

GUIDANCE on California Proposition 65 and Cannabis Products

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Prepared by the American Herbal Products Association



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DISCLAIMER

The information contained herein is not and should not be considered to be legal advice. This publication is not a substitute for the California Proposition 65 laws and regulations that apply to businesses in the State of California. Instead, it should be viewed as a supplementary guide to these laws and regulations. Information contained herein is not intended to replace or supersede instructions, guidelines or regulations issued by the State of California. In addition, no other issues related to the manufacture, marketing, or sale of products entering commerce in California are addressed herein.

While AHPA believes that all of the information contained here is accurate, any company that uses this information does so as its own choice; is wholly responsible for any policies established therefrom; and is advised to discuss all aspects related to compliance with Proposition 65 with a qualified attorney or consultant.



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What is Proposition 65?

Consumer goods sold in the State of California are, with certain exceptions, subject to that State's Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986. The regulations that have been implemented in the years since the Proposition was passed require that warnings be provided for products sold in the State of California if the products contain chemicals listed by the State as carcinogens or reproductive toxicants. Failure to provide such warnings can result in action by the California Attorney General, District or City Attorneys, or by "any person in the public interest."

Proposition 65 requires persons doing business to provide "clear and reasonable" warnings prior to exposing individuals to chemicals known to the State to cause cancer and/or reproductive toxicity. The State is required to publish a list of the chemicals it considers to cause cancer and/or reproductive toxicity.

Of particular interest to the cannabis industry is marijuana smoke, which was added to the Proposition 65 list in June 2009 as a chemical known to the State of California to cause cancer. The Hazard Identification Document¹ that outlines the basis for the classification of marijuana smoke as a carcinogen can be reviewed on the website of the California Office of Environmental Health Hazard Assessment (OEHHA). In addition to marijuana smoke, other chemicals on the Proposition 65 list that may be used in the cultivation and processing of cannabis, such as the pesticides myclobutanil and carbaryl, must be considered when cannabis businesses are determining compliance to this regulation.

This guidance document was prepared with a narrow focus; it is concerned only with the regulatory and liability implications for cannabis businesses or other entities in the State of California regarding exposure to marijuana smoke and potentially other chemicals listed under Proposition 65. It is not intended to address any other elements of Proposition 65 except as necessary for the present purpose, nor does it serve as a substitute for this law, its implementing regulations, or legal counsel.

AHPA has also produced the document *Guidance on California Proposition 65 and Herbal Products*,² which addresses the impact of this regulation to the broader herbal products industry and may also be of interest to the cannabis industry.

For more information on this law, see the website of the California Office of Environmental Health Hazard Assessment (OEHHA), which oversees Proposition 65 issues, at www.oehha.org.

Who is responsible for all of this? Who is liable?

The law states that "No person in the course of doing business shall knowingly and intentionally expose an individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual [with exceptions]." This "person" can be any

¹ This document is available at <https://oehha.ca.gov/media/downloads/cnr/finalmjsmokehid.pdf>. Accessed April 4, 2018.

² This document is available through the AHPA website at <http://www.ahpa.org/Resources/Regulations/State.aspx>.



company or entity in the stream of commerce, e.g., a manufacturer, distributor or retailer, including medical marijuana collectives and cooperatives. Enforcement is most often against the manufacturer of a product, but cases have been brought against retailers as well.

Companies with fewer than ten employees are exempt from the requirements under Proposition 65 to provide warnings. However, both the California Attorney General and private enforcers have taken the position that Proposition 65 liability applies to any company with ten or more employees that is in the stream of commerce for the product. In this view, a manufacturer with fewer than ten employees would not be liable under Proposition 65, but its distributors and retailers, assuming they each have at least ten employees, would be liable. As a result of common indemnity practices and business customs, therefore, the small manufacturer may still be asked to take financial responsibility for compliance by or a lawsuit against the larger distributor or retailer.

How is Proposition 65 enforced?

This law is enforced by civil suits against companies that are believed to be in violation of its requirements. The State Attorney General and local district and city attorneys have authority to take such actions, but, unlike most of the laws in the State of California, such a suit may also be brought by “any person in the public interest.” Private plaintiffs may be individuals or groups, and it is not a requirement to demonstrate harm or injury from alleged exposure to a Proposition 65 listed chemical.

