research on Cancer (IARC).” A chemical must be listed if it is classified by IARC as carcinogenic to humans, or if it is

¹ Health and Safety Code section 25249. The Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.5 et seq., is commonly known as “Proposition 65” and will be referred to as “Proposition 65” or “the Act.”

² Health and Safety Code section 25249.5.

³ Health and Safety Code section 25249.12(a).

probably or possibly carcinogenic to humans with sufficient evidence of carcinogenicity in experimental animals.⁴

IARC relied on studies that evaluated the effects of unbound respirable particles of titanium dioxide on experimental animals and found that “[t]here is sufficient evidence in experimental animals for the carcinogenicity of titanium dioxide.”⁵ IARC concluded that “titanium dioxide is possibly carcinogenic to humans.”⁶ OEHHA thus listed titanium dioxide (airborne, unbound particles of respirable size) as a carcinogen on September 2, 2011.⁷

In 2011, the National Institute for Occupational Safety and Health (NIOSH), a part of the US Centers for Disease Control and Prevention, determined that “ultrafine TiO₂ is a potential occupational carcinogen....”⁸ NIOSH is deemed an “authoritative body” with expertise on carcinogens under section 25306 and Health and Safety Code section 25254.8(b). Although NIOSH determined that there was not enough evidence at that time to classify fine TiO₂ in a similar manner as ultrafine, the agency explicitly supported IARC’s finding:

Since the public comment and peer review draft of this document was made available, NIOSH has learned that the IARC has reassessed TiO₂. IARC now classifies TiO₂ as an IARC Group 2B carcinogen, “possibly carcinogenic to humans” [IARC 2010]. NIOSH supports this decision and the underlying analysis leading to this conclusion.⁹

NIOSH developed a risk assessment to estimate cancer risks to those occupationally exposed to titanium dioxide particles. As discussed below, that assessment is the basis of the NSRL proposed in this rulemaking.

This regulatory proposal only pertains to titanium dioxide (airborne, unbound particles of respirable size) because other forms of titanium dioxide are not on the Proposition 65 list. No Proposition 65 warning should be given for exposure to these other forms. For

⁴ Cal. Code Regs., tit. 27, section 25904(b). This refers to listings that are required by statute under Health and Safety Code section 25249.8 and Labor Code section 6382(b)(1). There are other methods by which chemicals may be listed under Proposition 65.

⁵ IARC *Monographs on the Evaluation of Carcinogenic Risks to Humans vol. 93, Carbon Black, Titanium Dioxide, and Talc* (2010) p. 275.

⁶ *Id.*

⁷ Notice available at <https://oehha.ca.gov/proposition-65/cnr/chemical-listed-effective-september-2-2011-known-state-california-cause-cancer>. See also: “Notice of Intent to List Titanium Dioxide (Airborne, Unbound Particles of Respirable Size) by The Labor Code Mechanism,” (May 27, 2011), available at <https://oehha.ca.gov/proposition-65/cnr/notice-intent-list-titanium-dioxide-airborne-unbound-particles-respirable-size>.

⁸ NIOSH, Occupational Exposure to Titanium Dioxide, Current Intelligence Bulletin 63, Publication No. 2011-160 (2011), p. iii.

⁹ *Id.* at p. 76.

instance, titanium dioxide particles that are not airborne are not covered by the Proposition 65 listing.

Likewise, particles that are not of respirable size are not covered by the listing. Particles 10 µm or less are considered to be respirable. OEHHA and the California Air Resources Board stated that “[i]n general, particles 10 µm or less in diameter are considered respirable by humans.”¹⁰ In the context of the 2003 Proposition 65 listing for the chemical carbon black (airborne, unbound particles of respirable size), OEHHA also noted that particles 10 µm or less are considered to be respirable.¹¹ Similarly, IARC’s most recent monograph on carbon black also used 10 µm or less as the upper bound for respirable particles.¹²

Titanium dioxide that remains bound within a product matrix is also not included in the listing. To give an example, titanium dioxide particles can be bound within a product matrix of rubber, ink, or paint such that those particles, even if inhaled, will not expose a person to unbound titanium dioxide particles.¹³ Since a product containing only bound particles of titanium dioxide is not covered by the listing, it is not covered by this proposal, regardless of the size of the particles.

III. Problem to be Addressed by the Proposed Rulemaking and Overall Purpose

When exposures to a listed chemical from a product poses no significant risk, Proposition 65 warnings are not required.¹⁴ 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)). Under section 25705(a), OEHHA’s NSRLs are deemed to comply with the Act.

