October 21, 2026

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Submitted electronically via OEHHA's public comment portal

Re: Comments on the Pre-Regulatory Proposal to Adopt a No Significant Risk Level for Vinyl Acetate (§ 25705(b)) and New Section 25901

Dear Dr. Thayer,

The Household & Commercial Products Association[1] (HCPA) appreciates the opportunity to comment on the Office of Environmental Health Hazard Assessment's (OEHHA) pre-regulatory proposal to adopt a No Significant Risk Level (NSRL) of 11 micrograms per day (μg/day) for vinyl acetate in § 25705(b), and proposed new § 25901, which addresses the factual information needed to support a certificate of merit for an alleged exposure to vinyl acetate.[2] HCPA is the trade association representing companies that manufacture and sell products used to clean, protect, maintain, and disinfect homes and commercial environments. HCPA member companies employ hundreds of thousands of people in the United States, and their products are found in

[1] The Household & Commercial Products Association (HCPA) is the premier trade association representing companies that manufacture and sell $227 billion annually of trusted and familiar products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments. HCPA member companies employ more than 300,000 people in the U.S. whose work helps consumers and workers to create cleaner, healthier and more productive lives. HCPA represents products including disinfectants that kill germs in homes, hospitals and restaurants; air fresheners, room deodorizers, and candles that eliminate odors; pest management products for pets, home, lawn, and garden; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day.

[2] OEHHA, Notice to Interested Parties, Pre-Regulatory Workshop for Potential Amendments to Title 27, California Code of Regulations, Section 25705(b) and New Section 25901, Vinyl Acetate (Sept. 21, 2026), and accompanying draft regulatory text and explanatory document ("Explanatory Document"), available at https://oehha.ca.gov/sites/default/files/media/2026-09/Vinyl%20Acetate%20pre-regulatory%20workshop%20explanatory%20document_092126.pdf. Unless otherwise indicated, all regulatory references are to Title 27 of the California Code of Regulations.

most American households and workplaces.

HCPA welcomes OEHHA's decision to develop a safe harbor level for vinyl acetate and to address testing practices at the same time. As OEHHA has recognized, vinyl acetate monomer is uncommon in consumer products. Polymers and copolymers made from it, however, such as polyvinyl acetate, polyvinyl alcohol, ethylene-vinyl acetate, and vinyl acetate copolymers, are used widely as binders, film formers, adhesives, and packaging materials in the products HCPA members make, including floor finishes and polishes, adhesives and sealants, automotive appearance and maintenance products, aerosol formulations, pest control formulations and dispensers, and the water-soluble films used in unit-dose cleaning products. Warnings for vinyl acetate exposures have been enforceable since January 3, 2026, without a safe harbor level, leaving businesses to rely on product-specific risk assessments and vulnerable to notices premised on the presence of polymers or on content testing rather than on exposure. HCPA therefore supports prompt adoption of both an NSRL and § 25901. Our comments below address (1) the scientific basis for the proposed NSRL, which HCPA believes overstates risk and should be revisited before a formal proposal, and (2) refinements that would make § 25901 effective in practice.

The Proposed NSRL (§ 25705(b))

HCPA does not question OEHHA's authority to adopt an NSRL for vinyl acetate or the general framework of § 25703. HCPA is concerned, however, that the proposed value of 11 μg/day rests on a single small study whose principal findings are not reproduced in the larger bioassays OEHHA reviewed, and on a linear low-dose extrapolation adopted without engaging the substantial mode-of-action evidence for vinyl acetate. Applying OEHHA's own § 25703 methodology to each of the other four studies OEHHA modeled yields NSRLs of roughly 28 to 71 μg/day, 2.6 to 6.6 times the proposed value. Approaches that account for vinyl acetate's mode of action yield values several orders of magnitude higher.[3] A spread of that size, driven by a single 20-animal

[3] Calculated using OEHHA's formula, NSRL = (10^{-5} × 70 kg ÷ CSF_{human}) × 1,000 μg/mg, and the human cancer slope factors OEHHA derived from the male and female F1 Wistar rat and F1 Swiss mouse studies (0.0098 to 0.025 per mg/kg-day). Explanatory Document, Table 6. For values derived using a mode-of-action-based approach, see the 2026 expert panel review discussed below (oral NSRL of 110,000 μg/day; inhalation NSRL of 20,000 μg/day).

