



Proposed Proposition 65 “No Significant Risk Level” (NSRL) for Vinyl Acetate

Public Workshop on Draft Pre-Rulemaking Proposal
September 30, 2026

Outline

- Overview of the workshop process, Proposition 65, and NSRL development.
- Present the basis for the draft NSRL proposal for vinyl acetate.
- Present other proposed regulatory text related to vinyl acetate.
- Receive feedback.

The draft text is available online. This meeting is being recorded. Written comments are welcome.



Workshop Overview

- This is a pre-regulatory workshop **for discussion purposes only**. If some or all of the proposal is included in a rulemaking, the text may be different. OEHHA does not promise any future rulemaking actions.
- Do not rely on the discussion draft, which does not supersede existing laws and regulations.
- Although OEHHA provides guidance on Proposition 65 for the convenience of the public, OEHHA does not provide legal advice.



Instructions for Public Comment

- For Zoom Webinar attendees:
 - When the public comment period begins, click **Raise Hand**  in the Zoom webinar controls.
 - Unmute yourself when prompted.
 - Click “Raise Hand” again to lower your hand when you have finished speaking or your time has concluded.
- Comments are limited to three minutes or less per speaker.



Proposition 65: The Safe Drinking Water and Toxic Enforcement Act of 1986

- Requires California to publish a list of carcinogens and reproductive toxicants.
- Includes limits on release or discharge of a listed chemical where it “passes or probably will pass into any source of drinking water...”
- Prohibits knowingly and intentionally **exposing anyone to a listed chemical “without first giving clear and reasonable warning...”**



Prop 65 Safe Harbor Levels for Carcinogens

- OEHHA issues “No Significant Risk Levels” (NSRLs) for carcinogens
 - i.e., safe harbor levels of exposure which do not require a warning.



Scientific Process for Developing an NSRL

- Cancer potency estimation
 - A chemical's cancer potency estimate is an independent measure of a chemical's ability to cause cancer.
- Risk-specific intake level calculation
 - The NSRL is the daily intake level calculated to result in one excess case of cancer in a population of 100,000 exposed individuals (Section 25703).



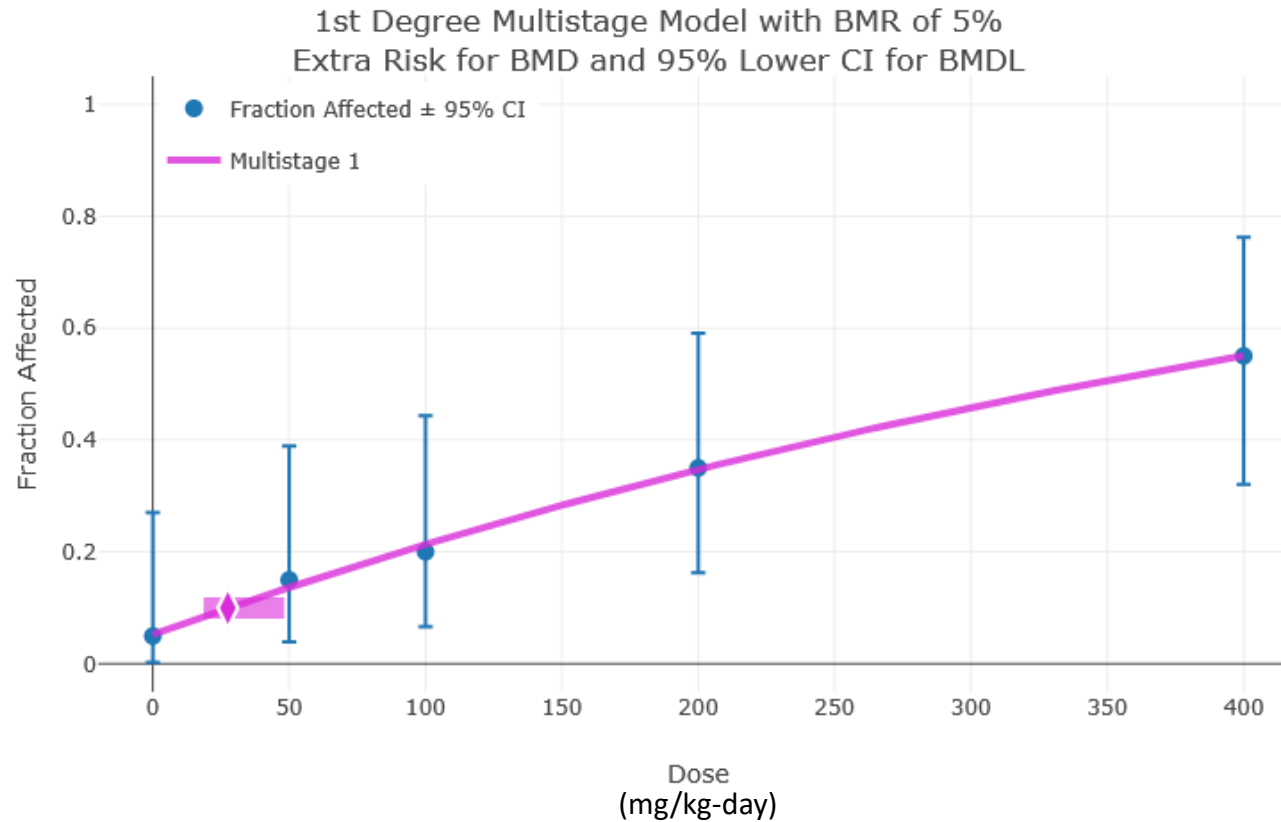
Model approach to cancer potency estimation

- Used the multistage polynomial model for cancer in US EPA's Benchmark Dose Software to derive cancer potency estimates.



