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INSIGHT



Proposition 65: Decision-making guidance for exporters to the US

Technical and regulatory considerations for companies planning US market entry

Companies outside the US are often unsure about the reach and relevance of California's Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986). In this Insight, Sagentia Regulatory outlines how the Act impacts products sold in the state of California, how technical evaluation and assessment can guide warning decisions, and key considerations when it is deemed appropriate to place a warning.

Exporters to the US face a complex set of regulatory considerations, but few create as much uncertainty as California's Proposition 65 (Prop 65).

Enacted in 1986, Prop 65 requires businesses to provide clear and reasonable warnings before exposing Californians to listed chemicals known to the state to cause cancer or reproductive or developmental toxicity. Businesses are responsible for determining whether a warning is needed.

Unlike the US Toxic Substances Control Act (TSCA) and EU Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH), there is not a defined compliance pathway for Prop 65. Instead, it functions as a liability framework.

If a product sold in California could expose "average consumers" to listed substances above concentrations known as Safe Harbor Levels a warning must be provided. Safe Harbor Levels, which have been established for many Prop 65-listed chemicals, represent thresholds below which exposure is deemed

to not pose significant risk. However, not all substances listed under Prop 65 have Safe Harbor Levels established, and the Prop 65 chemical list continues to grow. As such, there is some ambiguity around Prop 65 obligations, and companies need to consider the management of regulatory and litigation risk. Strategic decisions must be made for products or product lines, balancing compliance requirements with commercial and reputational considerations.

Here, we outline key questions to ask when evaluating product formulations and supplier information to determine whether testing is recommended and, if listed chemicals are present or detected, whether an exposure assessment is warranted. Exposure evaluation forms part of the manufacturer risk management process for determining whether a warning is necessary. We also highlight critical elements of Prop 65 warnings to help ensure that, when used, they are compliant.



How does Prop 65 affect products sold in the US?

California's Office of Environmental Health Hazard Assessment (OEHHA) explains that Prop 65 requires businesses to "provide warnings to Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm".¹ Around 900 naturally occurring and synthetic chemicals are currently listed under Prop 65, including many used as materials or ingredients in common household products, health and beauty products, food, children's products, and apparel. The current list is available [here](#).

Prop 65 is administered by OEHHA and enforced by the California Attorney General's Office, but lawsuits are also filed by district or city attorneys, consumer advocacy groups, private citizens, and law firms. A 60-day notice must be provided to the Attorney General and to the alleged violator for all potential violations. Companies found in violation of Prop 65 can be issued a penalty of up to \$2,500 per violation per day.

Although Prop 65 only applies to products sold in California, its reach extends beyond the state. Any company exporting products to the US may find that they are sold in California or purchased online by Californians. This puts them within scope of the Act, even if California is not a target market.



Technical considerations for Prop 65 warning decision-making

Technical assessment of products helps determine whether a Prop 65 warning is required, enabling informed, proportionate actions to be taken. There are four key questions to consider:

1. Does the product contain chemicals listed under Prop 65?

The first step is to ascertain whether the product, or its packaging, contains any chemicals of concern from the current Prop 65 list. These chemicals may be intentionally used as ingredients or raw materials, or unintentionally added or incorporated into the finished product as part of the manufacturing process or as impurities of product constituents.

It's advisable to conduct a detailed audit of supplier information on product ingredients, raw materials, and packaging composition. Searching the California Attorney General's 60-Day Notice database is also a good idea, to discover whether the same or similar product categories have been subject to Prop 65 enforcement action and to gain an understanding of which listed chemicals were the subject of alleged violations.

If no listed chemicals are identified during the audit, it's likely that a warning will not be needed. However, care

must be taken when evaluating information from the wider supply chain as suppliers outside of the US are often unfamiliar with Prop 65 or can be uncomfortable sharing relevant information that may be considered proprietary in nature. Due consideration should be given to the quality of available information on the presence of Prop 65 listed chemicals, in the absence of analytical test results on the finished product.

If one or more listed chemicals are known or found to be present, there are several options to consider. Some companies elect to provide a warning based solely on the presence of the listed chemical(s) whereas others choose to proceed without placing a warning, based on other considerations in their internal risk management decision process. The former reduces risk of litigation, but may result in unnecessary commercial or reputational damage, while the latter carries a much higher level of enforcement risk. (See Figure 1).