study, warrants a full explanation in the record. Specifically:

- *The critical study should be evaluated against § 25703(a)(1).* The proposed NSRL is derived from a single drinking-water study in female F344 rats (EPL 1982; Lijinsky and Reuber 1983) that used 20 animals per group and two dose levels. Section 25703(a)(3) directs that risk analysis be based on "the most sensitive study deemed to be of sufficient quality," and § 25703(a)(1) identifies "the number and size of exposed groups" and "the extent of tumor occurrence" among the generally accepted scientific principles that govern that judgment. OEHHA's 2024 hazard identification document acknowledges the small group sizes in this study.[4] By comparison, the F1 groups in the Belpoggi et al. (2002) and Maltoni et al. (1997) studies included between 37 and 95 animals per group. The Explanatory Document selects the F344 study because it yields the highest slope factor but does not explain why a 20-animal study is of sufficient quality to serve as the sole basis of the NSRL. HCPA asks OEHHA to address that question expressly. Study outcomes can vary with strain susceptibility, test substance preparation, study design, dose selection, and laboratory-specific variables. Reliance on the single study that yields the lowest point of departure may produce an overly conservative NSRL where the broader body of evidence does not support a comparable level of potency.
- *The F344 tumor profile is not replicated in the larger studies.* The F344 multisite slope factor is driven by hepatocellular adenoma, thyroid C-cell adenoma, pituitary adenoma, uterine endometrial stromal polyps, and uterine adenocarcinoma. Apart from uterine adenocarcinoma, none of these appear among the treatment-related tumors in the larger Wistar rat and Swiss mouse studies, where tumors were concentrated at sites of direct contact (oral cavity, tongue, esophagus, and forestomach) at the highest administered concentration. Most of the F344 tumors used in the model are benign, and pituitary adenoma, which showed only a trend-test response, occurred in 6 of 17 control animals. Several of these tumor types are

[4] OEHHA, Evidence on the Carcinogenicity of Vinyl Acetate (2024), available at https://oehha.ca.gov/sites/default/files/media/downloads/crnr/vinylacetatehid100424.pdf, at 25 (noting that some vinyl acetate studies, including this one, had small numbers of animals ($n \leq 20$) per dose group).

also common, and highly variable, in untreated female F344 rats: historical control data from National Toxicology Program feeding studies report background incidences of roughly 2 to 30 percent for uterine stromal polyps, 4 to 22 percent for thyroid C-cell adenomas, and 30 to 74 percent for pituitary (pars distalis) adenomas.[5] Tumor types with background rates this high and variable are a weak basis for benchmark dose modeling. 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 four other studies it modeled (0.0098 to 0.025 $(mg/kg\text{-}day)^{-1}$). HCPA asks OEHHA to explain why an outlier result from the smallest study should govern. At a minimum, OEHHA should present a sensitivity analysis showing how the slope factor changes when tumor types with high background incidence or trend-only responses are excluded, and should evaluate the F344 tumor responses against historical control incidences.

- *The mode-of-action evidence supports a nonlinear approach.* As the Explanatory Document recognizes, § 25703(a) permits departure from default assumptions where an assumption is "scientifically more appropriate, based upon the available data," and § 25703(a)(7) allows physiologic, pharmacokinetic, and metabolic data to be used when they can be taken into account with confidence. The Explanatory Document summarizes mechanistic data that OEHHA views as supporting genotoxicity and then concludes, in a single sentence, that no more appropriate approach exists. It does not discuss the extensive literature on vinyl acetate's mode of action, in which carboxylesterase-mediated hydrolysis to acetic acid and acetaldehyde, intracellular acidification, cytotoxicity, and regenerative cell proliferation at the site of contact precede tumor formation at high exposure levels. Aldehyde dehydrogenase normally oxidizes the acetaldehyde formed from vinyl acetate to acetic acid; only at high exposures, when that capacity is exceeded, does intracellular acetaldehyde rise to non-physiological levels at which cytotoxicity, mitogenic effects, and genotoxicity occur. Exposures that do not raise intracellular acetaldehyde above physiological levels would therefore not be

