



A Manufacturer's Guide to California Prop 65: Listing, Delisting, Safe Use Determinations, and Interpretive Guidelines

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Since 1986, the California law commonly known as “Prop 65” (the Safe Drinking Water and Toxics Enforcement Act) has required companies doing business in the state to provide “clear and reasonable” warnings before exposing residents to chemicals that are known to cause cancer, birth defects, or other reproductive harm. Prop 65 currently regulates approximately 900 chemicals, including chemicals present in common consumer products, foods, and buildings; some of our most commonly used materials, such as plastics, metals, and lumber; and byproducts of chemical processes.¹ The level of potential exposures in California to chemicals on the Prop 65 list must not only be below the standards established under this California law, but this same list of chemicals has been adopted by other North American and global regulatory authorities and NGOs as the foundation for their own regulations. Accordingly, the inclusion of a chemical onto the Prop 65 list significantly limits a chemical's use in the marketplace and triggers the need for manufacturers to perform due diligence to understand the specific chemicals included in a product's formulation and all chemicals produced as byproducts. When appropriate, concerned companies can also provide the Office of Environmental Health Hazard Assessment (OEHHA) with scientific data that demonstrates why a chemical should not be listed; why a formerly listed chemical should be delisted; or request that a Safe Use Determination (SUD) or Interpretive Guideline (IG) be issued.

A chemical can be added to the Prop 65 list in several ways. First, chemicals can be listed by the “State's Qualified Experts,” either through the Carcinogen Identification Committee (CIC) or the Developmental and Reproductive Toxicant Identification Committee (DARTIC). As both committees allow public input on the potential of the hazards for chemicals being considered, companies can provide scientific arguments and evidence for why chemicals do not meet the standards for listing under Prop 65. Testimony in front of a scientific panel can also potentially impact the decisions of the state's expert committees to list a compound.

Alternatively, chemicals can be listed without a CIC or DARTIC independent evaluation if an “authoritative body” that has been identified by either committee has listed

the chemical. The U.S. Environmental Protection Agency (EPA), U.S. Food and Drug Administration (FDA), and International Agency for Research on Cancer (IARC) are three examples of “authoritative bodies” under Prop 65. If an authoritative body made a mistake when classifying a compound, or if it used outdated data or erroneous references, a manufacturer can provide information and scientific data to debate the proposed chemical listing. Another listing mechanism, the “labor code” mechanism, automatically results in listings if chemicals are classified on specific lists established by regulatory authorities and identified in Prop 65. Unfortunately, scientific debate is considerably limited when it comes to this mechanism for Prop 65 listing.

¹ <https://oehha.ca.gov/proposition-65/general-info/proposition-65-plain-language>

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Once a chemical has been listed on Prop 65, attempts to delist it can be lengthy and complicated, but the advantages to not being on the Prop 65 list are often worth the effort for companies with financial stakes in the chemical. Those companies who have successfully delisted chemicals have done so by 1) proving that a regulatory agency's historical conclusions for listing are no longer sufficient or 2) providing new study data that counters the conclusions that led to the original listing.

Some manufacturers have had recent success requesting either an SUD or IG for their products. An SUD is a written statement issued by OEHHA that determines under what conditions the typical use of a specific product or chemical requires a Prop 65 warning. An SUD establishes an authoritative conclusion about how compliance can be followed for a particular product type and chemical combination moving forward. An IG is an interpretation by OEHHA on how a particular issue within the assessments of compliance under Prop 65 should be approached. The subjects of IGs have ranged widely, from the amounts of chemicals that should be allowed in food products to how to determine what is "naturally occurring" or "hand-to-mouth" exposure.

Compliance under Prop 65 is not easy, and enforcement is based on litigation, so experts are often needed for guidance. Processes such as those leading to listing, delisting, safe harbor levels, SUDs, and IGs typically require regulatory and scientific experts and regulatory knowledge regarding this very unusual and challenging state law. Exponent has the largest Prop 65 consulting group of its kind with the toxicology and epidemiology expertise needed to perform the science under Prop 65 and the regulatory expertise required to help resolve a manufacturer's concerns under the Prop 65 law.



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