

## Proposition 65 Qualifications



**ToxStrategies is a multidisciplinary scientific consulting firm that strives to develop innovative solutions to address the scientific, technical, and regulatory challenges confronting our clients. We have a reputation for applying sound science in all that we do, for leading-edge thinking, and for tailoring our approach to meet the specific needs of our clients, whether a rapid response or a comprehensive analysis is needed.**

ToxStrategies has California-based staff and decades of experience assisting clients, including their internal or external counsel, who may be subject to the requirements of Proposition 65 or involved in litigation. ToxStrategies is a leading firm providing Proposition 65 expertise, with toxicologists who understand the calculation of safe harbor levels, exposure experts with experience conducting human-use exposure simulations, and scientists who regularly assess chemical exposures via food.

**California's Proposition 65, officially known as the Safe Drinking Water and Toxics Enforcement Act of 1986, established two primary requirements:**

1. Prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water.
2. Requires businesses to provide warnings to Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm.

The Office of Environmental Health Hazard Assessment (OEHHA) is charged with implementing the requirements of Proposition 65. While perhaps well intentioned, Proposition 65 has spawned a slew of unintended consequences and significant litigation, greatly affecting companies doing business in California

**ToxStrategies has assisted clients in evaluating a variety of situations relevant to Proposition 65:**

- Air emissions
- Environmental exposures
- Food or food-contact products
- Household consumer products
- Industrial products
- Medical devices

**Our specific project experience includes:**

### Safe Harbor Levels

- Evaluation of safe harbor levels (i.e., no-significant-risk levels [NSRLs] for carcinogens, and maximum allowable daily limits [MADLs] for reproductive toxicants) derived by OEHHA
- Derivation of safe harbor levels consistent with statutory requirements, when none exist or as alternatives to OEHHA-derived values
  - Weight-of-evidence (WOE) assessments of carcinogenicity and/or reproductive toxicity
  - Mode-of-action (MOA) analyses to support a non-linear dose-response extrapolation, when warranted
  - Publication of analyses in peer-reviewed scientific literature

### Exposure Assessment

- Estimate daily exposure consistent with statutory requirements, using a tiered approach
  - Default and/or literature-based assumptions when sufficient to demonstrate that potential exposure is below the safe harbor level, including the use of information developed by OEHHA in their safe use determinations (SUDs)
  - Exposure models to evaluate ingestion (direct or via hand-to-mouth contact), dermal contact, or inhalation exposure
  - Exposure simulations when necessary to provide more realistic estimates of real-world exposure



## Summary of Significant and Recent California Proposition 65 Projects

Type of Exposure	Chemicals	Safe Harbor Level Calculated?	Analysis
Air emissions - Airborne emissions affecting community exposure	Hexavalent chromium	No	Served as testifying expert regarding industrial emissions, Prop 65 risk assessment and toxicology
Air emissions-Airborne exposures from stack emissions among residents	Nickel, arsenic, hexavalent chromium, cobalt, titanium dioxide, antimony, vanadium, lead, cadmium	Yes: MADL for oral Cr(VI) exposure and NSRLs for cobalt metal, titanium dioxide, antimony and vanadium by inhalation	Comprehensive analysis of air emissions and dispersion/deposition modeling for use in Prop 65-specific risk assessment
Consumer product	Beta-myrcene	Yes: NSRL	Evaluated the dose-response and calculated NSRLs for multiple cancer endpoints based on toxicology study
Consumer product-Confidential household product	Confidential	No	Participated in a comprehensive assessment of exposure to a residual contaminant in a consumer product, including design and conduct of experimental studies with radiolabeled compound to estimate transfer from the product to skin or food. Detailed information on habits and practices associated with routine use of the product was collected via a consumer diary study.
Consumer product-Dermal contact with cables used in household and office products	Lead	No	Conducted a detailed exposure assessment for lead in a wide variety of cables. Designed experimental studies to measure human exposure to lead from handling cables including transfer of lead from cables to hands during typical use. Also evaluated preliminary plaintiff studies.
Consumer product-Residents using a household product	Hexachloro-benzene	No	Developed household exposure model for use of spray product
Consumer product-Storage containers	Styrene, ethylbenzene, toluene	No	Assessed need for labeling due to potential off-gassing from plastic container when used and stored in warm conditions. Performed an exposure assessment and compared the results against the safe harbor levels.
Environmental-Contaminated groundwater-off-site exposures by vapor intrusion	TCE, PCE, 1,2-DCE and vinyl chloride	No	Extensive monitoring and modeling analysis of off-site buildings to evaluate Prop 65 compliance
Environmental-Golf course treated with herbicides	Glyphosate, Fluziafop-P	Yes: MADL developed for Fluziafop-P	Assessed exposures and requirement to warn associated with exposures to herbicide applicators, construction crew and future site users (grounds keepers, golfers), and off-site populations (residential) associated with treatment and redevelopment of a golf course
Food-Household product involving food contact	Confidential	No	Assisted in design and conduct of studies measuring transfer of chemical to food or skin and consumer use survey to provide inputs to exposure model; conducted Prop 65 risk assessment
Food-Food packaging material	Confidential	Yes: NSRL	Developed an exposure model to estimate exposure via ingestion of food contacting packing material and with dermal contact and conducted Prop 65 risk assessment
Food-Beverage	Confidential	Yes: NSRL	Evaluated the dose-response and calculated NSRLs for multiple cancer endpoints based on toxicology study
Food-Beverage	Multiple	No	Developed proactive approach to evaluating beverage ingredients within the context of Prop 65
General-Inhalation of particulates	Titanium Dioxide	Yes: NSRL developed using linear and non-linear models	Developed quantitative cancer risk assessment for titanium dioxide, published in Regulatory Toxicology and Pharmacology (Thompson et al. 2016)
Industrial product-Lubricant	Confidential	No	Estimated allowable chemical concentration in final product to ensure estimated exposure would be below safe harbor level
Industrial Product-Worker exposure while handling building materials	Dioxin, crystalline silica	Yes: NSRL for crystalline silica	Exposure simulation, Prop 65-specific health risk assessment
Medical Devices	Metals, VOCs and PAHs	Yes: NSRL developed for cobalt	Assessed need for labeling due to exposure by leaching and off-gassing of Proposition 65 chemicals from 14 medical devices for exposure during patient use and handling by medical professionals.