Scenario	Description	Relative risk of enforcement
Warning provided based on presence of a listed chemical	A warning is applied without completion of an exposure assessment. This poses minimal litigation risk, but it is technically discouraged by OEHHA and may have unnecessary commercial and reputational consequences.	Low
Warning provided following exposure assessment of a listed chemical	A listed chemical is present, and the assessment indicates that exposure is greater than the Safe Harbor Level. This provides evidence for defensibility; however, it does not eliminate the possibility of litigation.	Low
Warning omitted following exposure assessment of a listed chemical	A listed chemical is present, but an assessment indicates that exposure is below the Safe Harbor Level. This provides evidence for defensibility; however, it does not eliminate the possibility of litigation.	Medium
Warning omitted despite known presence of a listed chemical	One or more of the listed chemicals is present, but an exposure assessment is not carried out, and no warning is applied. This is a high litigation risk option, especially for contentious chemicals such as lead, phthalates, etc.	High

Figure 1: Risk gradient for warning label decisions

2. If the product contains listed chemicals, are the levels known?

After the identification of one or more listed chemicals, the next step is to determine how much of any listed chemical is present in the product. Manufacturer and supplier specifications, including formulation sheets and supplier data sheets (SDS), as well as any analytical testing on the products, are the best sources for understanding the estimated or actual concentration of listed chemicals in the finished product.





3. Does the concentration of the Prop 65-listed chemical of concern warrant consideration of warning?

The complexity and rigour of an exposure assessment can range from conservative screening estimates to advanced modelling of specific exposure scenarios. At the screening level, worst-case assumptions are applied to determine whether potential exposures of concern exist when compared with established Safe Harbor Levels. This approach reduces the financial burden of assessment, particularly where listed chemicals are present at very low concentrations.

If the results of the assessment under worst-case assumptions are of concern, the assessment can be refined using assumptions that better reflect the actual exposures experienced by typical users. This involves characterizing realistic exposure scenarios for the average user based on product use information and published data, quantifying average daily exposure for each scenario and known or potential routes of exposure, and comparing estimated exposures with Safe Harbor Levels for each chemical of interest.

An exposure-based law

Prop 65 is an exposure-based rather than a hazard-based law. This means that the amount of any Prop 65-listed chemicals in the product is of more importance than the mere presence of the chemical(s). Exposure factors that need to be considered include, but are not limited to, chemical concentration, frequency and duration of product use, product handling, and use of personal protective equipment. A robust technical exposure assessment helps companies move beyond uncertainty, enabling informed and defensible decision-making in relation to Prop 65 warnings. The most effective strategies balance key findings with sound commercial judgement to ensure products exported for sale in the US are both compliant and competitive.

If it's not possible to obtain sufficient detail from ingredient/material suppliers, laboratory testing may be required. The type of testing should align with product use and likely exposure routes. For example, products may range from food or dietary supplements to industrial shelving or children's art materials. Different product types may require different analytical approaches that align with the likely routes of exposure, but testing should always be performed by an accredited laboratory with experience in Prop 65 evaluations.

4. Have Safe Harbor Levels been established for chemicals of interest?

Around a third of the chemicals currently listed under Prop 65 have a defined Safe Harbor Level, below which a warning is not required. These levels include No Significant Risk Levels (NSRLs) for cancer-causing chemicals and Maximum Allowable Dose Levels (MADLs) for chemicals that can cause reproductive or developmental toxicity. The current Safe Harbor Level list is available [here](#).

For chemicals without official Safe Harbor Levels, it is possible to derive levels using OEHHA's published methodology and toxicological guidance. This involves reviewing toxicology literature and applying appropriate risk assessment methodologies. It rarely requires laboratory testing.

When is a warning not needed?

OEHHA states that Prop 65 warnings are not required in the following circumstances:

- If individuals are not exposed to Prop 65-listed chemicals
- If exposures to Prop 65-listed chemicals are at or below Safe Harbor Levels
- If a business can show that the exposure poses no significant cancer risk or is substantially below the level observed to cause reproductive health effects



Prop 65 warnings for consumer products

Results from an exposure assessment on a finished product are one aspect that should be considered for the wider risk management process. The technical assessment is often evaluated side-by-side with commercial and reputational considerations. If the business concludes that a Prop 65 warning is appropriate, labelling, signage, and/or online information must meet requirements stipulated by OEHHA. Some of these requirements were updated with changes to the Prop 65 regulatory text implemented on January 1, 2028 (under transition until January 1, 2028). Failure to adhere to the specifications can expose businesses to litigation risk.

Warnings generally consist of the warning symbol, signal wording, and warning content. Requirements for the signal wording and yellow warning symbol are outlined in Figure 2. The symbol may be printed in black and white for signs and labels where printing in the colour yellow is not an option.


