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New warning label requirements for California Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986

Your challenges

Businesses including product manufacturers, importers, distributors and retailers with 10 or more employees are required under California Proposition 65¹ to provide warnings to Californians about significant exposures to toxic chemicals. As of 30 August 2018, the new regulations for the provision of clear and reasonable warnings came into effect. These stakeholders need to understand how the new legislation impacts their products in California. It is important for these businesses to appreciate the compliance options and create the most effective programme to mitigate risk. They also have to keep abreast of any changes to the regulation. At the same time, stakeholders need to understand enforcement options and how settlements to lawsuits can impact a testing programme.

What is the California Proposition 65 List?

The official name of Proposition 65 is the Safe Drinking Water and Toxic Enforcement Act of 1986, which is aimed at protecting California citizens and the state's drinking

water sources from toxic chemicals, and to inform citizens about exposures to such chemicals. Proposition 65 requires the state of California to publish and maintain an updated list of chemicals known to cause cancer, birth defects and/or reproductive harm. The list² has grown to include approximately 1,000 chemicals since it was first published in 1987. The range of chemicals is diverse, ranging from solvents, plasticizers, additives or ingredients in pesticides, common household products, food, dyes and office products.

The California Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency administers the program and determines whether chemicals meet the scientific and legal requirements to be placed on the list. A chemical that meets the criteria for listing under Proposition 65 will be added to the list. The warning enforcement takes effect one year after the listing date.

Businesses must either provide a warning on the product,

or provide notice and warning materials to the authorised agent for a retail seller. The retail seller is responsible for placement and maintenance of the warning materials received.

What is the safe harbor level?

The law is not a restriction on substances in products. Rather, it requires businesses to provide a warning to notify Californians if they are exposed to chemicals above a safe harbor level. The safe harbor levels consist of No Significant Risk Levels (NSRLs) for chemicals listed as causing cancer and Maximum Allowable Dose Levels (MADLs) for chemicals listed as causing birth defects or other reproductive harm. OEHHA has established safe harbor levels, which are measured in micrograms per day, for over 300 chemicals listed. Exposure levels that are below the safe harbor levels are exempt from the requirements of Proposition 65.

For listed substances without a safe harbor level, businesses can use the guidance created within Article 7³ and 8⁴ of Title 27 of the California Code of Regulations to determine if they are required to provide consumers with a clear and reasonable warning about their product. The Proposition 65 regulation does not provide any means to achieve compliance via testing. However, via settlements to lawsuits, many companies have entered into agreements to test specific products named in the settlements in order to demonstrate compliance. The testing described in the settlements applies only to those companies party to the settlement. In addition, the testing methods and requirements set forth in the settlements can provide some guidance to those companies which choose not to use the warning label. This testing may mitigate risk but does not indemnify the product.

Consumer Product Exposure Warnings

A product that is sold in California, either in a store or online, must be compliant. Since Proposition 65 is a “Right to Know” law, the regulations provide instructions for using a warning label. The proper use of the warning provides full indemnification.

On 30 August 2016, OEHHA adopted new regulations⁵ for the provision of clear and reasonable warnings⁶. This aims to provide more detailed guidance and compliance assistance for businesses which must comply with the warning requirements of the Law. After a two-year transition period, the new warning regulations will become effective from 30 August 2018.

A consumer product that is manufactured after the effective date and labelled with an old warning is deemed to be non-compliant with the new regulations. The date the product is available for purchase does not determine whether the product should have a new warning.

Key changes in the new warning regulations include:

- Updated warning statements and allowing for the use of short-form warning;
- Standard warnings must now include the name of at least one chemical requiring a warning;
- A triangle symbol be placed to the left of the text of the warning;
- Products are to provide consumer information in a language other than English, and warnings must also be provided in that language in addition to English;
- The OEHHA Proposition 65 website URL must be provided.

The new Proposition 65 warning regulations provide two forms of warning statements. A business may use either one for communicating consumer product exposure risk. There is no prohibition on using the short-form warning on larger products as long as the warning is legible. The shorter version is offered for products where, due to size of the product or packaging, the long label is not practical.

Consumer product exposure warnings must generally be prominently displayed on a label, labelling or sign, and must be displayed conspicuously compared with other words, statements, designs or devices on the label, labelling or sign, to make the warning likely to be read and understood by ordinary Californians under customary conditions of purchase or use.

The short-form warning cannot be used on a sign. It can be affixed to or printed on a product or its immediate container or wrapper. The entire short-form warning must not be smaller than 6-point type and the largest size used for other consumer information on the product.

Warnings are also required for purchases made over the Internet and must be provided to the consumers prior to completing the purchases. If a label is used for a product warning, a business may opt to provide a hyperlink to the warning or a picture of the warning label used on the product. In addition, if a short-form warning is provided on the product label, the website warning may use the same content.