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

¹⁰ California Environmental Protection Agency, Air Resources Board, Staff Report, Public Hearing to Consider Amendments to the Ambient Air Quality Standards for Particulate Matter and Sulfates (2002) [prepared by staff of the Air Resources Board and OEHHA].

¹¹ OEHHA, Notice to Interested Parties, Chemical Listed Effective February 21, 2003, as Known to the State to Cause Cancer, California Regulatory Notice Register Notice [listing for carbon black (airborne, unbound particles of respirable size)] (Feb. 21, 2003), available at <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/22103not.pdf>.

¹² IARC, Monographs on the Evaluation of Carcinogenic Risks to Humans, vol. 93 (2010) p. 125.

¹³ OEHHA is making no claims as to the safety of such materials but merely noting that such materials are not covered by the listing and therefore should not carry a Proposition 65 warning for Titanium dioxide (airborne, unbound particles of respirable size).

¹⁴ Health & Safety Code section 25249.10(c).

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. The safe harbor level is intended to simplify compliance.

OEHHA is aware that, in recent years, potential plaintiffs have sent businesses an increasing number of “60-day Notice” letters (Notices) for consumer exposure to titanium dioxide (airborne, unbound particles of respirable size).¹⁵ Although these Notices do not necessarily lead to lawsuits, they are the first step in private enforcement of Proposition 65. OEHHA is not an enforcement agency and is not a party to any enforcement actions. The Attorney General’s Office evaluates the merit of the claims made in the Notices and has the authority to identify those they believe are not meritorious. However, OEHHA recognizes that the promulgation of an NSRL may help both plaintiffs and defendants evaluate the significance of an exposure, which can reduce the need for litigation.

The risk of litigation can increase the number of unnecessary warnings being provided for exposures to listed chemicals. Ubiquitous warnings may prevent consumers from distinguishing between products that can cause significant exposures to a listed chemical from those that cause considerably lower exposures. In the absence of regulatory action, an increase in enforcement actions could result in businesses putting warnings on products that do not require them, which is contrary to the statutory purpose of enabling consumers to make informed choices. Having an NSRL in place will make it easier for businesses to evaluate whether their product requires a warning for exposure to titanium dioxide (airborne, unbound particles of respirable size and thus reduce unnecessary warnings.

In May 2023, a complaint was filed alleging a First Amendment challenge to the Proposition 65 warning for the subject matter of this rulemaking, titanium dioxide (airborne, unbound particles of respirable size) in cosmetic and personal care products.¹⁶ While OEHHA was in the process of drafting this regulatory proposal, the plaintiffs in that case filed a request for preliminary injunction seeking to prevent enforcement of the warning requirement for exposures by cosmetic and personal care products. However, even if a preliminary injunction is granted, that does not eliminate the need for this proposed rulemaking because businesses that produce or sell other types of products not covered by the preliminary injunction would still benefit from the guidance provided by the NSRL. Additionally, the existence of a preliminary injunction does not necessarily mean that a permanent injunction will ultimately be issued, or that it will address all exposures to the listed form of titanium dioxide which are covered by

¹⁵ 60 day notices may be found at <https://oag.ca.gov/prop65/60-day-notice-search>.

¹⁶ *The Personal Care Products Council v. Bonta* (E. Dist.Cal. 2023) No. 2:23-CV-01006-TLN-JDP, filed May 26, 2023. OEHHA’s ability to list titanium dioxide (airborne, unbound particles of respirable size) or to establish an NSRL is not at issue in that litigation; the case only addresses *enforcement* of warning requirements.

the warning requirements of Proposition 65. Businesses that would benefit from OEHHA's evaluation of exposures posing a significant risk of cancer should be able to rely on the proposed NSRL, regardless of the ongoing litigation.

IV. Proposed Amendments

This proposed amendment sets the following NSRL for titanium dioxide (airborne, unbound particles of respirable size). It states:

Titanium dioxide (airborne, unbound particles of respirable size). If daily exposure to this chemical ($\mu\text{g}/\text{day}$) is at or below both of the following levels, it is deemed to pose no significant risk:

Airborne, unbound particles with diameters of 10 micrometers or less	440
Airborne, unbound particles with diameters of 0.8 micrometers or less	44

Thus, a product that exposes people to titanium dioxide (airborne, unbound particles of respirable size) falls below the NSRL if the exposure to particles with diameters of 0.8 μm or less is below 44 $\mu\text{g}/\text{day}$, *and* the exposure to particles with diameters of 10 μm or less is below 440 $\mu\text{g}/\text{day}$. Both parts of the NSRL must be met before it applies.

