

Proposition 65 Labeling – What’s at Stake?

A summary for Wallcovering Association by Jeff Rezin

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

Businesses are required to provide a clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical, unless the business can show that the anticipated exposure level will not pose a significant risk of cancer or is significantly below levels observed to cause birth defects or other reproductive harm.

This warning can be given in several ways, such as by labeling a consumer product, posting signs at the workplace, or publishing notices in a newspaper. The requirement to provide warnings takes effect one year after a chemical is added to the list.

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 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 are significantly below levels observed to cause birth defects or other reproductive harm.

How can businesses determine if a warning is required?

Using its knowledge of its business operations and the chemicals it uses, a business can review the Proposition 65 list to determine whether its operations or products are likely to expose people in California to any listed chemicals. Depending on the level of exposure, the business may be required to provide a warning for those exposures. A business that determines it is causing exposures to a listed chemical may be able to use OEHHA’s safe harbor numbers to determine if it needs to provide a warning.

What are safe harbor numbers?

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 for many Proposition 65 chemicals. A safe harbor level identifies a level of exposure to a listed chemical that does not require a Proposition 65 warning. A business does not need to provide a warning 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 more than 300 safe harbor levels and continues to develop more levels for listed chemicals.

Proposition 65 Safe Use Determination (SUD) Process

OEHHA uses a process to develop Safe Use Determinations (SUDs) under Proposition 65. This is often a rigorous process that can nevertheless clarify important questions as to whether a business’ products are subject to Proposition 65 requirements.

Are there exceptions to the warning requirements or discharge prohibition?

Yes. Small businesses with fewer than 10 employees, governmental agencies, and public water systems are exempt from the warning requirements and discharge prohibition of Proposition 65.

Also, businesses do not have to provide a warning if the exposures they cause are so low as to create no significant risk of cancer or birth defects or other reproductive harm. It is the responsibility of the business causing the exposure to determine whether the exposure poses no significant risk.

For a chemical that causes cancer, the No Significant Risk Level (NSRL) 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 NSRL for 70 years would not have more than a one in 100,000 chance of developing cancer as a result of that exposure.

For a chemical that causes birth defects or reproductive harm, the No Observable Effect Level (NOEL) is determined by identifying the highest level of exposure that has been shown to pose no harm to humans or laboratory animals. Proposition 65 then requires this NOEL to be divided by 1,000. 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 1/1000th of the NOEL, also referred to as the Maximum Allowable Dose Level (MADL).

To assist businesses, the Office of Environmental Health Hazard Assessment (OEHHA) develops numerical guidance levels, known as “Safe Harbor numbers.” A business does not need to provide a warning for exposures below the “Safe Harbor” level and the discharge prohibition also does not apply if discharges are below the Safe Harbor level. OEHHA has established Safe Harbor numbers for over 300 chemicals and continues to develop Safe Harbor numbers for listed chemicals. More information about Safe Harbor numbers can be found here ([link is external](#)).

What is a Safe Use Determination (SUD)?

A Safe Use Determination (SUD) is a written statement issued by OEHHA, which interprets and applies Proposition 65 and its implementing regulations to a specific set of facts in response to a request by a business or a trade group. Requests for SUDs seek OEHHA’s determination whether an exposure or discharge of a listed chemical resulting from specific business actions or the average use of a specific product is subject to the warning requirement or discharge prohibition. The SUD determines if the discharge or exposure is at or below the Safe Harbor number.

What are some of the reasons a business or trade group might request a SUD from OEHHA?

A SUD is a tool that can provide verification to businesses that their product or operating practices comply with the requirements of Proposition 65. A SUD can also provide important assurance to the public that a given product or activity is in compliance with Proposition 65. Businesses that request a SUD are usually fairly certain that their product or activities do not require a warning or do not violate the discharge prohibition, and would like a best judgment made by OEHHA to reinforce their claim. Based upon the specific set of facts presented in your request, OEHHA can issue a decision representing our best judgment on whether the discharge or exposure in question complies with the law and regulations, or whether the exposure in question requires a warning.

Who can request a SUD?

