



California Proposition 65 Primer and Frequently Asked Questions

NMMA members manufacture, distribute, and sell a wide variety of products, and many of them are sold into California. These products may contain chemicals known to the State of California to cause cancer, birth defects or other reproductive harm, and may therefore require a warning under the California Safe Drinking Water and Toxic Enforcement Act, otherwise known as Proposition 65. A warning required in California may impact products sold nationally or internationally. This FAQ will provide a general summary of Proposition 65, including an overview of new regulations that take effect in August 2018.

What is Proposition 65?

Proposition 65 requires businesses to warn Californians before exposing them to significant amounts of chemicals in the consumer products they buy and use. Proposition 65 requires the State to publish a list of chemicals known to cause cancer, birth defects or other reproductive harm, known as the “Prop 65 List”. The California Office of Environmental Health Hazard Assessment (OEHHA) administers the Proposition 65 program and maintains the Prop 65 List, which is updated at least once annually. The list presently contains over 1,000 chemicals.

Proposition 65 applies to environmental exposures as well as consumer product exposures, but for this FAQ we only focus on consumer products.

Which chemicals are on the Proposition 65 List?

There is a range of naturally occurring and synthetic chemicals on the Prop 65 List. These chemicals include ones you expect, such as lead, asbestos and tobacco smoke, but also chemicals that may come as a surprise, such as aspirin. Certain chemicals on the list, such as styrene, are commonly found in consumer products. Of note to NMMA members, listed chemicals may also be byproducts of chemical processes, such as diesel exhaust. The updated Prop 65 List can be found at: <https://oehha.ca.gov/proposition-65/proposition-65-list>.

What is the warning requirement for businesses?

Businesses¹ are required to provide a “clear and reasonable”² warning before knowingly and intentionally exposing anyone to a chemical on the Prop 65 List. For consumer products, this usually means providing a warning on the product or packaging.

¹ So as not to burden small businesses, there is a compliance exemption for businesses with fewer than 10 employees.

² To be “clear,” the language in the warning must clearly communicate that the chemical in question is known to the State to cause cancer, or birth defects or other reproductive harm. To be “reasonable,” the method used to warn must be reasonably calculated, considering alternatives, to make the warning message available to an individual prior to exposure.

On Product or Package Warnings

For consumer products with exterior packing, a warning label is not required on both the packaging and on the product itself, as long as the warning label is placed in a manner to ensure that consumers receive the warning prior to exposure.

Owner's Manual

For products that include an owner's manual, a warning in the manual by itself is not an appropriate warning method for consumer product exposures. A warning in an owner's manual would need to be paired with another warning, such as on the product or the packaging.

Internet and Catalog Warnings

Warnings are required for internet purchases prior to the consumer completing the purchase, and must also be included with a product purchased in a catalog (a general warning on a website or catalogue that some products on that website or in that catalogue may cause cancer or reproductive harm is likely not going to suffice – a specific warning for a specific product will usually be required).

Manufacturers vs. Retailers

To limit the burden on retailers, Proposition 65 regulations place primary responsibility for providing warnings on product manufacturers, producers, packagers, importers, suppliers or distributors. For consumer product exposures, businesses in the above categories must either provide a warning on the product, or provide notice and warning materials to their retail seller and receive an acknowledgment that the notice and materials were received. The retail seller is then responsible for placement and maintenance of the warning materials they receive from the product manufacturer, producer, packager, importer, supplier or distributor.

A consumer product manufacturer that does not sell directly to retailers has two options for compliance: (1) label the product with the required warning; or (2) provide a warning notice and the warning materials to the packager, importer, supplier or distributor. Manufacturers and others in the chain of commerce should take appropriate actions to ensure that the warning is passed along to the retailer and ultimately to the consumer. A manufacturer or producer may choose to enter into a contract with other businesses along the chain of commerce for their product to ensure that the warning is appropriately transmitted to the retailer and end consumer.

When do I have to give a warning?

If your product contains or emits a chemical on the Prop 65 List, and if the exposure is either above the “no significant risk level” for cancer or above the “no observable effect level” for reproductive harm, you must provide a warning. By law, a warning must be given for listed chemicals unless exposure is low enough to be “safe” meaning that it poses no significant risk of cancer or the risk is significantly below levels observed to cause birth defects or other reproductive harm.

Cancer: For a chemical that is known to the State of California to cause cancer, the “safe” or “no significant risk level” is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. In other words, a person exposed to the chemical at the “no significant risk level” (NSRL) for 70 years would not have more than a “one in 100,000” chance of developing cancer as a result of that exposure.

Birth Defects/Reproductive Harm: For chemicals that are known to the State of California to cause birth defects or reproductive harm, the “safe” or “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. As an added measure of safety, Proposition 65 then requires this level to be divided by 1,000 before defining the “no observable effect level” (NOEL).

Together, NSRLs and NOELs are known as “Safe Harbor Levels.”

How do I know if I have a chemical above the Safe Harbor Level?

California has developed Safe Harbor Levels for many of the chemicals on the Prop 65 List. If the State has not set a Safe Harbor Level, or if the business wants to know how an established Safe Harbor Level impacts their product, the business may conduct a risk assessment to determine the level of allowable exposure. The risk assessment is conducted by a consultant experienced in Prop 65 compliance.

This type of testing is not required. For liability prevention, businesses may choose to provide a warning based on their knowledge, or assumption, of the presence of a listed chemical without evaluating the levels of exposure. This is discouraged by the State of California, and may have the unintended consequence of creating an “admission” that your product causes cancer when perhaps it does not. It is best to consult with an attorney when deciding whether to give a warning.