A product that exposes people to airborne, unbound titanium dioxide particles, *all* of which have diameters equal to or less than 0.8 μm , will fall under the NSRL if use of the product exposes people to less than 44 $\mu\text{g}/\text{day}$.

A product that does *not* expose people to airborne, unbound titanium dioxide particles with diameters at or below 0.8 μm , but *does* expose people to diameters above 0.8 μm and at or below 10 μm , will satisfy the NSRL if use of the product exposes people to less than 440 $\mu\text{g}/\text{day}$.

For some products, people may be exposed to airborne, unbound titanium dioxide particles with diameters at or below 0.8 μm *and* between 0.8 and 10 μm . In that situation, both parts of the NSRL will have to be evaluated. For instance, a product could expose someone to 43 $\mu\text{g}/\text{day}$ of airborne, unbound particles of 0.8 μm or less, and 400 $\mu\text{g}/\text{day}$ of such particles above 0.8 μm and no greater than 10 μm . That product would not satisfy both parts of the NSRL, because there would be a total of 443 $\mu\text{g}/\text{day}$ of airborne, unbound particles of 10 μm or less. However, if the product exposed a person to the same 43 $\mu\text{g}/\text{day}$ of airborne, unbound particles of 0.8 μm or less but only 300 $\mu\text{g}/\text{day}$ of such particles between 0.8 and 10 μm , then both parts of the NSRL would be satisfied.

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).

NIOSH’s quantitative cancer risk assessment uses dose-response data from rat studies in which exposures to respirable titanium dioxide resulted in lung tumors. The NIOSH risk assessment received independent, external review by a panel of experts.

The NIOSH assessment utilizes a lung dosimetry model to extrapolate lung tumor findings in rats to humans, taking particle size into account. The assessment reported concentrations of titanium dioxide that result in one per 100,000 risk estimates. One per 100,000 is the same risk level used for quantitative risk assessments conducted under existing section 25703(b).¹⁷

NIOSH reports 95% lower confidence bound concentrations associated with one per 100,000 risk for occupational exposure, as follows:

Fine TiO₂: 0.1 milligram per meter cubed (mg/m³)

Ultrafine TiO₂: 0.01 mg/m³

In their assessment, NIOSH defined fine titanium dioxide particles as “all particle sizes collected by respirable particle sampling.” NIOSH defined ultrafine titanium dioxide particles as “the fraction of respirable particles with a primary particle diameter < 0.1 μm.” NIOSH also indicated that exposures to agglomerated ultrafine titanium dioxide particles with diameters of 0.8 μm or less should be controlled to the ultrafine level because, even though these particles are frequently measured as fine, the surface area of the constituent particles causes them to behave biologically as ultrafine.

In making its estimates, NIOSH assumed a 40-hour work week over a 45-year working lifetime. For purposes of Proposition 65, OEHHA converts these 45-year air concentrations to 70-year lifetime daily intake levels, expressed in units of μg per day.

OEHHA is relying on these concentrations and the NIOSH analysis to calculate the NSRL for titanium dioxide (airborne, unbound particles of respirable size), pursuant to 25705(c). The use of the 95% lower confidence bound on concentration comports with the use of the upper confidence limit on potency found in section 25703(a)(5).¹⁸

¹⁷ That subsection states, in part, “the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level....”

¹⁸ That subsection states, in part, “[a] linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized.”

During a 40-hour work week, workers exposed to air containing 0.1 mg/m³ of fine titanium dioxide particles would be exposed on a weekly basis to 5 mg of these particles. This assumes that workers breathe 10 m³ of air per 8-hour workday and work 5 days per work week.

$$5 \text{ mg per work week} = 0.1 \text{ mg/m}^3 \times (10 \text{ m}^3 \text{ per work day}) \times (5 \text{ work days per work week})$$

Accounting for 50 work weeks per year this results in 250 mg per working year:

$$250 \text{ mg per working year} = 5 \text{ mg per work week} \times (50 \text{ work weeks per working year})$$

Assuming a working life of 45 years, this results in a cumulative exposure of 11,250 mg:

$$11,250 \text{ mg} = 250 \text{ mg per working year} \times 45 \text{ years}$$

Spreading this same cumulative exposure over a 70-year lifetime with daily exposure results in 440 µg per day:

$$440 \text{ µg per day} = 11,250 \text{ mg} \times (1,000 \text{ µg per mg}) \div 70 \text{ years} \div (365 \text{ days in a year})$$

Thus, exposure to airborne, unbound titanium dioxide particles with diameter of 10 micrometers (µm) or less at 440 µg per day on average, over a 70-year lifetime, is associated with a risk of one additional case of cancer per 100,000 people.

