

# CALIFORNIA

# PROPOSITION 65

## PHARMACEUTICALS & MEDICAL DEVICES

### California Prop 65 Compliance

California Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, was developed to protect consumers in California from exposures to reproductive/developmental toxicants and potential cancer-causing substances. This program is administered by the California Office of Environmental Health Hazard Assessment (OEHHA), which can require a “clear and reasonable warning” on products containing a listed carcinogen or reproductive or developmental toxicant. For only some of these chemicals has OEHHA proposed or promulgated “safe harbor levels”, which include No-Significant-Risk-Levels (NSRLs) for carcinogens and Maximum-Allowable-Dose-Levels (MADLs) for developmental and reproductive toxicants. The NSRLs and MADLs are regulatory benchmarks to which chemical exposure estimates may be compared. Safe harbor levels may also be based on risk assessments conducted outside of OEHHA.

**toXcel** staff have extensive experience in assessing Proposition 65-related exposures to chemicals in a variety of products, including antimicrobial chemicals, crop protection chemicals, residential use pesticides, cosmetics, personal care products, indoor air care products, cleaning and laundry products, medical devices, and other categories of consumer products. **toXcel** routinely develops product-specific exposure assessments in advance of regulatory or other actions against a product in order to provide insurance against these actions.

toXcel can:

- **Use** exposure models to determine product compliance with Proposition 65
- Implement model refinements to avoid Proposition 65 warning labels
- Submit dissenting opinions to California OEHHA on proposed draft NSRLs and MADLs
- Submit dissenting opinions to OEHHA regarding the validity of the listing of specific chemicals
- Engage in discussions and negotiations with California OEHHA staff scientists and regulators
- Develop de novo NSRLs and MADLs for use in risk assessments

**toXcel** has been successful in defending clients against Proposition 65 actions, and is one of the few companies that has ever been able to successfully suspend OEHHA action on a listed chemical and to get a chemical de-listed from the Proposition 65 list. In the few cases where warning labels are unavoidable, toXcel can help clients identify an appropriate warning strategy and can develop the least damaging yet compliant warning statement language.

For further discussion on how **toXcel** please contact Alan Katz at 703-754-0248 extension 111 or by email at [Alan.Katz@toxcel.com](mailto:Alan.Katz@toxcel.com).

### **toXcel, LLC**

7140 Heritage Village Plaza  
Gainesville, Virginia 20155  
USA

Phone: 703-754-0248 x111  
Email: [Alan.Katz@toxcel.com](mailto:Alan.Katz@toxcel.com)

### **toXcel International Ltd.**

P.O. Box 93  
Ledbury, HR8 9JE  
United Kingdom

Phone: +44 (0) 1531 638999  
E-mail: [Christine.McAlinden@toxcel.co.uk](mailto:Christine.McAlinden@toxcel.co.uk)

[www.toxcel.com](http://www.toxcel.com)