!!!THE LAW IS CHANGING!!! – Safe Harbor Warning Language Changes are Coming

Until August 30, 2018, businesses providing a warning can comply by affixing the following warning on the product itself or with the product packaging:

“WARNING: This Product Contains Chemicals Known To The State of California to Cause Cancer, And Birth Defects Or Other Reproductive Harm.”

What Happens After August 30, 2018?

After August 30, 2018, new Prop 65 regulations will take effect. For products manufactured after August 30, 2018, the warning must identify one or more chemicals on the Proposition 65 List, must add a symbol, as depicted below *but which also may be printed in black and white*, and the new Safe Harbor Language will be as follows (either the long form or short form warning is okay):

For cancer:



WARNING: This product can expose you to chemicals including XXXXX, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Or;



WARNING: Cancer – www.P65Warnings.ca.gov.

For reproductive harm:



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

Or;



WARNING: Reproductive Harm – www.P65Warnings.ca.gov.

For cancer and reproductive harm:



WARNING: This product can expose you to chemicals including XXXXX, which is 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.

Or;



WARNING: Cancer and Reproductive Harm – www.P65Warnings.ca.gov.

A consumer product that is manufactured prior to August 30, 2018 and labeled with a warning that is compliant with the old version of the regulations is deemed to be compliant with the new regulations. These products do not require a new warning. The date the product is available for purchase does not determine whether the product should have a new warning.

During the two-year phase-in period from August 30, 2016 to August 30, 2018, a business can follow the safe harbor methods and content from either the old regulations or for the new regulations.

How Do I Know What Chemical to Pick?

There is little guidance in determining which chemical to list for the longer form safe harbor warnings – it is within the discretion of the business providing the warning. If there are multiple chemicals to choose from, you can choose any of them.

Are there Safe Harbor Warnings Specific to the Recreational Marine Vessel Industry?

To provide greater clarity for the industry, NMMA lobbied for safe harbor language specific to marine vessels and engines (though other consumer products, including unattached spark ignited marine engines which cannot utilize the safe harbor language, would need to use the more general warning set forth above):

Recreational Marine Vessel Warning – Content



“WARNING: Operating, servicing and maintaining a recreational marine vessel can expose you to chemicals including engine exhaust, carbon monoxide, phthalates, and lead, which are known to the State of California to cause cancer and birth defects or other reproductive harm. To minimize exposure, avoid breathing exhaust, service your vessel in a well-ventilated area and wear gloves or wash your hands frequently when servicing this vessel. For more information go to www.P65warnings.ca.gov/marine.”

Recreational Vessel Exposure Warnings – Method of Transmission

A warning for exposures that occur during the operation or maintenance of a recreational vessel meets the requirements of Prop 65 if:

- (1) The warning is printed in the owner’s manual for the specific recreational vessel, in no smaller than 12-point type enclosed in a box printed or affixed to the inside or outside of the front or back cover of the manual or on the first page of the text, and;
- (2) The warning is provided on a hang tag readily visible from the helm of the vessel printed in no smaller than 12-point type. (Note: The hang tags that are required can be purchased directly from NMMA. Please visit our website for further information on how to order:

<https://www.nmma.org/certification/products/safety-information-labels>)

Diesel Engine Exposure Warning (Except Passenger Vehicle Engines, if an engine is attached to a vessel, the engine is covered by the vessel’s warning) – Content



“WARNING: Breathing diesel engine exhaust exposes you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

- Always start and operate the engine in a well-ventilated area.
- If in an enclosed area, vent the exhaust to the outside.
- Do not modify or tamper with the exhaust system.
- Do not idle the engine except as necessary.
- For more information go to www.P65warnings.ca.gov/diesel.”

Who enforces Proposition 65?

The California Attorney General's Office enforces Prop 65. Any district attorney or city attorney (for cities whose population exceeds 750,000) may also enforce the law. In addition, any individual acting in the public interest may enforce Prop 65 by filing a lawsuit against a business alleged to be in violation of this law. Lawsuits have been filed by the Attorney General's Office, district attorneys, consumer advocacy groups, and private citizens and law firms (sometimes referred to as "bounty hunters" as they share in the civil enforcement penalty recovery). Penalties for violating Prop 65 by failing to provide notices can be as high as \$2,500 per violation per day, e.g., \$2,500 per unit of product sold.

Penalties can be quite significant for consumer product exposures where the business has sold a significant volume of products. For example, if a business has sold 10,000 units of a non-compliant product without a required warning in California, a relatively small product sales volume in a state with over 35 million people, the potential penalty could be as high as \$25 million.

Where can I get more information on Proposition 65?

For general information on the Prop 65 list of chemicals and list of safe harbor levels, you may contact OEHHA's Prop 65 program at (916) 445-6900, or visit:

- <http://www.oehha.ca.gov/prop65.html>

For enforcement information, contact the California Attorney General's Office at (510) 622-2160, or visit:

- <http://caag.state.ca.us/prop65/index.htm>

For regular updates, you may also wish to subscribe to the Prop65 News which provides a monthly report on all Prop 65 developments:

- <http://prop65news.com>

If you have further questions regarding Proposition 65, you can also feel free to reach out to NMMA's Director of Federal Government Affairs, Mike Pasko, at mpasko@nmma.org or 202-737-9760 or NMMA's Senior Vice President of Government Affairs, John McKnight, at jmcknight@nmma.org or 202-257-3754.