Dose-Response Assessment: Example

- A chemical's likelihood of causing cancer depending on the dose received.



Proposed Vinyl Acetate NSRL

Vinyl acetate was added to the Proposition 65 list for cancer on January 3, 2025



Vinyl Acetate

- Vinyl acetate is a synthetic chemical with a high production volume.
- It is used as a monomer in the production of polymers and copolymers.
 - These polymers are used in adhesives, heat sealing films, paper coatings, textile and leather finishings, plastics, resins, paints, inks, lacquers, pesticides, and cosmetics.
- Vinyl acetate is approved as a food additive.
 - Vinyl acetate-based polymers have been approved as food additives for use in chewing gum bases.



Vinyl Acetate Studies Considered for Cancer Potency Estimation

13 animal studies of vinyl acetate with tumor findings reported ([OEHHA 2024](#))

- 1 inhalation study in male rats
- 12 drinking water studies
 - 8 studies in rats
 - 4 studies in mice



Pharmacokinetic Considerations

- No route-specific differences were identified
 - Rapidly absorbed and widely distributed following both inhalation and oral administration
 - Majority of radiolabeled products were excreted into expired air regardless of exposure route (inhalation or gavage)



Study Selection for Dose-Response Analysis

Considered studies that had:

- A higher incidence of tumors across more tissue sites
- Tumors at multiple administered concentrations
- Tumors at lower administered concentrations



Five Animal Studies Selected for Dose-Response Analysis

- Male F1 Wistar rats (Belpoggi et al. 2002)
- Female F1 Wistar rats (Belpoggi et al. 2002)
- Male and female F1 Swiss mice (Maltoni et al. 1997)
- Female F1 Swiss mice (Maltoni et al. 1997)
- Female F344 rats (Lijinsky and Reuber 1983; EPL 1982)

The NSRL shall be based on the most sensitive study deemed to be of sufficient quality (Section 25703)



Cancer Potency Values

Publications	Sex/ Strain/ Species/ Tumor sites	CSF _{animal} (mg/kg-day) ⁻¹	CSF _{human} (mg/kg-day) ⁻¹
Belpoggi et al. (2002)	Female F ₁ Wistar rats Lymphoma and leukemia, Oral cavity SCC, Tongue SCC, Esophagus SCC, Forestomach SCC, Uterine adenocarcinoma	0.00252	0.0098
	Male F ₁ Wistar rats Oral cavity SCC, Pharynx SCC, Esophagus SCC, Forestomach SCC, Pancreas exocrine adenoma, Adrenal gland pheochromoblastoma	0.00740	0.025
EPL (1982), Lijinsky and Reuber (1983)	Female F344 rats Liver adenomas, Uterine adenocarcinoma, Uterine endometrial stromal polyps, Thyroid C-cell adenoma, Pituitary adenoma	0.0160	0.065
Maltoni et al. (1997)	Female F ₁ Swiss mice Oral cavity SCC, Tongue SCC, Esophagus Acanthoma, Esophagus SCC, Forestomach SCC, Uterine Leiomyosarcoma, Mammary gland liposarcoma, Zymbal gland carcinoma	0.00292	0.019
	Male F ₁ Swiss mice Oral cavity SCC, Tongue SCC, Esophagus SCC, Forestomach Acanthoma	0.00160	0.010

SCC: Squamous cell carcinoma



Calculation of Vinyl Acetate NSRL

- The NSRL can be calculated from the cancer slope factor as

$$\text{NSRL} = \frac{10^{-5} \times 70 \text{ kg}}{\text{cancer potency}} \times 1000 \text{ } \mu\text{g}/\text{mg}$$

- Cancer potency: $0.065 \text{ (mg/kg-day)}^{-1}$
- Daily intake posing 1 in 100,000 lifetime risk of cancer (NSRL):
11 $\mu\text{g}/\text{day}$



Additional Proposed Text

“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 must provide facts showing exposure to the listed vinyl acetate monomer, CAS no. 108-05-4. If such factual information includes the concentration of vinyl acetate monomer in a product, that concentration must not include the amount of vinyl acetate monomer resulting from the breakdown of vinyl acetate-containing polymers in a manner which would not otherwise occur during a consumer product exposure, as defined in Cal. Code Regs., tit. 27, section 25600.1.”



Instructions for Public Comment

- For Zoom Webinar attendees:
 - When the public comment period begins, click **Raise Hand**  in the Zoom webinar controls.
 - Unmute yourself when prompted.
 - Click “Raise Hand” again to lower your hand when you have finished speaking or your time has concluded.
- Comments are limited to three minutes or less per speaker.



Comment/Discussion