The second part of the NSRL applies to particles with diameters of 0.8 µm or less. NIOSH explicitly calculated the risk for the ultrafine category using the particle diameter size of 0.8 µm, based on the size of the agglomerated ultrafine titanium dioxide particles in the animal studies used in the analysis. OEHHA has therefore also used a particle diameter of 0.8 µm or less for this part of the NSRL. For these particles, NIOSH determined that the concentration associated with one per 100,000 risk of cancer is 10 times lower (0.01 mg/m³) than for particles with diameter of 10 µm or less. Thus, the daily exposure associated with this part of the NSRL is also 10 times lower, 44 µg.

For an exposure to pose no significant risk under the proposed NSRL, both of the NSRL's quantitative criteria must be met: for particles of 10 µm or less, and for particles of 0.8 µm or less.

V. Necessity

OEHHA has proposed an NSRL because it is necessary to assist businesses who would prefer to rely on OEHHA's analysis rather than calculating their own NSRL. Ease

of compliance will ultimately benefit the public by furthering the goals of Proposition 65. This will benefit public health and can potentially reduce unnecessary warnings.

VI. Benefits

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.

VII. Other Required ISOR Elements

Economic Impact Assessment Required by Gov. Code section 11346.3(b)

In compliance with Government Code section 11346.3, OEHHA has assessed all the elements identified in sections 11346.3(b)(1)(A) through (D).

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.

Creation or Elimination of jobs within the State of California

This regulatory action will not impact the creation or elimination of jobs within the State of California. The proposed regulation will help businesses already subject to the requirements of Proposition 65 by providing the No Significant Risk Level for titanium dioxide (airborne, unbound particles of respirable size).

Creation of new businesses or elimination of existing businesses within the State of California

This regulatory action will not impact the creation of new businesses or the elimination of existing businesses within the State of California. Businesses are not required to take any action, as described above.

Expansion of businesses currently doing business within the State of California

This regulatory action will not impact the expansion of businesses within the State of California. Businesses are not required to take any action, as described above.

Technical, Theoretical, and/or Empirical Study, Reports, or Documents Relied Upon

Citations to documents relied on for this proposal are provided in this document. Copies of these documents will be included in the regulatory file for this action and are available from OEHHA upon request.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has determined there are no reasonable alternatives to the proposed regulatory action that would carry out the purposes of the Act. The proposed action provides an NSRL to assist with evaluations of when a Proposition 65 warning is not required.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business and the Agency's Reasons for Rejecting Those Alternatives

OEHHA has initially determined that no reasonable alternative considered by OEHHA, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the proposed action, or would be as effective and less burdensome to small business, or would be more cost-effective and equally effective in implementing the statutory policy or other provision of law to small business. The current proposal furthers the purposes of Proposition 65 by providing non-mandatory guidance for businesses concerning how safe harbor warnings can be provided for exposures to titanium dioxide (airborne, unbound particles of respirable size), as well as non-mandatory guidance on when warnings are not required based on the NSRL. Small businesses that are covered by Proposition 65 (i.e. those with 10 or more employees) would benefit from this proposal, particularly the development of an NSRL, which requires scientific resources that smaller businesses may lack.

Use of specific technologies or equipment

This proposal does not mandate the use of any specific technology or equipment.

Evidence Supporting Finding of No Significant Adverse Economic Impact on Business

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. Products that caused a significant exposure to airborne, unbound particles of titanium dioxide already required a Proposition 65 warning, prior to this rulemaking. The proposed regulatory action will provide non-mandatory guidance for businesses, specifically, an NSRL to assist businesses in determining when a warning is not required.

Efforts to Avoid Unnecessary Duplication or Conflicts with Federal Regulations Contained in the Code of Federal Regulations Addressing the Same Issues

Proposition 65 is a California law that has no federal counterpart. OEHHA has determined that the regulations do not duplicate and will not conflict with federal regulations.