October 21, 2026

Dr. Kristina Thayer, Director
Office of Environmental Health Hazard Assessment
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Via electronic submission to: https://oehha.ca.gov/comments

RE: Possible Amendments to: Section 25705(b) Specific Regulatory Levels Posing No Significant Risk and New Section 25901

Dear Dr. Thayer:

The Consumer Healthcare Products Association (CHPA)[1] and the Personal Care Products Council (PCPC)[2] appreciate the opportunity to provide comments on the Office of Environmental Health Hazard Assessment's proposed No Significant Risk Level (NSRL) for vinyl acetate as well as the proposed possible new Section 25901 outlining the factual information needed to demonstrate what would constitute a consumer product exposure to vinyl acetate monomer.[3]

Below, we address a number of concerns with OEHHA's scientific basis for the proposed NSRL and suggest that the calculated value represents an overestimation of the risk and should therefore be revised. We ask that OEHHA make available the benchmark dose modeling inputs and outputs for all evaluated studies so that stakeholders can evaluate the derivation. We also note our agreement with proposed Section § 25901 and suggest several modifications which we believe would make this more effective.

[1] CHPA, founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter ("OTC") medicines, dietary supplements, and OTC medical devices. For more than 145 years, CHPA has served as a vital advocate for the consumer healthcare products industry. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases. www.chpa.org

[2] PCPC is the leading national trade association representing the global cosmetic and personal products industry. Founded in 1894, PCPC member companies manufacture, distribute, and supply the vast majority of finished cosmetic and personal care products marketed in the United States. Our companies represent some of the most trusted and beloved brands in beauty and personal care, and we remain committed to product safety, quality, and innovation.

[3] Pre-Regulatory Workshop for Potential Amendments to Title 27, California Code of Regulations Section 25705(b), Specific Regulatory Levels Posing No Significant Risk and New Section 25901, Vinyl Acetate; September 21, 2026.

The proposed NSRL (11 µg/day) is based on one small study,[4,5] whose key findings were not reproduced in larger bioassays, and on a linear low-dose extrapolation adopted without engaging the substantial mode-of-action evidence for vinyl acetate.

Applying OEHHA's § 25703 methodology to other studies[6,7] considered to be "sensitive" and of "sufficient quality" yields much higher NSRLs.[8] Further, a peer-reviewed, published mode-of-action-based approach to determining inhalational and oral NSRLs yields values several orders of magnitude higher.[9] Given the large discrepancy in these NSRL values, and OEHHA's reliance on a single study utilizing only 20 animals per group, and only two dose levels, we ask that OEHHA address their choice of this study and provide a full explanation in the record.

The F344 multisite slope factor was driven by uterine adenocarcinomas, uterine endometrial stromal polyps, hepatocellular adenoma, thyroid C-cell adenoma, and pituitary gland adenomas.[4] Most of these tumors are benign and exhibit substantial variability in the background incidence rates in female F344 rats.[10] Further, pituitary adenoma, which showed only a trend-test response, occurred in 35% of control animals. Except for uterine adenocarcinoma, these tumors were not identified as treatment-related in the larger rat[7] and mouse[6] studies, where tumors occurred primarily at the highest concentration tested at direct-contact sites (e.g., oral cavity, tongue, esophagus, and forestomach). The resulting human cancer slope factor of 0.065 $(mg/kg\text{-}day)^{-1}$ is roughly 2.6 to 6.6 times higher than the values OEHHA derived from each of the other studies it modeled (0.0098 to 0.025 $(mg/kg\text{-}day)^{-1}$). We ask OEHHA to justify relying on this small-study outlier and provide a sensitivity analysis excluding tumor types with high background incidence or trend-only responses.