Any business that meets all of the following conditions can request a SUD:

- The business (or businesses represented by a trade organization) is subject to the requirements of Proposition 65 (it has 10 or more employees);
- The chemical of concern is listed under Proposition 65 as known to cause cancer, or reproductive or developmental harm;
- The subject matter of the request is not:
 - at issue in a civil or criminal case pending in any court,
 - the subject of a notice of violation to the Attorney General, or a district attorney; or
 - at issue in any administrative proceeding pending before a federal, state or local agency; and
 - The business process or subject matter to be considered for the SUD involves a current or planned activity (e.g., it is not hypothetical or a request for a determination on several alternative plans).

How broadly may a SUD be applied?

A SUD applies only to the business or trade group that requested it and the specific chemical(s), product(s), uses or processes specified in the determination.

What is the Requester's role in the SUD process?

The requester is required to provide all relevant facts and information, such as:

- A complete description of and all relevant information on the processes, product or activity in question.
- Data concerning anticipated consumer or public exposure to the chemical through the product or activity in question.
- Data concerning the frequency and duration of use of the product or activity.
- The requester is responsible for paying any costs we will incur in evaluating the request.

What is OEHHA's role in the SUD process?

OEHHA will:

- Review the information and data submitted.
- Evaluate the adequacy of information and data submitted.
- Request additional information, data and/or published literature and other supporting documents, if needed.
- Estimate exposure to the listed chemical through use of the product or activity and compare it with the Safe Harbor number.
- Develop a Safe Harbor number or some other estimate of an intake level if no Safe Harbor number has been adopted.
- Issue the SUD, decline to issue the SUD or issue its opinion in an alternative form (information letter or an interpretive guidance).

What is the usual process for requesting a SUD?

Individuals or businesses interested in a SUD are encouraged to contact OEHHA informally to discuss the request. By doing this, we can provide guidance on the types of data and information that should be included in the SUD request. For any questions or assistance, please contact OEHHA Proposition 65 Implementation staff at 916-445-6900.

The SUD request and the **required non-refundable application fee of \$1,000** are submitted to the OEHHA Deputy Director for Scientific Affairs. This fee does not cover the entire cost of OEHHA's evaluation of the request. Unless OEHHA grants a waiver, the requester will be periodically charged for all costs that are incurred by OEHHA in considering the request, including compensation for staff time.

A SUD request is considered confidential until it is formally accepted in writing by OEHHA.

During the initial review of the request, we may request additional information, such as exposure data. If the information is not received within 30 days, the request will be closed. If the requested information is submitted after 30 days, the request may be reopened and a new application fee will be required.

After we have determined that the request is complete, a written notice of acceptance will be sent to the requester. The acceptance will include an estimate of the anticipated costs associated with evaluation of the SUD.

A public notice of the acceptance will simultaneously be submitted for publication in the California Regulatory Notice Register (CRNR) and a public hearing will be held on request. At this point, the SUD request is no longer considered confidential, though certain information provided by the requester (such as trade secrets) may be protected.

What happens after the SUD request is accepted?

Following the evaluation, OEHHA can respond by:

1. Issuing a SUD.
2. Declining to issue a SUD.
3. Issuing an information letter.
4. Issuing an interpretive guideline.

What types of data make OEHHA's acceptance of the request and issuance of the SUD more likely?

Proposition 65 regulations require that the request for a SUD must contain "a complete statement of all relevant facts and information related to the activity for which the SUD is requested. Data generated by scientifically valid testing according to generally accepted principles are needed to support scientific conclusions regarding potential safe uses of products containing listed chemicals. Successful past applicants have provided information such as product analysis data (concentrations or levels of the listed chemical in products, for example), exposure data, and product use data (this can include frequency of use, duration of use, amount of the product used

per application). Our confidence in analytic data is generally enhanced by increasing the number of samples tested or the number of trial runs in an experimental setting. Data that help to establish that the information provided is representative of the average users of the product are also helpful.

What if I don't have data or information on exposure to a listed chemical in my product or business activity?

If you lack data on exposure to the listed chemical, consider hiring a qualified consultant to help you identify and collect appropriate data prior to making the SUD request. OEHHA does not generate data for SUDs, although we may advise or inform you of the types of data that are needed. When such data are unavailable, our evaluation of the request will rely on conservative assumptions (worst-case scenarios) to estimate exposure and risks if such an evaluation is possible. Furthermore, relying on worst case assumptions will make it less likely that a SUD can be issued.

How much will a SUD request cost?

