

Prop 65 Warning Labeling Summary

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Introduction

Proposition 65, officially known as the [Safe Drinking Water and Toxic Enforcement Act of 1986](#), requires businesses to inform Californians about exposures to chemicals that could potentially cause cancer or reproductive harm. Each year the attached chemical list is updated and businesses must inform consumers if any of the 900 plus items may be present in their products above specified limits. Many of these chemicals may occur naturally and are present in common food. Businesses selling products in the State of California complain that Proposition 65 put them at risk for frivolous lawsuits by law firms claiming to be acting in the public interest. It is estimated that the vast majority of litigation proceeds are currently collected by plaintiff attorneys.

In order to protect your brand from litigation, the following phrase may be suggested for the retail label.

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

You may notice that products have multiple variations of the Proposition 65 warning label and often the same product will have a different or no warning. It is the responsibility of the brand to assess the necessity and wording of the Proposition 65 warning label.

Simpson Labs is often asked if it can certify that its products are Proposition 65 compliant. Simpson Labs cannot claim to guarantee Proposition 65 compliance because of the custom nature of our customer's products. The numerous listed chemicals are often found in common food and dietary supplements above Prop 65-allowable levels. These levels are much lower than federal standards and are based on different limits. We at Simpson Labs are happy to test for any of the chemicals on the attached list to ensure compliance and customer satisfaction. This can be done on incoming raw material and/or on finished products. Simpson Labs can offer a post-production Proposition 65 label service if needed. Please inquire about this service if interested.

Resource:

<https://oehha.ca.gov/proposition-65>

Common Consumer Questions about Proposition 65

What is this warning?

Sometimes you will see a product for sale that has a label with a warning along the lines of the following:

This product contains a chemical known to the State of California to cause cancer or reproductive harm.

You may also see this warning at the point of purchase at an online retailer or for a catalog item.

California has two different types of warnings – those for cancer and those for reproductive health effects. Some products have one or the other and some products have both warnings. These are required by California labeling law, Proposition 65 (or Prop 65 for short), which is meant to notify individuals in California of exposures to Prop 65-listed chemicals. Prop 65 does not ban the sale of any products containing these chemicals; it only requires warnings.

What's the difference between cancer and reproductive toxicity?

A chemical listed under Prop 65 as a carcinogen has been shown (often in laboratory animal studies) to cause cancer. A chemical listed under Prop 65 as a reproductive toxin has been shown (again, often in laboratory animal studies) to cause male or female reproductive toxicity or developmental toxicity. These tests are often performed with very high doses of chemicals. NOTE: NOW Foods does not test its products on animals.

Does this law apply everywhere?

The “Prop 65” warnings are only required under California law. Prop 65 standards are among the most stringent in place anywhere and are often far more stringent than federal standards.

What kinds of substances require warnings?

Over 800 chemicals have been listed under California Prop 65. They include pesticides, heavy metals, and Vitamin A at certain levels.

Certain listed chemicals, such as lead, are widely distributed through the environment in air, soil, water, and rocks. As a result, these types of chemicals are often found in commonly eaten foods and throughout the food supply even though these chemicals are not intentionally added to foods or nutritional supplements.

Should I be concerned?

You should always be aware and take heed of all product warnings. Does a Prop 65 warning mean that the product will actually cause cancer or other reproductive harm when the product is used in its typical way? Not necessarily. The listing of a chemical under Prop 65 could be the result of tests on laboratory animals. Prop 65 standards for warnings are often very stringent. For example, for reproductive toxicants, the level for warnings is 1000 times lower than the lowest level at which animal studies reported no reproductive health effect. A Prop 65 warning does not automatically mean that the product is unsafe.

How are these warnings determined?

California has a formal process for adding chemicals to the Prop 65 list. Prop 65 allows chemicals to be listed in various ways, including through reports that are based on animal studies. In many instances, these animal studies involve extremely high dosages of chemicals.

What kinds of substances are we talking about?

Many dietary supplements contain substances that require a warning in California. One vitamin that requires a warning above a certain level is Vitamin A. Incidental contaminants such as lead and mercury also require warnings above a certain level even if they are not added intentionally to a product.

How do the California warnings compare to federal limits?

It should be noted that California product label warning requirements are not usually the same as federal safety requirements. This causes a mismatch between warnings on products sold in California and what is required elsewhere in the U.S.A. So this can explain why sometimes you may see a California Prop 65 warning on a product sold in California but no warning on the same product sold elsewhere. The products are not different; it's just that Prop 65 warnings are required for sales to California consumers.

Additionally, there are various substances that require a California Prop 65 warning at levels that are far more stringent than federal action limits. One example is lead. The Prop 65 standard for warnings for lead is 0.5 micrograms per day, which is far more stringent than federal and international standards.

Why don't all similar products carry the warning?

There could be a variety of reasons. If a company has been involved in a Prop 65 lawsuit and reaches a settlement, that settlement may require Prop 65 warnings for products. Other companies that are not involved in the settlement, although they may sell similar products, may not provide a warning on their product. Inconsistent Prop 65 enforcement sometimes explains why you will see certain products in the market with warnings, and virtually identical products without warnings. Other companies may elect not to provide warnings because, in their assessment, they conclude that they are not required to do so under Prop 65 standards. A lack of

warnings for a product does not necessarily mean that the products are free of the same substances at similar levels.

