



Proposition 65 Guidance

A EUROFINS WHITE PAPER



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The following document is provided to introduce and help food, ingredient, and supplement companies navigate the regulatory and testing challenges that Proposition 65 presents when selling products into the state of California. Be advised that you should consult legal advice prior to initiating a go-to-market strategy.

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What is California Prop 65?

In 1986, California voters approved an initiative to address their growing concerns about exposure to toxic chemicals. The initiative became the Safe Drinking Water and Toxic Enforcement Act of 1986, also known as "Proposition 65" (Prop 65). The state published a list of chemicals known to cause cancer or birth defects or other reproductive harm. The Office of Environmental Health Hazard Assessment (OEHHA) updates this list annually and it now includes over 800 chemicals.

What are the requirements?

Prop 65 requires businesses to notify Californians about significant amounts of the associated chemicals in the products they purchase with 'clear and reasonable' warning labels. These labels will allow Californians to make informed decisions about protecting themselves from exposures to these chemicals. Any business that sells their product in California must be in compliance with Prop 65.

How is Prop 65 enforced?

The law does not ban or restrict the sale of products containing chemicals on the list. If companies meet the requirements of the law through proper disclosure and labeling of products, they are protected from any legal action. Failing to disclose a Prop 65 listed chemical that is over the established safe harbor levels may result in fines up to \$2,500 per violation per day by California Attorney General's Office, as well as potential lawsuits by private parties/citizens.



What are Safe Harbor Levels?

The OEHHA developed 'safe harbor levels' for chemicals contained on the list which allows a business to be exempt from Prop 65 warning requirements if exposure is at or below these levels. These established levels consist of the following:

- No Safe Harbor Level = no exemption
- No Significant Risk Levels (NSRLs) for chemicals listed as carcinogens = exempt
- Maximum Allowable Dose Levels (MADLs) for chemicals listed as causing birth defects or reproductive harm/toxicity = exempt if at or below level

The list of NSRLs and MADLs are provided in a "safe harbor" list for businesses. These NSRLs and MADLs are established in regulation in Title 27, Cal. Code of Regulations, Sections 25705, 25709, and 25805. If a company can provide other means of scientific proof that their product meets safe harbor levels, and prove a low risk, then it is certainly advisable to do this. An example would be to have a certified toxicologist render a conclusion based on facts, testing, and previous claims as to the appropriate Safe Harbors levels for a particular chemical. You can find the full list online at The Office of Environmental Health Hazard Assessment (OEHHA)'s website.

Additionally, due to certain legislative action, specific food products have established limits. Some examples include:

- Seaweed: Inorganic Arsenic (10µg/day) Lead (15µg/day) Cadmium (4.1µg/day)
- Tea Leaf: Lead (15µg/day)
- Ginger: Lead (15µg/day)
- Canned/ Bottled Item: BPA - Bisphenol A (3µg/day)
- Caramel Color: 4-Methylimidazole (29µg/day)

How do I know which of the chemicals might be in my products?

There are many chemicals on the list, however not all are typically found in food products. Since many food products are formulated with more than one raw material, it is important to start with your suppliers to determine if they have conducted research on their specific risks and related chemical exposure. Some of the common chemical risks are as follows:

- Heavy Metals (Arsenic, Cadmium, Lead, Mercury) are found in soils all over the world and can be found in naturally occurring amounts. They are taken up through the roots of the plants (e.g. lead in chocolate) or from the water (e.g. arsenic in rice).
- Acrylamides are formed by high-temperature processes such as baking, roasting, and frying foods (e.g. chips, coffee, bread). It is not added to food product or packaging and are not absorbed environmentally.
- 4-methylimidazole (4-MEI) is a byproduct formed in certain foods and beverages during the normal heating and browning processes and in some cases from fermentation. The chemical is a naturally occurring compound in certain caramel colors, roasted, and cooked foods; it is not added to the product.

How do I determine if these chemicals are in my products?

