

Proposition 65 Whitepaper – Nov. 12, 2013

Background Information

California's Office of Environmental Health Hazard Assessment (OEHHA) administers the Proposition 65 system, which took effect when California's *Safe Drinking Water and Toxic Enforcement Act of 1986* (Prop 65) was approved by voters. Prop 65's primary function is to promote informed consumer decision-making.

The purpose of Prop 65 is to notify consumers that the product they are considering for purchase may expose them to chemicals that are known to the State of California to cause cancer, birth defects and/or reproductive toxicity.¹ This enables consumers to decide on their own if they want to purchase or use the product. A Prop 65 warning does not necessarily mean a product is in violation of any product safety standards or requirements.² Businesses are exempt from the warning requirement if the exposures they cause are so low as to create *no significant risk* of cancer or birth defects or other reproductive harm.³

Implications

The need to notify consumers about the presence of chemicals which fall under the provisions of Prop 65 (hereafter "Prop 65 chemicals") hinges on the answers to two questions: 1) Is the chemical present, and 2) at what level will the consumer be "exposed" to it? If the chemical has been granted a "Safe Harbor Level" of exposure (also known as *No Significant Risk Level* (NSRL))⁴ for chemicals believed to be carcinogens, or "Maximum Allowable Dose Levels" (MADLs) for chemicals believed to cause reproductive toxicity⁵, it is easier to determine the "safe" exposure level under which a company does not have to add a warning to its products. For the remainder of this report, NSRL will be used universally to cover both carcinogens and chemicals harmful to reproduction.

Warning Determination

To determine the appropriate step a manufacture needs to take, it is important to know whether their products contain one or more of the Proposition 65 chemicals. There are multiple ways to make this determination. The manufacture could have its products tested for the presence of such chemicals. Alternatively, the manufacture could make a determination based on information from its component suppliers. It is important to note that the manufacturer is expected to act with "due diligence" in making

¹ OEHHA "Proposition 65 in Plain Language!" updated March 2010.

² <http://oehha.ca.gov/prop65/p65faq.html>

³ OEHHA "Proposition 65 in Plain Language!" updated March 2010.

⁴ OEHHA in March 2010 defined NSRL 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.... [Not] more than a one in 100,000 chance."

⁵ No Observable Effect Levels: determine the maximum dose level having no observable effect, and divide that level by one thousand (1,000) to arrive at the maximum allowable dose level. The Maximum Allowable Dose Level (MADL) is the maximum exposure level of a chemical to which people can be safely exposed in a product under California Law and not experience reproductive toxicity.

For example:

1,001 = The minimum dose level of exposure to a chemical at which people DO experience reproductive toxicity.

1,000 = The maximum dose level of exposure to a chemical at which people do NOT experience reproductive toxicity.

Thus, 1= the maximum allowable dose level.

such determinations. In some cases, such as the use of recycled materials, it may be difficult if not impossible to know if such materials contain Prop 65 chemicals without testing each batch/lot of materials or products. In such cases, if it is reasonable to expect the product may contain a subject chemical, the manufacturer may choose to provide a warning for all such products. Upon completing the product assessment, there are three potential outcomes. The following describe actions that may be taken depending on the condition:

1) The product **DOES** contain Prop 65 chemical(s):

The next step is to determine whether the user can be exposed to the chemical, and whether the exposure exceeds NSRL levels or safe harbor levels if they exist. These determinations are generally made by qualified toxicologists. Such professionals consider exposure scenarios (inhalation, ingestion, dermal) along with exposure models that consider time, usage, environmental conditions, etc. to predict exposure. The predicted exposure can be compared to the NSRL or safe harbor level to determine the need for a warning. Many Prop 65 chemicals do not have established Safe Harbor or NSRL/MADL; in such cases, the manufacturer has the obligation to provide the research needed to demonstrate the appropriate NSRL to the State, or, alternately, provide Warning statements.

2) The product **DOES NOT** contain Prop 65 chemical(s):

No product warning is required.

3) It **CANNOT REASONABLY BE DETERMINED** that the product contains Prop 65 chemical(s):

If it cannot reasonably be determined that the product contains Prop 65 chemicals (such as may be the case with recycled materials with batch to batch material variability) a determination should be made as to the maximum likely content. Then, it should be determined whether the product in that condition would lead to the user being exposed to the chemical, and whether the likely exposure exceeds NSRL levels or safe harbor levels if they exist. The predicted exposure can be compared to the NSRL or safe harbor level to determine the need for a warning. If a manufacturer determines warning statements are necessary, potential impact to products in the distribution channel (in inventory, at sales locations, etc.) should be considered.

Distribution Channel Considerations (Retail vs. Commercial)

How you warn may be dependent on distribution channel. It is the intention of Prop 65 that users of a product be informed of the potential exposure to a listed chemical *before* the purchase so that they make an informed choice about buying the product.

For products sold through the retail channel, such warnings may be placed on the product, on the product packaging, or near the point of purchase (such as shelving, display kiosks, etc.). Retail sales through the internet will require placement of the warning on the site such that it is seen prior to purchase.

For products sold through “commercial” distribution channels, such as through dealerships, warnings placed on the product probably are not effective since the user (purchaser) would be unlikely to see them before purchase. In such cases, warnings may need to be placed in sales literature, price books, internet sites, etc., such that the purchaser would be warned about the potential exposure before the sale.

Products sold through multiple channels may require multiple placements of the warning.

Labeling the product alone may not be sufficient, especially if the purchaser is not likely to see the warning until after the purchase. Such warnings may be deemed to be insufficient and therefore care should be taken before choosing that path as the sole route of the warning. Ideally, a manufacturer would include warnings only for products being shipped to California. However, most furniture companies build products in large quantities for stock. At the time of production a manufacturer may not know where the product will be sold/delivered. In such cases, there may be no alternative except to include these warnings with all products, whether it ends up in California or not. If so labeled, it is also important for all retailers to leave the warning on the furniture when they are shipping to California destinations.

Warning Language

Prop 65 provides the requirements for adequate warnings:

"Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.⁶ (Emphasis added.)

Prop 65 provides the required text for the warnings. Examples, depending on the resulting risk, include:

- 1) WARNING: This product contains a chemical known to the State of California to cause cancer.
- 2) WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.
- 3) WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

The regulations concerning the specifications of warnings, including dimensional requirements for signs and labels, appear at <http://www.oehha.org/prop65/law/12601.html>.

⁶ California *Safe Drinking Water and Toxic Enforcement Act of 1986*, Section 25249.11(f).