The cost of the SUD includes the following:

1. Processing fee: \$1,000. This initial non-refundable fee must be paid by check to OEHHA.
2. Initial review costs prior to acceptance: OEHHA will provide an estimate of the costs to review the SUD request for completeness and bill the requester periodically for these costs.
3. Evaluation costs: Once a request has been accepted, OEHHA will provide an estimate of the additional costs to evaluate the SUD. These costs will be periodically billed to the SUD requester.

Safe Use Determination Request Checklist

- A complete statement of ALL relevant facts, data, and information related to the activity for which the SUD is requested, including:
 - A complete description of, and all relevant information on, the processes, product or activity.
 - Consumer/public exposure levels via product/activity in question.
 - Frequency/duration of product/activity use by the public.
- A description of the business reason for the activity.
- Any copies of contracts, agreements, instruments, reports, data, analyses and other documents that may be relevant to the request.
- A description of the entire process if the activity for which the SUD is sought is part of a larger integrated process.
- If seeking a specific finding (e. g., a product does not require a Proposition 65 warning), include data to support the finding.
- A non-refundable processing fee of \$ 1,000, in the form of a check made payable to OEHHA. If a waiver is being sought, due to financial hardship, an explanation of the basis for granting the waiver must be included.
- A statement concerning whether to the best of the requester's knowledge the subject matter of the request is:
 - At issue in a civil or criminal case pending in any court.

- At issue in any administrative proceeding pending before a federal, state or local agency.
- The subject of a 60-day notice of violation.
- The signature of the person making the request for determination. In the case of an applicant representing an individual or organization, proof of authority must also be provided.

What if there is no safe harbor level?

If OEHHA has not established a 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 businesses in calculating their own level in the absence of an OEHHA safe harbor level.

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.

Where can I get information on the warning symbol?

With some exceptions, the warning symbol is a required element of safe harbor warning content. The symbol consists of a black exclamation point in a yellow equilateral triangle with a bold, black outline. The symbol must be placed to the left of the text of the warning in a size no smaller than the height of the word “**WARNING**”. 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. Businesses may download the symbols provided [here](#) for use in Proposition 65 warnings. A business wishing to provide a safe harbor warning must meet all applicable requirements of the [Article 6 Clear and Reasonable Warnings](#) regulations.

Is Your Business Ready for the New Proposition 65 Rules?

On August 30, 2018, California’s complex new Proposition 65 requirements for “clear and reasonable warnings” will take full effect, impacting companies across the country that do business in the Golden State. Though the Office of Environmental Health Hazard Assessment (OEHHA) adopted the new regulations in August 2016, businesses have had a 2-year phase-in period to adopt the new warning system. If your organization is still using the old warnings, here is what you need to know to become compliant before the August deadline.

What Is Prop 65?

Safe Drinking Water and Toxic Enforcement Act of 1986 (Cal. Health 7 Safety Code §§ 25249.5 -.13

- Response to concerns over exposure to substances known to the state to cause cancer, birth defects or reproductive harm
- Prohibits
 - Discharging listed chemicals into drinking water sources

- Knowingly and intentionally exposing any individual to listed chemicals without “clear and reasonable warnings”
- Substance list contains a wide range of chemicals:
 - Dyes, solvents, pesticides, drugs, food additives, and by-products of certain processes
- Businesses with 10 or more employees
 - Occupational exposure
 - Environmental discharges
 - Consumer product sale or use
- Office of Environmental Health Hazard Assessment (OEHHA)
 - Publishes and updates ~ 950 chemicals by:
 - Scientific Advisory Board
 - Authoritative Body
 - Federal or State Agency
 - California Labor Code
 - Adopts and modifies Prop 65 regulations
 - Safe use determination
 - Safe harbor levels
 - Clear and reasonable warnings
- Carcinogens: No Significant Risk Level (NSRL)
 - Level that would result in not more than 1 excess case of cancer in an exposed population of 100,000
 - Assumes lifetime exposure (70 years)
- Reproductive toxicants: Maximum Allowable Dose Level (MADL)
 - Exposure to reproductive toxicant at <1/1000th of NOEL
- “Naturally occurring in food” (not due to human activity)
 - Very difficult to demonstrate
- Clear and Reasonable Warning
 - Existing safe harbor for products (expires August 30, 2018)

WARNING: This product contains a chemical known to the State of California to cause cancer [and/or birth defects or other reproductive harm].