According to a recent FDA Guidance document discussing the derivation of acceptable intakes for impurities with positive carcinogenicity data,[11] the Lijinsky and Reuber (1983) study would be regarded as "lower quality" because it included fewer than 50 animals per dose per sex (20 per sex per group) and evaluated fewer than three dose levels (two dose levels). Further, the Agency for Toxic Substances and Disease Registry (ATSDR; 2025) recently chose not to include the Lijinsky

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[4] Lijinsky W and Reuber MD 1983. Chronic toxicity studies of vinyl acetate in Fischer rats. *Tox Appl Pharmacol*; 68(1):43-53.
[5] Experimental Pathology Laboratories (EPL 1982). Bioassay of Vinyl Acetate in F344 Rats Pathology Report Addendum.
[6] Maltoni C, Ciliberti A, Lefemine G, Soffritti M 1997. Results of a long-term experimental study on the carcinogenicity of vinyl acetate monomer in mice. *Ann N Y Acad Sci* 837:209-238.
[7] Belpoggi F, Soffritti M, Minardi F, Ciliberti A, Padovani M, Cattin E, and Maltoni C 2002. Results of a long-term carcinogenicity bioassay on vinyl acetate monomer in Wistar rats. *Eur J Oncol* 7:279-293.
[8] Approximately 28–71 µg/day -2.6–6.6 times the proposed value of 11µg/day.
[9] Kirman CR, Dekant W, Dellarco VL, Dourson ML, Klauning JE, Simon TW, Hays SM 2026. Consideration of carcinogenicity and mode of action information by an independent expert panel to support derivation of no-significant-risk-level values for vinyl acetate monomer. *Regul Toxicol Pharmacol*;171:106170.
[10] Haseman JK, Hailey JR, Morris RW. 1998. Spontaneous neoplasm incidences in Fischer 344 rats and B6C3F1 mice in two-year carcinogenicity studies: a National Toxicology Program update. *Toxicol Pathol* 26(3):428-441.
[11] FDA Guidance for Industry M7(R2) Addendum: Application of the Principles of the ICH M7 Guidance to Calculation of Compound-Specific Acceptable Intakes. July 2023.

and Reuber study in its Toxicological Profile for Vinyl Acetate[12] since an accurate dose estimate could not be determined.

OEHHA acknowledges that § 25703(a) permits scientifically supported alternatives to default assumptions and that § 25703(a)(7) allows reliable physiologic, pharmacokinetic, and metabolic data to be used for risk assessment purposes. However, after summarizing evidence OEHHA views as supporting genotoxicity,[13] it concludes without analysis that no more appropriate approach than the default exists. The extensive evidence that vinyl acetate tumors arise through carboxylesterase-mediated hydrolysis to acetic acid and acetaldehyde, followed by intracellular acidification, cytotoxicity, and regenerative proliferation at high-exposure contact sites is not addressed in detail.

The Texas Commission on Environmental Quality adopted a threshold-based value,[14] and a 2026 expert review[9] similarly found strong support for a cytotoxicity-driven mode of action, but not direct genotoxicity. This evidence is particularly relevant because, excluding the F344 rat study, the tumor database is dominated by direct-contact squamous cell tumors consistent with a threshold mechanism. We ask that OEHHA evaluate this evidence and, if it retains a linear multistage based extrapolation, explain why the available data discussed above do not support a more scientifically appropriate approach.

The data should be evaluated in their totality. The Lijinsky and Reuber study, considered in isolation, does not provide an adequate scientific basis for deriving a cancer slope factor and establishing the NSRL, given its small sample size, limited dose spacing, uncertainty regarding the actual administered dose, pathological discrepancies and the availability of more robust carcinogenicity bioassays.

Per § 25703(a)(4), the results of the most sensitive study apply "to all routes of exposure for which the results are relevant." The proposed NSRL is derived from drinking-water studies, whereas exposures to vinyl acetate monomer, a volatile compound, would be expected to occur primarily by inhalation and skin contact. While OEHHA noted that no route-specific pharmacokinetic differences were identified, the tumors observed at the site of first contact differ by route of exposure. We ask that OEHHA explain how the oral, drinking-water-derived value is relevant to inhalation and dermal exposures and to consider whether a route-specific inhalation NSRL would be more appropriate.

The vinyl acetate NSRL should be based on a robust, science-based record. We ask that OEHHA address the issues above before issuing a formal proposal.

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[12] US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry January 2025. Toxicological Profile for Vinyl Acetate.

[13] See International Agency for Research on Cancer (IARC) 1995. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 63, Dry Cleaning, Some Chlorinated Solvents and Other Industrial Chemicals. IARC, World Health Organization, Lyon, France.

[14] Texas Commission on Environmental Quality, Vinyl Acetate, Development Support Document (Final, Sept. 4, 2015). https://www.tceq.texas.gov/downloads/toxicology/dsd/fact-sheets/vinylacetate.pdf.