STANDARD WARNINGS	SHORT-FORM WARNINGS
FOR EXPOSURES TO LISTED CARCINOGENS	
<p> WARNING: This product can expose you to chemicals including [name of one or more chemicals] that is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.</p>	<p> WARNING: Cancer - www.P65Warnings.ca.gov.</p>
FOR EXPOSURES TO LISTED REPRODUCTIVE TOXICANTS	
<p> WARNING: This product can expose you to chemicals including [name of one or more chemicals] that 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.</p>	<p> WARNING: Reproductive Harm - www.P65Warnings.ca.gov.</p>
FOR LISTED CARCINOGENS AND LISTED REPRODUCTIVE TOXICANTS	
<p> WARNING: This product can expose you to chemicals including [name of one or more chemicals] that is [are] known to the State of California to cause cancer, and [name of one or more chemicals], that 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.</p>	<p> WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov.</p>
FOR CHEMICALS LISTED AS BOTH A CARCINOGEN AND REPRODUCTIVE TOXICANT	
<p> WARNING: This product can expose you to chemicals including [name of one or more chemicals], that 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.</p>	<p> WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov.</p>

Note: These are not official warning labels and should only be used as a reference.

How is Proposition 65 Enforced?

Enforcement is carried out through civil lawsuits⁷. The California Attorney General's Office (OAG), district attorney and city attorney have the authority to take such actions. In addition, private parties acting in the public interest are also allowed to bring Proposition 65 lawsuits, but only if they have provided at least 60 days' notice of the alleged violation to the business, as well as to the Attorney General and the appropriate district attorney and city attorney, and if the Attorney General, district attorney or city attorney has not taken action.

If a business is found to be in violation of Proposition 65, a court may order the business to stop committing the violation. The penalties can be as high as US\$2,500 per violation per day.

How to Comply with Proposition 65

The proper use of a warning label provides for full compliance. However, many companies see the warning label as not desirable at point of sale and therefore choose to test their products. Proposition 65 does not have any testing process to achieve compliance.

However, if a company has been party to a settlement then they are required to test their products and they will be in compliance if the test meets the requirements of the settlement. A company which chooses not to use a proper warning label and which is not part of a settlement is exposed and can employ testing only to mitigate risk.

How can we help you?

The Proposition 65 regulation can be difficult to understand and raises questions on how companies can ensure product compliance. TÜV SÜD is a recognised industry leader in product compliance and monitors and keeps abreast of the latest regulations that will affect your products' safety and compliance. The professionals at TÜV SÜD can serve as your compliance partner to build a better and safer product for your customers.

Our services for California Proposition 65

■ Testing

TÜV SÜD testing laboratories are equipped to conduct testing related to Proposition 65 requirements. TÜV SÜD is a leader in product compliance and maintains vigilance over industry regulations and standards.

■ Documentation

We can review your documentation and advise on any changes necessary to ensure compliance.

■ Regulations

TÜV SÜD technical experts keep up to date on applicable regulations, and participate in a number of key industry groups and trade organisations.

■ Other Requirements

We can offer testing in support of Proposition 65 requirements in conjunction with other international regulations and standards.

Your business benefits

- **Save time and money** – by identifying compliance considerations at the earliest possible stages of the product development process.
- **Minimise risk** – by avoiding supply chain problems that can result in product recalls and reputational harm.
- **Gain a competitive edge** – by delivering products of consistent quality and safety, without compromising time to market.
- **Ensure global support** – by leveraging TÜV SÜD's worldwide expertise in regulations and requirements, regardless of where your products are manufactured or sold.

Why choose TÜV SÜD?

TÜV SÜD is universally renowned as a leader in product compliance. By partnering with us, you benefit from our acclaimed track record in quality and safety, increasing customer confidence in your brand. The blue octagon mark and the TÜV SÜD brand name are widely recognised. We provide extensive customer service and technical support, ensuring that our clients always come first.

TÜV SÜD has experts who can educate and advise on how to comply with Proposition 65 and your other compliance needs.

Add value. Inspire trust.

TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specialises in testing, certification, auditing and advisory services. Through more than 24,000 employees across over 1,000 locations, the company adds value to customers and partners by enabling market access and managing risks. By anticipating technological developments and facilitating change, TÜV SÜD inspires trust in a physical and digital world to create a safer and more sustainable future.

¹ Proposition 65 <https://oehha.ca.gov/proposition-65/about-proposition-65>

² Proposition 65 List <https://oehha.ca.gov/proposition-65/proposition-65-list>

³ Article 7. No significant risk levels (NSRLs) [https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I4E0842D0D45011DEA95CA4428EC25FA0&originationContext=documenttoc&transitionType=Default&contextData=\(sc.Default\)&bhcp=1](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I4E0842D0D45011DEA95CA4428EC25FA0&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1)

⁴ Article 8. No observable effect levels (MADLs) [https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I51672540D45011DEA95CA4428EC25FA0&originationContext=documenttoc&transitionType=Default&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I51672540D45011DEA95CA4428EC25FA0&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default))

⁵ Clear and Reasonable Warnings, Article 6 of Title 27, California Code of Regulations [https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I498B7BC4FCC04E1FA663C4E3EC97D6A5&originationContext=documenttoc&transitionType=Default&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I498B7BC4FCC04E1FA663C4E3EC97D6A5&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default))

⁶ Sample warning statements for businesses <https://www.p65warnings.ca.gov/sample-warnings-and-translations-businesses>

⁷ OAG 60-day notice search <https://oag.ca.gov/prop65/60-day-notice-search>