[5] J.K. Haseman, J.R. Hailey, R.W. Morris, Spontaneous Neoplasm Incidences in Fischer 344 Rats and B6C3F1 Mice in Two-Year Carcinogenicity Studies: A National Toxicology Program Update, 26 Toxicologic Pathology 428, 430–32 (1998) (Table I, female feeding-study controls), available at https://doi.org/10.1177/019262339802600318.

expected to produce a carcinogenic response.[6] The Texas Commission on Environmental Quality has concluded that vinyl acetate acts through a threshold mode of action and derived a threshold-based value rather than a unit risk factor.[7] A 2026 expert panel review published in Regulatory Toxicology and Pharmacology reached a similar conclusion, finding a cytotoxicity-driven mode of action well supported and direct genotoxicity not supported.[8] This evidence matters here because, if the F344 study is set aside, the tumor response across the vinyl acetate database is dominated by squamous cell tumors at sites of direct contact, the very response the threshold mode of action explains. HCPA asks OEHHA to evaluate this evidence explicitly, and to explain in the record the basis for linear extrapolation rather than a threshold mode-of-action approach.

- *The NSRL should be reconciled with OEHHA's NSRL for acetaldehyde.* The Explanatory Document identifies metabolic activation of vinyl acetate to acetaldehyde, an electrophilic metabolite that forms DNA adducts, as part of the mechanistic basis for vinyl acetate's carcinogenicity.[9] OEHHA has adopted an NSRL of 90 μg/day for acetaldehyde by inhalation. Complete conversion of 11 μg of vinyl acetate would yield approximately 5.6 μg of acetaldehyde, so for inhalation exposures the proposed vinyl acetate NSRL is, on a molar basis, roughly 16 times more stringent than OEHHA's existing NSRL for what its own hazard identification document calls "vinyl acetate's genotoxic and carcinogenic

[6] M.S. Bogdanffy, R. Valentine, Differentiating Between Local Cytotoxicity, Mitogenesis, and Genotoxicity in Carcinogen Risk Assessments: The Case of Vinyl Acetate, 140–141 Toxicology Letters 83 (2003).

[7] Texas Commission on Environmental Quality, Vinyl Acetate, Development Support Document (Final, Sept. 4, 2015), available at https://www.tceq.texas.gov/downloads/toxicology/dsd/final/vinylacetate.pdf; see also TCEQ.

[8] C.R. Kirman, W. Dekant, V.L. Dellarco, M.L. Dourson, J.E. Klaunig, T.W. Simon, S.M. Hays, 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, 171 Regulatory Toxicology and Pharmacology 106170 (2026), available at https://doi.org/10.1016/j.yrtph.2026.106170. The authors disclose that the review managers (C.R. Kirman and S.M. Hays of SciPinion) received financial support from the Vinyl Acetate Council and that the five panelists were compensated through SciPinion. The panel was recruited and run through a triple-blinded process, in which the sponsor did not know who the panelists were, the panelists did not know who the sponsor was, and the panelists did not know each other's identities. Each panelist stated that he or she had no conflict of interest. Id. § 2.1, § 3.1 & Declaration of Competing Interest.

[9] Explanatory Document at 9.

metabolite."[10] Given the central role of acetaldehyde in vinyl acetate's mode of action, this difference warrants scientific justification. HCPA asks OEHHA to address the relationship between vinyl acetate and acetaldehyde expressly and to explain how the proposed NSRL aligns with OEHHA's existing cancer risk assessment for acetaldehyde.

- *Route of exposure should be considered.* Under § 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 residual vinyl acetate monomer, a volatile compound, from household and commercial products would be expected to occur primarily by inhalation and skin contact. OEHHA's database includes an inhalation bioassay, and although OEHHA's workshop slides state that no route-specific pharmacokinetic differences were identified, the tumors observed at the site of first contact differ by route, and differences in absorption, metabolism, and target-tissue dose may significantly affect cancer risk across routes. HCPA asks OEHHA to explain why 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.