Research and testing are your best methods for determining if certain chemicals are in your product(s). The following are typical steps taken by companies:

1. Research the chemicals that are most likely to occur in your product and raw materials. Utilize resources such as trade associations, suppliers, and laboratories.
2. Request statements of Prop 65 compliance from your raw material suppliers.
3. Obtain test results for identified Prop 65 chemicals of concern from your raw material suppliers.
4. If your supplier does not have existing compliance statements, or test results to reference for Prop 65, conduct additional verification by sending the raw material to an accredited 3rd-party laboratory yourself.
5. Conduct testing of finished product through an accredited third-party laboratory for the chemicals of concern.
6. Compare this information and test results with the Prop 65 chemical list to determine if there are Safe Harbor Levels and if they exceed the Maximum Allowable Doses.
7. Based on the comparison, take a moment to understand and further investigate measures to reduce the levels (if present). Then take the next steps for consideration to minimize exposure (region, seasonality) if applicable.

What do I do with the results?

First, understand the limits are set in two parts:

The NSRL is a daily intake level calculated to result in one excess case of cancer in an exposed population of 100,000 assuming lifetime exposure. The MADL is the level at which the chemical would have no observable adverse reproductive effect assuming exposure at 1,000 times that level.

Second, conduct a calculation of the results:

A company must calculate an exposure analysis in their product to determine whether a warning is necessary. The analysis further determines presence or absence of a chemical substance. If present, even in small quantities, the "consumption factor" must be taken into account. A business must make their calculations based on serving size and potential to consume more than a serving size in one day (e.g. could be eaten throughout the day). This additional calculation may lead to a value that is over the limit and a warning must be placed on the product. See our handy calculation example on the next page.

Result Calculation Examples.

Due to the minute concentrations of several of these chemicals, nearly all are reported in ug/kg, which is the same as ppb (parts per billion). In order to determine if your product is below or exceeds the limits set by Prop 65, you must first calculate the amount present per serving.

See the example below:

- Serving Size = 40 grams
- Acrylamide Result = 49 ug/kg (ppb)
- To determine the amount of acrylamide per serving, the result is multiplied by the serving size (in grams) and dividing by 1000.
- $49 \text{ ug/kg} = 0.049 \text{ ug / g} \times 40 \text{ g serving} = 2.0 \text{ ug/serving}$
- *The acrylamide test reports in ug/kg (ppb). The ug/kg result is divided by 1000 to give the ug/g result; the ug/g result is multiplied by the serving size in grams.*

As of February 2019, the NSRL level for acrylamide is 0.2 ug/day and the MADL is 140 ug/day. Since there are a total of 2.0 ug of acrylamide in a serving it is reasonable to suggest that one would consume over the NSRL which means the manufacturer would need to consider placing the respective warning on the packaging regarding its potential risk for cancer.

Understanding ug/day and ug/serving is not the same measurement, the manufacturer must then consider the reasonable daily consumption of the product to further determine what and if any warnings are necessary for labeling.



What is the new Prop 65 labeling requirement and how do I comply?

On August 30, 2016, California adopted amendments to the Prop 65 regulations that govern clear and reasonable warnings under Prop 65. The following provides details on how companies must communicate the warning. The deadline for compliance to these new amendments was August 2018. If not already, companies must begin the necessary label modifications or face the potential for costly fines and litigation.

- Warnings must be no smaller than the largest type size used for other consumer information on the product. No smaller than 6-point type.
- Either a yellow or black/white equilateral triangle is required. This symbol is followed by the word "WARNING" in capital letters and bold print the same size as the triangle symbol. Download the symbols from <https://www.p65warnings.ca.gov/warning-symbol>.
- There are 4 types of Warnings statements:
 - WARNING: This product can expose you to chemicals such as [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov/food.
 - WARNING: This product can expose you to chemicals such as [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.
 - WARNING: This product can expose you to chemicals such as [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals] which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov/food.
 - 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.
- When a product label includes product information in a language other than English, the warning must also be provided in that language in addition to English.

Examples:

<Food Products>



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause [cancer and birth defects or other reproductive harm]. For more information go to www.P65Warnings.ca.gov.

<Alcohol Products>



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.

Reference Links:

Summary of Proposition 65 requirements:

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

Information on clear and reasonable notice requirements adopted in 2016 rule-making:

<http://oehha.ca.gov/proposition-65/crnr/notice-adoption-article-6-clear-and-reasonable-warnings>

Information about chemicals and substances regulated by Proposition 65:

<http://oehha.ca.gov/proposition-65/proposition-65-list>

Links to the statutory and regulatory text for Proposition 65:

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