Proposed Section 25901 (Vinyl Acetate Exposure Information)

CHPA and PCPC support the proposed section 25901 with modifications. This section appropriately codifies the principle expressed in OEHHA's December 23, 2025, information letter, which is that a Certificate of Merit must provide evidence of an exposure to a listed chemical, not merely evidence of the theoretical existence of the listed chemical within a consumer product matrix. The proposed regulation is also consistent with the Attorney General's regulation requiring "documentation of *exposure* to a listed chemical." 11 C.C.R. § 3101 (emphasis added).

Proposed section 25901 also embodies the clear intent of Proposition 65 to require warnings for real, reasonably foreseeable exposures rather than theoretical exposures to listed chemicals. It is the same principle behind the law's exemptions for exposures presenting no significant risk and those 1,000 times below the no observable effect level. To broaden warnings to include the hypothetical and the risk-free would be to stretch Proposition 65 into irrelevance.

For the same reasons, we recommend that section 25901 be modified to apply to all listed chemicals, not merely vinyl acetate; and to cover occupational and environmental exposures, not merely consumer product exposures. In isolation, a new section 25901 that applies only to vinyl acetate exposures is not objectionable. But to expressly limit its scope to only vinyl acetate risks an interpretation by courts that the rule it embodies ought not to apply to other listed chemicals when, in fact, the intent behind 25901 is to clarify that the broader rule applies to vinyl acetate as much as any other listed chemical. Accordingly, we recommend the following language:

> To provide the Attorney General with factual information sufficient to establish the basis of a certificate of merit, as required by Health and Safety Code section 25249.7(d), a private party alleging exposure to ~~vinyl acetate~~ a listed chemical must provide facts showing exposure to the listed chemical, including, for purposes of an alleged exposure to vinyl acetate, an exposure to vinyl acetate monomer, CAS no. 108-05-4. If such factual information includes the concentration of the listed chemical ~~vinyl acetate monomer~~ in a product, that concentration must not include the amount of the listed chemical ~~vinyl acetate monomer~~ resulting from the dissolving, digesting, extracting, or breaking down of ~~vinyl acetate-containing~~ polymers, copolymers, or other encapsulating product matrices containing the listed chemical in a manner which would not otherwise occur during a consumer product exposure, an environmental exposure, or an occupational exposure as defined in Cal. Code Regs., tit. 27, section 25600.1.

In the alternative, instead of modifying section 25901 with the above language to apply to all listed chemicals, not merely vinyl acetate, we recommend adding an in-text savings clause as follows:

> Nothing in this section shall be construed to imply that the presence of a polymer or copolymer of any other listed chemical in a product is, by itself, sufficient to establish an exposure to that chemical.

At minimum, clarification should be added in the Final Statement of Reasons that no negative inference is to be drawn for any listed chemicals, including other monomers, from the chemical–specific scope of proposed section 25901. However, given the potential for misinterpretation of that risk expanding Prop 65 so broadly as to undermine its fundamental purpose, we respectfully recommend that OEHHA address these concerns in the text of the regulation itself.

In summary, we are supportive of the proposed modifications within the proposed Section 25901:

- Retaining the statement of the core principle previously stated by OEHHA in the December 23, 2025, information letter. To be consistent with the proposed broader scope of section 25901, we recommend addition of the language noted above regarding the factual information sufficient to establish a potential exposure to a listed chemical.
- Retain the broader and more accurate "dissolving" standard from the December 23, 2025, information letter with a further clarification for chemical "separation." We specifically recommend that the text exclude, for purposes of determining what evidence is required for a Certificate of Merit, listed chemicals "liberated by dissolving, digesting, separation, or breaking down" in a manner that would not otherwise occur during an exposure.
- Clarify, in the text or Final Statement of Reasons, that the rule embodied in the proposed section 25901 applies not just in determining the sufficiency of the Certificate of Merit, but also for purposes of determining whether a person in the course of doing business has "exposed" a person to a listed chemical in violation of Health & Safety Code section 25249.6.

CHPA and PCPC welcome the opportunity to comment on the proposed NSRL and new Section 25901. We recognize the significant effort undertaken by OEHHA to evaluate the data and value continued stakeholder engagement throughout this process.

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