

# Proposition 65 in Plain Language

Office of Environmental Health Hazard Assessment California Environmental Protection Agency

### What is Proposition 65?

In 1986, California voters approved an initiative to address their growing concerns about exposure to toxic chemicals. That initiative became the Safe Drinking Water and Toxic Enforcement Act of 1986, better known by its original name of Proposition 65. Proposition 65 requires the State to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list, which must be updated at least once a year, has grown to include over 800 chemicals since it was first published in 1987.

Proposition 65 requires businesses to notify Californians about significant amounts of chemicals in the products they purchase, in their homes or workplaces, or that are released into the environment. By providing this information, Proposition 65 enables Californians to make informed decisions about protecting themselves from exposure to these chemicals. Proposition 65 also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water.

The Office of Environmental Health Hazard Assessment (OEHHA) administers the Proposition 65 program. OEHHA, which is part of the California Environmental Protection Agency (Cal/EPA), also evaluates all currently available scientific information on substances considered for placement on the Proposition 65 list.

### What types of chemicals are on the **Proposition 65 list**?

The list contains a wide range of naturally occurring and synthetic chemicals that are known to cause cancer or birth defects or other reproductive harm. These chemicals include additives or ingredients in pesticides, common household products, food, drugs, dyes, or solvents. Listed chemicals may also be used in manufacturing and construction, or they may be byproducts of chemical processes, such as motor vehicle exhaust.

#### How is a chemical added to the list?

There are four principal ways for a chemical to be added to the Proposition 65 list. A chemical can be listed if either of two independent committees of scientists and health professionals finds that the chemical has been clearly shown to cause cancer or birth defects or other reproductive harm. These two committees—the <a href="Carcinogen">Carcinogen</a> <a href="Identification Committee">Identification Committee</a> (CIC) and the <a href="Developmental and Reproductive Toxicant">Developmental and Reproductive Toxicant</a> (DART) <a href="Identification Committee">Identification Committee</a>—are part of OEHHA's Science Advisory Board. The

committee members are appointed by the Governor and are designated as the "State's Qualified Experts" for evaluating chemicals under Proposition 65. When determining whether a chemical should be placed on the list, the committees base their decisions on the most current scientific information available. OEHHA staff scientists compile all relevant scientific evidence on various chemicals for the committees to review. The committees also consider comments from the public before making their decisions.

A second way for a chemical to be listed is if an organization designated as an "authoritative body" by the CIC or DART Identification Committee has identified it as causing cancer or birth defects or other reproductive harm. The following organizations have been designated as authoritative bodies: the U.S. Environmental Protection Agency, U.S. Food and Drug Administration (U.S. FDA), National Institute for Occupational Safety and Health, National Toxicology Program, and International Agency for Research on Cancer.

A third way for a chemical to be listed is if an agency of the state or federal government requires that it be labeled or identified as causing cancer or birth defects or other reproductive harm. Most chemicals listed in this manner are prescription drugs that are required by the U.S. FDA to contain warnings relating to cancer or birth defects or other reproductive harm.

A fourth way requires the listing of chemicals meeting certain scientific criteria and identified in the California Labor Code as causing cancer or birth defects or other reproductive harm. This method established the initial chemical list following voter approval of Proposition 65 in 1986 and continues to be used as a basis for listing as appropriate.

# What requirements does Proposition 65 place on companies doing business in California?

Businesses are required to provide a <u>"clear and reasonable" warning</u> before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by labeling a consumer product, posting signs at the workplace, distributing notices at a rental housing complex, or publishing notices in a newspaper. Once a chemical is listed, businesses have 12 months to comply with warning requirements.

Proposition 65 also prohibits companies that do business within California from knowingly discharging listed chemicals into sources of drinking water. Once a chemical is listed, businesses have 20 months to comply with the discharge prohibition.

Businesses with less than 10 employees and government agencies are exempt from Proposition 65's warning requirements and prohibition on discharges into drinking water sources. Businesses are also exempt from the warning requirement and discharge prohibition if the exposures they cause are so low as to create no significant risk of cancer or birth defects or other reproductive harm. Health risks are explained in more detail below.

### What does a warning mean?

If a warning is placed on a product label or posted or distributed at the workplace, a business, or in rental housing, the business issuing the warning is aware or believes

that one or more listed chemicals is present. By law, a warning must be given for listed chemicals 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.

For chemicals that are listed as causing cancer, the "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" for 70 years would not have more than a "one in 100,000" chance of developing cancer as a result of that exposure.