I have heard of possible changes to Proposition 65 labeling required by California. What are these possible changes?

Currently, most Prop 65 warnings simply state that a chemical is present that causes cancer or reproductive harm, but they do not identify the chemical or provide specific information about how a person may be exposed or ways to reduce or eliminate exposure. With the new proposed requirements, warnings will have to say that the product “can expose” users to a chemical(s).

The new warning requirements may also include these three additional elements:

- The name of at least one listed chemical that prompted the warning.
- Link to the state’s [Prop 65 internet site](#), which includes additional information on the health effects of listed chemicals and ways to reduce or eliminate exposure to them.
- A triangular yellow and black warning symbol (can be white and black only if the label for the product does not use the color yellow). The warning triangle symbol can be downloaded [here](#).

How can I be sure that my label is Proposition 65-compliant?

The best way to ensure label compliance is to have your label proof checked by qualified legal counsel. As a brand you are responsible for the label compliance of your product. Below is some information about enforcement and abuse of Proposition 65.

Enforcement and Abuse of Proposition 65

Enforcement is carried out through [civil lawsuits](#) against Proposition 65 violators. These lawsuits may be brought by the [California Attorney General](#), any [district attorney](#), or certain [city attorneys](#) (those in cities with a population exceeding 750,000). Lawsuits may also be brought by private parties "acting in the public interest," but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation.

A Proposition 65 Notice of Violation must provide adequate information to allow the recipient to assess the nature of the alleged violation. A notice must comply with the information and procedural requirements specified in regulations. A private party may not pursue an enforcement action directly under Proposition 65 if one of the government officials noted above initiates an action within sixty days of the notice. After 2003, private enforcers must also serve a certificate of merit (statement of expert consultation(s) supporting belief of reasonable and meritorious private action) as a means of preventing frivolous enforcement actions.

A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court of law to stop committing the violation.^[10] Other penalties may apply, including unfair business practices violations as limited under [California Proposition 64 \(2004\)](#).

Businesses can become compliant by learning upfront whether or not their products contain chemicals that match the current Proposition 65 list of 910 chemicals. Users can do this by searching in a [Microsoft Excel](#)^[11] chemical list or on a website offering the search by chemical name or [CAS Number](#).^[12] Product manufacturers may also learn if a chemical in their products has been removed from the Proposition 65 list, such as [saccharin](#), removed December 2010.^[13] Alternatively, they can post generic Prop 65 warnings just in case their products contain any listed chemicals.

Some businesses in the state post similar notices on their premises, even when they have not evaluated the actual level of risk from a listed chemical they know is present.^[22] Warning signs are often posted at gas stations,^[23] hardware suppliers,^[24] grocery stores, drug stores, medical facilities, and many other businesses.^{[25][26]} Government agencies,^[27] parking garages, hotels,^[26] apartment complexes,^[28] retail stores,^[29] banks, and restaurants^[30] also post warning signs because of the possibility of hazardous chemicals being present in everyday items or the nearby environment. Some large businesses, such as utility companies, mail a Prop 65 notice to all customers each year to warn them of dangerous substances like natural gas^[31] or the sand used in sandblasting.^[32]

There is no penalty for posting an unnecessary warning sign.^[33] Because of the overuse of the vague warning, the ubiquitous signs ultimately communicate very little information to the end user.^{[23][34]} This problem has been recognized by California courts,^{[35][36]} advocates,^{[23][37]} and businesses.^[26]

Political controversy over the law, including industry attempts to have it [preempted by federal law](#), have died down, although preemption bills continue to be introduced in the U.S. Congress, most recently H.R. 6022 ^[38] (introduced June 6, 2018). However, enforcement actions remain controversial. Most of the Proposition 65 complaints are filed on behalf of [straw man](#) plaintiffs by private attorneys, some of whose businesses are built entirely on filing Proposition 65 lawsuits.^{[35][39][40]}

Proposition 65 has also been criticized because the majority of settlement money collected from businesses has been used to pay plaintiffs' attorney fees.^[41] Businesses paid over \$14.58 million in attorney fees and costs in 2012, 71% of all settlement money paid.^[42]

Labeling requirements conceded the reality that listing and classifying substances did not help the consumer if the contents of a purchase were unknown. At the same time, there were no other labeling requirements to support the proposition. Industry critics and corporate defense lawyers charge that Proposition 65 is "a clever and irritating mechanism used by litigious [NGOs](#) and others to publicly spank politically incorrect opponents ranging from the American gun industry to seafood retailers, etc."^[43]

In addition, because the law allows private citizens to sue and collect damages from any business violating the law, there have been cases of lawyers and law firms using Proposition 65 to force monetary settlements out of California businesses.^[44] The Attorney General's office has cited

several instances of settlements where plaintiff attorneys received significant awards without providing for environmental benefit to the people of California, resulting in the requirement of the Attorney General's approval of pre-trial Proposition 65 settlements.^[45] The Attorney General also objected to efforts in [settlements](#) between private parties to pre-empt the Attorney General's right and duty to protect the [public interest](#) against future violations.^[35]