Since the original warning regulations took effect in 1988, companies were simply required to state that a chemical was present in a product or area that could cause cancer or reproductive harm, but they were not required to provide further information. Now the rules have become exceedingly more complex.
 - Deemed inadequate
 - Lack specific and useful information about potential exposure
 - Technology and communication advancements
 - Demographic changes – Requires warnings to be provided in other languages in addition to English in certain circumstances
 - New Warning Regulations Article 6—mandatory on August 30, 2018

Under the extensive new requirements, warnings for consumer products must state that the product “can expose you to” a listed chemical rather than simply stating that the product “contains” the chemical. The warnings must also include the name of at least one listed chemical that triggered the warning, the word “**WARNING**” in all capital letters and bold print, a warning symbol consisting of a black exclamation point in a yellow or black and white triangle, and the Internet address for OEHHA’s Proposition warnings website (www.P65Warnings.ca.gov)

- Specifies warnings obligations for supply chain
Clarifies the roles and responsibilities of manufacturers and retailers in providing warnings. Specifically, the new system places the primary responsibility for providing the warnings on manufacturers, that can choose to put warning labels on the products directly or to provide notices to distributors, importers, or retailers.
- Specific safe harbor warnings for:
 - Consumer products
 - Occupational exposure
 - Environmental exposure
- Tailored warnings for specific products and facilities
- Supply Chain Obligations
 - Intended to minimize retailer burden for consumer product labeling:
 - any article, or component part thereof, including food, produced, distributed, or sold for the personal use, consumption or enjoyment of a consumer.
 - Manufacturer, producer, packager, importer, supplier, or distributor either:
 - Places compliant label directly on product, or
 - Written notice to the authorized agent for a retailer
 - States that a warning is required
 - Name or description of product or identifying info, e.g. UPC
 - Provides all necessary warning materials, e.g. label, signs etc. Must include Internet warning if product may be sold online
 - Must obtain written or electronic receipt
 - Notice must be renewed by Feb. 28, 2019 and annually thereafter
- Retailer Obligations
 - Retailer obligated to provide warning
 - Private labeling
 - Introduced listed chemical
 - Thwarts supplier obligation (liability shift)
 - Obscures warning; or
 - Sells product without provide labels, signs, etc.
 - Actual knowledge
 - Specific knowledge from reliable source, including news media, customers, or trade association
 - Five business days after legal notice
 - Supplier is not person doing business in state

Existing Safe Harbor	New Safe Harbor
No Pictogram	 or  left of warning
“This product contains...”	“This product <u>can expose you to...</u> ”
No chemical specified	Must identify at least one chemical per endpoint at issue
No translation requirement	Translation required if shelf sign, product label includes consumer info in other language
No website specified	Warnings must refer to new website: www.P65Warnings.ca.gov/product

- New Consumer Product Warnings
 - New warning for consumer 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/birth defects and/or other reproductive harm].**
For more information, go to www.P65Warnings.ca.gov/product.
 - New “On Product” warning options
 - ▲ **WARNING: Cancer (and/or Reproductive Harm)** www.P65Warnings.ca.gov/product
 - Can be on product, immediate container or wrapper
 - Type size can be no smaller than the largest type size on the product, but no smaller than 6-point font
 - Business may use other than safe harbor provided can demonstrate warning is “clear and reasonable”
- Environmental Exposure Warnings
 - ▲ **WARNING: Entering this area can expose you to [name of chemical] from [name of one or more sources of exposure]. [Name of chemical] is known to the State of California to cause [cancer and. or and birth defects or other reproductive harm].**
For more information, go to www.P65Warnings.ca.gov
 - Method of transmitting the information
 - Warning poster at clearly defined entrances
 - Notice sent via mail, electronic or other delivery to each occupant
 - Notice in main or local news with larges circulation
- Occupational Exposure Warning
 - A warning to an exposed employee about a listed chemical meets the requirements of this subarticle if it fully complies with all warning information, training, and labeling requirements of

the federal Hazard Communication Standard (29 Code of Federal Regulations, section 1910.1200 (Feb. 8, 2013)), hereby incorporated by reference, the California Hazard Communication Standard (Title 8, California Code of Regulations section 5194), or, for pesticides, the Pesticides and Worker Safety requirements (Title 3, California Code of Regulations section 6700 et seq.).