For chemicals that are listed as causing birth defects or reproductive harm, 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. Proposition 65 then requires this "no observable effect level" to be divided by 1,000 in order to provide an ample margin of safety. Businesses subject to Proposition 65 are required to provide a warning if they cause exposures to chemicals listed as causing birth defects or reproductive harm that exceed 1/1000<sup>th</sup> of the "no observable effect level."

To further assist businesses, OEHHA develops numerical guidance levels, known as "safe harbor numbers" (described below) for determining whether a warning is necessary or whether discharges of a chemical into drinking water sources are prohibited. However, a business may choose to provide a warning simply based on its knowledge, or assumption, about the presence of a listed chemical without attempting to evaluate the levels of exposure. Because businesses do not file reports with OEHHA regarding what warnings they have issued and why, OEHHA is not able to provide further information about any particular warning. The business issuing the warning should be contacted for specific information, such as what chemicals are present, and at what levels, as well as how exposure to them may occur.

#### What are safe harbor levels?

As stated above, to guide businesses in determining whether a warning is necessary or whether discharges of a chemical into drinking water sources are prohibited, OEHHA has developed safe harbor levels. A business has "safe harbor" from Proposition 65 warning requirements or discharge prohibitions if exposure to a chemical occurs at or below these levels. These safe harbor levels consist of No Significant Risk Levels for chemicals listed as causing cancer and Maximum Allowable Dose Levels for chemicals listed as causing birth defects or other reproductive harm. OEHHA has established over 300 safe harbor levels to date and continues to develop more levels for listed chemicals.

#### What if there is no safe harbor level?

If there is no safe harbor level for a chemical, businesses that expose individuals to that chemical would be required to provide a Proposition 65 warning, unless the business can show that the anticipated exposure level will not pose a significant risk of cancer or reproductive harm. OEHHA has adopted regulations that provide guidance for calculating a level in the absence of a safe harbor level. Regulations are available at

Article 7 and Article 8 of Title 27, California Code of Regulations. Determining anticipated levels of exposure to listed chemicals can be very complex. Although a business has the burden of proving a warning is not required, a business is discouraged from providing a warning that is not necessary and instead should consider consulting a qualified professional if it believes an exposure to a listed chemical may not require a Proposition 65 warning.

### Who enforces Proposition 65?

The California Attorney General's Office enforces Proposition 65. Any district attorney or city attorney (for cities whose population exceeds 750,000) may also enforce Proposition 65. In addition, any individual acting in the public interest may enforce Proposition 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. Penalties for violating Proposition 65 by failing to provide notices can be as high as \$2,500 per violation per day.

# How is Proposition 65 meeting its goal of reducing exposure to hazardous chemicals in California?

Since it was passed in 1986, Proposition 65 has provided Californians with information they can use to reduce their exposures to listed chemicals that may not have been adequately controlled under other State or federal laws. This law has also increased public awareness about the adverse effects of exposures to listed chemicals. For example, Proposition 65 has resulted in greater awareness of the dangers of alcoholic beverage consumption during pregnancy. Alcohol consumption warnings are perhaps the most visible health warnings issued as a result of Proposition 65.

Proposition 65's warning requirement has provided an incentive for manufacturers to remove listed chemicals from their products. For example, trichloroethylene, which causes cancer, is no longer used in most correction fluids; reformulated paint strippers do not contain the carcinogen methylene chloride; and toluene, which causes birth defects or other reproductive harm, has been removed from many nail care products. In addition, a Proposition 65 enforcement action prompted manufacturers to decrease the lead content in ceramic tableware and wineries to eliminate the use of lead-containing foil caps on wine bottles.

Proposition 65 has also succeeded in spurring significant reductions in California of air emissions of listed chemicals, such as ethylene oxide, hexavalent chromium, and chloroform.

Although Proposition 65 has benefited Californians, it has come at a cost for companies doing business in the state. They have incurred expenses to test products, develop alternatives to listed chemicals, reduce discharges, provide warnings, and otherwise comply with this law. Recognizing that compliance with Proposition 65 comes at a price, OEHHA is working to make the law's regulatory requirements as clear as possible and ensure that chemicals are listed in accordance with rigorous science in an open public process.

## Where can I get more information on Proposition 65?

For general information on the Proposition 65 list of chemicals, you may contact OEHHA's Proposition 65 program at (916) 445-6900, or visit <a href="http://www.oehha.ca.gov/prop65.html">http://www.oehha.ca.gov/prop65.html</a>. For enforcement information, contact the California Attorney General's Office at (510) 873-6321, or visit <a href="http://oag.ca.gov/prop65">http://oag.ca.gov/prop65</a>.

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