An action against a company by a private plaintiff is initiated by submittal of a “60-day Notice of Violation,” filed to the California Attorney General and also provided to District and City Attorneys. In this Notice the company is informed that the plaintiff claims violations of Proposition 65 and intends to bring enforcement action against the company within 60 days unless the Attorney General has first begun to prosecute the company for the alleged violations.

Furthermore, although the law specifies that exposure to a listed chemical be made “knowingly and intentionally,” these terms have not proven to be a practical impediment to enforcers in the past.

How can companies comply?

Companies that provide cannabis products in California in full compliance with state and local laws and regulations should consider whether to provide Proposition 65 warnings. As previously stated there is an exemption for businesses that employ nine or fewer persons, though voluntary compliance by such small firms may be a good business decision.

With respect to marijuana smoke, OEHHA has not determined a threshold of exposure to marijuana smoke below which a Proposition 65 warning is not required, and expensive evaluation by scientific experts would be needed to assess if such a level can be defined. Companies can determine whether any “safe harbor” thresholds have been determined by OEHHA for other chemicals that may be present in the cannabis they provide or on their physical premises by consulting the agency’s website for the list



of No Significant Risk Levels (NSRLs) for carcinogens and Maximum Allowable Dose Levels (MADLs) for reproductive toxicants.

Businesses supplying marijuana itself as well as other marijuana-derived products that will be consumed in a manner that produces an exposure to marijuana smoke or other chemicals potentially present in marijuana may consider providing a warning for these exposures, both to comply with the warning provision of Proposition 65 and to reduce potential Proposition 65 liability.

It is important to understand that Proposition 65 does not forbid the sale of products that contain listed chemicals in amounts that might exceed the standards or even in amounts that might cause harm. Rather, the law places an obligation on companies to provide “clear and reasonable” warnings if they choose to sell such products in California.

What warnings are required by Proposition 65?

Any company with ten or more employees that operates within the state or sells products in California must provide a “clear and reasonable” warning before knowingly and intentionally exposing anyone to a listed chemical in an amount exceeding established standards.

Cannabis businesses should consider whether Proposition 65 warnings are needed for other products or substances that may be used or stored at their facility and to which consumers, employees, or contractors may be exposed. Businesses that provide marijuana for vaping may consider providing a Proposition 65 warning for exposure to formaldehyde, another listed chemical, which is produced in some types of vaping pens when components of vaping liquid are heated. Products used for cleaning and building maintenance should also be checked to determine if they require appropriate environmental warnings.

Warnings provided by the product manufacturer

Proposition 65 warnings are typically provided by the manufacturer, producer, packager, importer, supplier, or distributor of a product in commerce in California. Examples of the new warnings as applicable to cannabis and cannabis-derived products are as follows:

- For any chemical listed as a carcinogen:

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. For more information go to www.P65Warnings.ca.gov.

- For any chemical listed as a reproductive toxicant:

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 birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

- For a chemical listed as a carcinogen and a different chemical listed as a reproductive toxicant:

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 [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.

- For any chemical listed as both a carcinogen and as a reproductive toxicant:

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.



Where a warning is being provided for an exposure to a single chemical, the words “chemicals including” may be deleted from the warning above, but in that circumstance the warning will only cover the identified chemical.

Companies can also comply with the warning regulation using the short-form warning option. This warning option contains a symbol consisting of a black exclamation point in a yellow equilateral triangle with a bold black outline³ placed to the left of the warning text, as well as the following:

- For consumer products that cause exposures to a listed carcinogen:
 **WARNING:** Cancer - www.P65Warnings.ca.gov.
- For consumer products that cause exposures to a listed reproductive toxicant:
 **WARNING:** Reproductive Harm - www.P65Warnings.ca.gov.
- For consumer products that cause exposures to both a listed carcinogen and a reproductive toxicant:
 **WARNING:** Cancer and Reproductive Harm - www.P65Warnings.ca.gov.