- OEHHA can request from manufacturers:
 - Identity and concentration of listed chemicals in manufacturers' products;
 - Location of chemical in product;
 - Potential routes of exposure;
 - Estimated levels of human exposure based on product's use; and
 - "Any other related information concerning exposures to listed chemicals"
- Manufacturers must respond within 90 days
- No new information not already in company possession
- May mark information as trade secret, opportunity to object to public release
- OEHHA may not obtain privileged information
- Proposition 65 –Enforcement
 - Legal practice area devoted to filing and defending Prop. 65 lawsuits
 - In 2017, 688 private Prop. 65 settlements generated \$25.7 million. 76% went to bounty hunters.
 - The purpose of the litigation is to obtain warnings for consumers, or reformulated products, or both.
 - California Attorney General can bring cases, but... More common for private lawsuit
 - Any citizen can sue a company that fails to provide a warning prior to causing an exposure to a listed chemical
 - The exposure must be in California
 - The company must employ 10 or more persons

Proposition 65 contains a unique private enforcement provision that allows and encourages individual citizens to file lawsuits against businesses that fail to comply with its requirements. Citizens who successfully bring an action against a company can keep 25 percent of any penalty recovered, earning their "bounty hunter" nickname. These lawsuits are often the most expensive result of violations of Proposition 65, and bounty hunters are likely to be on the lookout for companies that are too slow to adapt to the new clear and reasonable warnings regulations by August 30.

- The matter is initiated via a 60-day notice
- Plaintiff only has to allege that one of 900+ listed chemicals is found in the substance
 - Plaintiff does not need to plead or prove the level is unsafe
 - Any level will do
- • If the parties don't settle within that period, or some extended period, a complaint is filed
- Odd Facts regarding Prop 65 Litigation
 - Burden of proof is on the Defendant in a Proposition 65 case to prove the exposure is less than safe harbor level
 - Plaintiff is not required to show physical harm
 - No exposure to an actual person must be proven, only a theoretical exposure
 - To prevail, the Defendant must prove:
 - exposure levels for the average consumer; and
 - the exposure is within a safe harbor level
 - MADL
 - NSRL

- Consequently, almost all cases settle
- Theoretically, each product is a violation = \$2500 penalty
- If I settle out of court, can other bounty hunters sue me?
 - Theoretically yes, but typically, they don't cross claim lines
- • How do I get better protection?
 - Complaint with a Consent Judgment entered by the Court
- • What are the costs of a Complaint/Consent Judgment?
 - A bit more expensive but this is the trend
- • How does one arrive at fair and reasonable settlement terms?
 - Look at other settlements, level of sales
- Practical Considerations
 - Manufacturer obligation for consumer products
 - Testing vs. supplier specifications/certifications
 - Very few defenses for listed chemicals
 - Burden is on you, the defendant
 - Prophylactic –A warning can remove future liability
 - Past liability (one year) up to \$2500/violation
- Safe Use Determination (SUD)
 - Written determination by OEHHA
 - Applies to specific facts or product
 - Exposure is at or below safe harbor
 - Elements of SUD request
 - By business or trade association
 - Product and intended use
 - Estimated exposure from use
 - Demonstrate that level of exposure is safe (below safe harbor)
- How to Prepare
 - Though most businesses should have begun their labeling changes and evaluating their warning systems by now, you should continue to monitor OEHHA's website for ongoing regulatory adjustments and interpretive guidance as the compliance deadline approaches.
 - Retailers and other distributors should contact their suppliers to make sure they will be fully prepared for the new requirements, and, if necessary, prepare new website and catalog warnings
 - Though the existing warning system will suffice for products manufactured before August 30, companies should evaluate their existing inventory to make sure they can prove when these products were manufactured or be prepared to update their warning labels.

Where Can I Find More Information On Proposition 65 Warning Requirements?

Proposition 65 and its regulations are posted at <https://oehha.ca.gov/proposition-65/law/proposition-65-law-and-regulations>.

For a side-by-side comparison of the current and new warning regulations, see <https://oehha.ca.gov/media/downloads/crn/side-sidearticle6.pdf>.

You can also contact the Proposition 65 Implementation Program office: (916) 445-6900 or email P65.Questions@oehha.ca.gov.

Background information and documents used in preparing this summary include information directly from the OHHEA website, California regulations, Industry presentations, related articles and direct communications with industry representatives. A full list can be provided upon request.