

# Proposition 65 and Alcohol

*This article is intended for general information purposes only and should not be construed as legal advice or legal opinions on any specific facts or circumstances.*

**WHAT IS PROPOSITION 65?** The Safe Drinking Water and Toxic Enforcement Act was approved by California voters in 1986 and is known today as Proposition 65. It requires the State of California to publish a list of chemicals and substances known to cause cancer or birth defects or other reproductive harm. Proposition 65 is administered by the Office of Environmental Health Hazard Assessment (OEHHA). To date, OEHHA has listed over 900 chemicals, including naturally occurring and synthetic chemicals present in foods, beverages, pesticides, commonly used household products and personal care products, and more. Proposition 65 is a right-to-know statute; it does not prohibit businesses from selling anything in California. Rather, it requires businesses to provide a “clear and reasonable” warning to Californians before knowingly and intentionally exposing them to a listed chemical or substance. This warning must be given for listed chemicals and substances unless exposure is low enough to pose no significant risk of cancer, or is significantly below levels observed to cause birth defects or other reproductive harm.

**PROPOSITION 65 AND ALCOHOLIC BEVERAGES.** OEHHA listed alcohol under Proposition 65 over two decades ago, first listing “ethyl alcohol in alcoholic beverages” as a reproductive toxicant in 1987, then “alcoholic beverages when associated with alcohol abuse” as a carcinogen in 1988, and most recently, “alcoholic beverages” as a carcinogen in 2011.

**SAFE HARBOR LEVELS.** For chemicals listed as carcinogens, the “no significant risk level” (NSRL) is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 people exposed to the chemical over a 70-year lifetime. For chemicals listed as reproductive toxicants, the “no observable effect level” is determined by identifying the level of exposure that has been shown to not pose any harm to humans or laboratory animals. This number is then divided by 1,000 to establish the “maximum allowable dose level” (MADL). OEHHA has established NSRLs and MADLs known as “safe harbors” for some, but not all, of the listed chemicals. If your product contains a Proposition 65 listed chemical at levels below the

established safe harbors, you do not need to provide a warning.

**NO SAFE HARBOR GUIDANCE FOR ALCOHOL.** OEHHA has not established safe harbors for any of the Proposition 65 alcohol listings. Businesses that expose individuals to a Proposition 65 listed chemical that does not have an established safe harbor must either provide a Proposition 65 warning, or must show that the exposure level will not pose a significant risk of cancer or reproductive harm. Determining the anticipated exposure level is not a simple endeavor and often requires an expensive scientific exposure assessment.

**SAFE HARBOR WARNING FOR ALCOHOLIC BEVERAGES.** The current regulations provide the following tailored “safe harbor” warning for alcoholic beverages:

**WARNING:** Drinking distilled spirits, beer, coolers, wine and other alcoholic beverages may increase cancer risk, and, during pregnancy, can cause birth defects. For more information go to [www.P65Warnings.ca.gov/alcohol](http://www.P65Warnings.ca.gov/alcohol).

**HOW TO WARN.** Although most manufacturers may apply Proposition 65 warnings directly to product labels, this is not the case for alcoholic beverages. Why? All alcoholic beverage labels must be approved by the Federal Alcohol & Tobacco Tax and Trade Bureau (TTB) and contain the federal warning on the products. The federal warning is not the same as—and is not compliant with—the Proposition 65 warning requirements and thus does not provide a safe harbor under California law. The above warning does not apply to non-alcoholic beverages.

For **retail sales of alcoholic beverages in stores**, businesses may warn by (1) posting the above warning on an 8 ½ x 11-inch sign in at least 22-point font, placed at eye level so it is conspicuous to customers upon entering the area where alcoholic beverages are sold, or by (2) posting the above warning on a 5 x 5-inch sign in at least 20-point font, placed at each retail point of sale or display so it is conspicuous to customers. For **alcohol provided for consumption on premises, or sold over-the-counter**, the above warning language must be provided on the drink menu. For **alcohol sold or distributed within California through delivery services**, warning must be placed on or in the shipping container/delivery package, in a font at least as big as the rest of the text on the package (and at least 8-point font).

**DOES PROPOSITION 65 APPLY TO YOUR PRODUCT?** If an alcoholic beverage is sold in California, Proposition 65 applies. The place of manufacture does not matter. If you violate Proposition 65’s warning requirements, you risk facing significant monetary penalties and attorneys’ fees from the robust and active plaintiffs’ bar with penalties of

up to \$2,500 per exposure. Any California citizen can bring a Proposition 65 enforcement action in the public interest after first serving a 60-day notice on the alleged violator. Because the burden of proof is on the defendant to prove that the level of exposure to the noticed chemical does not pose a significant risk of cancer or reproductive harm, and because this is often prohibitively expensive to prove, the majority of private actions settle.

**PROPOSITION 65 AND NON-ALCOHOLIC BEVERAGES:** While Proposition 65 is nothing new for the alcoholic beverage industry, Proposition 65 private enforcers have recently targeted traditionally non-alcoholic products based on the alcohol-related Proposition 65 chemicals. Several kombucha retailers and manufacturers have recently been served with notices of violation based on alleged exposure to “ethyl alcohol in alcoholic beverages” and “alcoholic beverages.” In many cases, kombucha is not produced or marketed as an alcoholic beverage, but trace amounts of alcohol may result from the fermentation process, none of which are knowingly or intentionally added to the product before sale. Proposition 65 does not define alcoholic beverage. Rather, it is defined in the Alcoholic Beverage Control Act as containing 0.5% alcohol by volume or more. *See* CA Bus. & Prof. Code § 23004. It is yet to be seen how the plaintiffs’ bar will attempt to tie the 0.5% ABV definition to Proposition 65, a potential safe harbor level, or the risk of cancer or reproductive toxicity. In the meantime, it is important to have a comprehensive compliance program in place with regular product testing.




**Greenberg Traurig is well qualified to provide experienced and effective advocacy in all types of Proposition 65 matters,** including political, as well as legal and financial, components. We have key relationships with OEHHA, the attorney general’s office, the governor’s office and the few consultants who interpret the science used in both the listing process and enforcement actions.

**GREENBERG TRAUIG CAN HELP WHEN:**

California proposes to place a chemical on the state’s list of known carcinogens and reproductive toxicants; when you stand accused of discharging a listed chemical into state waters or exposing Californians to a listed chemical without warning; and to help you create and maintain a comprehensive Proposition 65 compliance program.

Our experience includes:

- Lobbying the California State Legislature to adopt a rational safety factor for reproductive toxicants;
- Monitoring every meeting of the advisory panels and identification committees that decide to list chemicals;
- Working with the Office of Environmental Health Hazard Assessment (OEHHA) to ensure fair risk assessments;
- Helping develop applications to OEHHA for determinations that certain uses of listed chemicals are safe without a warning;
- Defending numerous enforcement actions by the Attorney General and private plaintiffs to favorable resolutions;
- Defending businesses and trade groups in actions targeting industries or consumer products, including food, beverage, and pharmaceuticals;
- Prevailing in the California Supreme Court on federal preemption of Proposition 65 warning requirements for some FDA-regulated products;
- Working with many industry scientists and compliance officers to identify Proposition 65 liabilities and develop realistic solutions; and
- Marshaling legal argument and scientific data to convince OEHHA and its identification committees that certain chemicals should not be listed as carcinogens or reproductive toxicants.

		
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