For short-form warnings, the warning language must be no smaller than the largest type size used for other consumer information⁴ on the product, and in no case shall the warning appear in a type size smaller than 6-point type. Short-form warnings are not required to include the name or names of a listed chemical within the text of the warning.

Examples of on-site exposure warnings that may be utilized by cannabis businesses are as follows:

- For any chemical listed as a carcinogen:
 **WARNING:** Entering this area can expose you to chemicals known to the State of California to cause cancer, including [name of one or more chemicals], from [name of one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov.
- For any chemical listed as a reproductive toxicant:
 **WARNING:** Entering this area can expose you to chemicals known to the State of California to cause birth defects or other reproductive harm, including [name of one or more chemicals], from [name of one or more sources of exposure]. For more information go to www.P65Warnings.ca.gov.

³ If the sign, label, or shelf tag for the product is not printed using the color yellow, the symbol may be provided in black and white. The warning symbol can be downloaded from the OEHHA website.

⁴ “Consumer information” includes warnings, directions for use, ingredient lists, and nutritional information. “Consumer information” does not include the brand name, product name, company name, location of manufacture, or product advertising.



Warnings provided by the product retailer

The manufacturer, producer, packager, importer, supplier, or distributor of a cannabis product may also comply with the Proposition 65 warning requirements by providing a written notice directly to the authorized agent for a retail seller, which includes all of the following:

1. States that the product may result in an exposure to one or more Proposition 65 listed chemicals;
2. Includes the exact name or description of the product or specific identifying information for the product such as a Universal Product Code (UPC) or other identifying designation;
3. Includes all necessary warning materials such as labels, labeling, shelf signs or tags, and warning language for products sold on the Internet;
4. Has been sent to the retail seller, and the manufacturer, producer, packager, importer, supplier, or distributor has obtained confirmation electronically or in writing of receipt of the notice.

The product retailer is directly responsible for providing Proposition 65 warnings to consumers under certain other circumstances, such as when the retailer knowingly introduces a listed chemical into the product, or when the retailer obscures a warning label that has already been affixed to the product.

How is this relevant to businesses selling *Cannabis*?

Since 2014, numerous businesses have received 60-day Notices regarding exposure to marijuana smoke due to the presence of cannabis and paraphernalia used in the smoking of cannabis. Each 60-day Notice describes the alleged violation as failure to provide a clear and reasonable warning as required by Proposition 65 regarding potential consumer exposure to marijuana smoke. These 60-day Notice documents are publicly available through the California Attorney General's website⁵ by searching "marijuana" in the Source/Product field. In addition, in AHPA's experience, initiation by a private plaintiff of actions against a new product class is followed promptly by many more such actions. To date, civil penalties up to \$31,000 and attorney's fees up to \$64,500 have been incurred by some of the businesses who have received these notices.

Some of the 60-Day Notices inaccurately describe the allegedly affected products as including "all marijuana products not in an edible form," since this language implies that topical products, which do not produce marijuana smoke, are subject to the law's warning provisions regarding this substance.

In addition, 2017, a private plaintiff initiated numerous 60-day Notices against businesses selling cannabis products alleging that the products contain one or more pesticides listed under Proposition 65. Examples of such pesticides are myclobutanil and carbaryl. No settlement information is yet available for any of these actions.

⁵ The Attorney General's website can be searched for 60-day Notices at <http://oag.ca.gov/prop65/60-day-notice-search>.



What should a company do if it gets a 60-day Notice?

The defense of a lawsuit brought under California Proposition 65 is a complex process requiring special expertise. It is strongly advised that any cannabis business in receipt of a 60-day Notice promptly contact an attorney who is knowledgeable about this law. AHPA maintains communications with several legal firms who specialize in environmental and consumer law and can sometimes provide an introduction.

Any business providing cannabis – whether it is smoked or consumed on the premises of the business or elsewhere – and other businesses that may allow smoking or other consumption of cannabis on their premises should be prepared to answer any charges that are brought against them in this matter promptly, as the burden of proof is generally placed on the defendant.

Providing the required warnings following the receipt of a 60-day Notice does not relieve a business of the potential liability for failure to warn for exposures that may have occurred prior to provision of the warning.