- *Other regulatory benchmarks indicate substantially higher tolerable exposures.* The European Union authorizes vinyl acetate as a monomer in plastic food contact materials subject to a specific migration limit (SML) of 12 mg per kg of food. EU migration limits are set on the conventional assumption that a person weighing 60 kg consumes 1 kg of food in contact with plastic each day, so the SML corresponds to a permitted oral intake of up to 12,000 μg/day of vinyl acetate, more than 1,000 times the proposed NSRL.[11] The SML is set under a different regulatory

[10] § 25705(b) (acetaldehyde, 90 μg/day (inhalation)). The molar conversion uses molecular weights of 86.09 g/mol for vinyl acetate and 44.05 g/mol for acetaldehyde: 11 μg/day × (44.05 ÷ 86.09) ≈ 5.6 μg/day of acetaldehyde, and 90 ÷ 5.6 ≈ 16. See also OEHHA, Evidence on the Carcinogenicity of Vinyl Acetate (2024), at 84.

[11] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended, Annex I, Table 1 (FCM substance No. 231, vinyl acetate, CAS No. 108-05-4, SML 12 mg/kg), and recital 34 (conventional assumption that 1 kg of food is consumed daily by a person of 60 kg body weight); see also European Chemicals Agency, Union List of Authorised Substances, Annex I, Plastics Food Contact Regulation 10/2011/EU, available at

framework and is not a Proposition 65 risk level. Still, a gap of that size for ingestion, which is not an intended route of exposure for most household and commercial products, reinforces the need for OEHHA to confirm that the proposed NSRL is not overly conservative.

- *Internal inconsistencies should be corrected.* Several items in the Explanatory Document should be reconciled so the record is accurate: (i) the lifetime average daily doses stated in the text for male F1 Wistar rats (64.16 and 320.82 mg/kg-day) differ from those in Table 5 (48.00 and 240.02 mg/kg-day), which are the values produced by the Table 4 inputs; (ii) the notes to Tables 1 and 2 define "**" as $p < 0.1$, whereas the note to Table 3 defines it as $p < 0.01$; and (iii) the male Wistar rat multisite model includes pancreatic exocrine adenoma, for which Table 2 reports a non-significant trend and a non-monotonic response (6/86, 14/64, 4/82), without explaining its inclusion.
- *The underlying data and modeling should be made available.* The EPL (1982) pathology report addendum on which the critical study relies, and OEHHA's benchmark dose modeling inputs and outputs for each study, should be placed in the rulemaking file so that stakeholders can evaluate the derivation.

HCPA recognizes that businesses benefit from having a safe harbor level in place promptly, and does not ask OEHHA to delay. Although § 25701(a) preserves the ability of businesses to rely on other scientifically valid assessments, an adopted NSRL functions in practice as the benchmark against which exposures are judged in enforcement, and a value set lower than the science supports will drive warnings that convey little useful information to consumers. Because the vinyl acetate NSRL is likely to be relied upon for many years, it should rest on a sound scientific record. HCPA asks OEHHA to address the issues above before issuing a formal proposal.

Proposed Section 25901 (Vinyl Acetate Exposure Information)

HCPA strongly supports proposed § 25901. It reflects the point made in OEHHA's December 23, 2025, information letter that vinyl acetate polymers and copolymers are not listed chemicals and that the presence of a polymer in a product does not

https://echa.europa.eu/plastic-material-food-contact/-/legislationlist/details/EU-PLST_FCM-ANX_I_AUTHORIS-100.003.224-VSK-24A187.

demonstrate exposure to the listed monomer.[12] It is also consistent with the Attorney General's certificate-of-merit regulations, which require "documentation of exposure to a listed chemical."[13] Placing this principle in regulation will deter notices premised on test methods that do not reflect actual exposure, and HCPA appreciates OEHHA's decision to address it together with the NSRL. HCPA recommends the following refinements:

- *Include the core principle in the regulatory text.* The Explanatory Document indicates that "[t]he fact that a consumer product contains a vinyl acetate-based polymer or copolymer is not, by itself, factual information sufficient to establish a potential exposure to vinyl acetate." That sentence, which also appears in the information letter, states the rule most clearly and should be included in § 25901 itself. Consistent with HCPA's recommendation below to extend § 25901 beyond consumer product exposures, the regulatory text should refer to "a product" rather than "a consumer product."
- *Retain the "dissolving" standard from the information letter.* The information letter advised that a test "should not … reflect the amount of vinyl acetate obtained from dissolving vinyl acetate-containing polymers in a manner which would not otherwise occur during the foreseeable use, purchase, storage, maintenance, or repair of the product." The draft regulation refers only to monomer "resulting from the breakdown of vinyl acetate-containing polymers." A total-content method that dissolves or digests the polymer matrix can liberate residual monomer entrapped in the polymer that would not be released during use; that may not be "breakdown" of the polymer, but it overstates exposure in the same way. HCPA recommends that the text exclude monomer "liberated by dissolving, digesting, extracting, or breaking down" vinyl acetate-containing polymers or copolymers in a manner that would not otherwise occur during an exposure.
- *Focus on measurements during the actual exposure.* The information letter stated that "[t]he ideal test for this chemical would reflect the amount of vinyl acetate

[12] OEHHA, Proposition 65 – Information Letter, Exposures to Vinyl Acetate from Consumer Products (Dec. 23, 2025), available at https://oehha.ca.gov/sites/default/files/media/2025-12/vinylacetateletter122325.pdf.

[13] Cal. Code Regs., tit. 11, § 3101(a).

released from the product during use or at other times when people could be exposed." HCPA recommends that § 25901 follow this approach, for example by basing the required factual information on the amount of vinyl acetate released under reasonably foreseeable conditions of use, as measured by emission, headspace, or migration testing.

- *Extend the provision beyond consumer product exposures.* The draft text is limited to a "consumer product exposure" as defined in § 25600.1(e). Many HCPA member products, including janitorial, institutional, and automotive service products, are used by workers at their place of employment, and § 25600.1 separately defines occupational exposure (subsection (k)) and environmental exposure (subsection (f)). The scientific principle is the same regardless of the setting. HCPA recommends that the final clause refer to monomer that "would not otherwise occur during a consumer product, occupational, or environmental exposure, as defined in section 25600.1."

- *Apply the principle to exposure determinations generally.* As drafted, § 25901 addresses only the factual information supporting a certificate of merit. The same principle should govern whenever the existence or level of a vinyl acetate exposure is determined, including in litigation following a notice and in a business's own compliance assessment. Under § 25102(i), to "expose" means to cause a person to "ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical." Monomer that is liberated only by laboratory dissolution or digestion of a polymer is not monomer with which any person comes into contact. HCPA asks OEHHA to make clear, in the text or in the Final Statement of Reasons, that the principle is not limited to the certificate-of-merit stage and applies equally in determining whether a person has been exposed to vinyl acetate within the meaning of Health and Safety Code section 25249.6, and to consider a cross-reference in the exposure assessment provisions of Article 7.

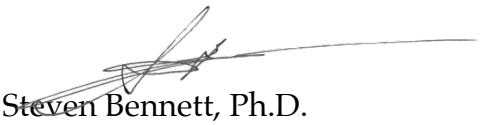
- *Avoid a negative inference for other listed monomers.* OEHHA acknowledges that other listed monomers may be components of unlisted polymers and present similar testing issues. Several listed carcinogens, including styrene, vinyl chloride, acrylonitrile, and 1,3-butadiene, are monomers for widely used polymers. HCPA recommends that OEHHA make clear that no negative inference should be drawn

for other monomers from the vinyl acetate–specific scope of § 25901. Because a court construing the regulation will look first to its text, HCPA recommends adding a sentence to § 25901 such as: "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 a minimum, OEHHA should confirm this point in the Final Statement of Reasons. HCPA also asks OEHHA to consider a general provision for listed monomers in unlisted polymers in a future omnibus rulemaking.

Conclusion

HCPA appreciates OEHHA's engagement on vinyl acetate and supports moving promptly to formal rulemaking on both the NSRL and § 25901, with the refinements described above. HCPA respectfully requests the opportunity to meet with OEHHA scientific staff, together with interested member companies, to discuss the NSRL derivation before a formal proposal is issued. Please direct any questions regarding these comments to the undersigned.

Sincerely,



Steven Bennett, Ph.D.
Executive Vice President, Scientific & Regulatory Affairs