<p>Warning symbol (must be placed to the left of signal wording, and be no smaller than the height of signal wording)</p>	<p>Signal wording (must be placed to the left of warning content)</p>
	<p>WARNING or CA WARNING or CALIFORNIA WARNING</p>

Figure 2: Prop 65 warning symbol and signal wording requirements

Specific warning content must be used for consumer products which risk exposing people to:

- One or more chemicals listed as carcinogens
- One or more chemicals listed as reproductive/developmental toxicants
- Listed carcinogens AND listed reproductive/developmental toxicants (different chemicals)
- Chemicals listed as BOTH a carcinogen and reproductive/developmental toxicant

For some consumer products, businesses can choose between long and short-form variants of the applicable warning content. Changes implemented in 2025 extend the requirements of short-form content to include the name of at least one of the listed chemicals which it contains. Products manufactured and labelled from January 1, 2028 must follow the new format when a short-form warning is used.

Figure 3 illustrates different formats of warning content for products containing Prop 65 listed carcinogens and listed reproductive/developmental toxicants.

Type of warning	Warning content for exposure to listed carcinogens and reproductive/developmental toxicants
Full length 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 .
Short-form warning	Risk of cancer from exposure to [name of chemical] and reproductive harm from exposure to [name of chemical]. See www.P65Warnings.ca.gov . OR Can expose you to [name of chemical], a carcinogen, and [name of chemical], a reproductive toxicant. See www.P65Warnings.ca.gov .
Old short-form warning (being phased out, but may be used on products manufactured and labelled prior to January 1, 2028)	Cancer and Reproductive Harm – www.P65Warnings.ca.gov .

Figure 3: An example of Prop 65 warning content options

Certain product types require tailored warning content. This includes but is not limited to furniture, food, and alcoholic beverages.

For example, where furniture contains or is treated with a listed chemical, a tailored warning label must be fixed directly to the product. In addition, furniture display areas must include a warning sign at the point of public entrance, alternatively product receipts can include a warning notice. Minimum size requirements apply to these warnings.

Warning content for food products follows similar formats to general consumer products in most cases, but specifies that the exposure risk comes from consumption. There are additional, more complex requirements for exposure to acrylamide, in terms of the wording and the way the warning is displayed on the food product label. Short-form options are not provided for acrylamide exposure warnings.

OEHHA also stipulates a single, full-length warning for alcoholic beverages, with minimum sizes specified for label dimensions and typeface.

The 2025 changes to the Prop 65 regulatory text introduce tailored wording requirements for two new categories: passenger or off-highway motor vehicle parts and recreational marine vessel parts.

Prop 65 is a dynamic framework. It's important to keep on top of ongoing developments for warnings, as well as updates to the chemicals included on the Prop 65 list.

How can Sagentia Regulatory help?

Sagentia Regulatory provides expert support in the development and implementation of Prop 65 strategies. From a technical perspective, this includes developing a product-specific strategy, setting up and monitoring analytical testing, if needed, deriving Safe Harbor Levels as needed, and preparing screening and/or refined exposure assessments. This information can be used to aid and enable decision making concerning the placement of warnings by our clients' in-house teams or their appointed attorneys. We also provide regulatory services such as reviewing the design and wording of existing warnings or preparing new warnings for labels, signage, or online use in the event the client has made the decision to warn, or technical assessments suggest the need to consider placing a warning.

Prop 65 projects are handled by our US team, on behalf of US-based companies and international companies looking to export to the US.



Get in touch to find out how we can support your entry into US markets: info@sagentiaregulatory.com

References

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

Key questions to guide proportionate, defensible Prop 65 decisions

There is no single compliance pathway for Proposition 65. These questions are designed to help businesses assess where uncertainty exists – and where targeted action can reduce risk without unnecessary warnings.

1. Have we systematically audited product formulations and packaging against the current Prop 65 chemical list, including potential impurities, contaminants, or substances introduced during manufacturing?

2. How confident are we in the quality and completeness of our supplier data, and can that information be relied upon without independent verification?

3. Where listed chemicals are present, do we know the concentration in the finished product, or do data gaps indicate the need for targeted analytical testing aligned to realistic exposure routes?

4. Have we conducted, or appropriately scoped, an exposure assessment that reflects how products are actually used, rather than applying overly conservative assumptions that may trigger unnecessary warnings?

5. Where Safe Harbor Levels are unavailable, have we evaluated whether a level could be derived to support a defensible decision, or whether inaction would introduce avoidable litigation or reputational risk?

6. Where a decision to warn is made, are warnings technically compliant with current and upcoming OEHHA requirements, including product-specific wording, short-form changes, and transition deadlines through to 2028?



Taking the next step

If one or more of these questions cannot be answered with confidence, targeted technical evaluation can help reduce uncertainty and support defensible decision making. Our team can help you assess the options at info@sagentiaregulatory.com

About Sagentia Regulatory

Sagentia Regulatory, formerly TSG Consulting, provides scientific and regulatory expertise to help clients navigate the technical and compliance challenges of bringing their products to market across multiple jurisdictions. With deep knowledge in environmental science, human health, chemistry and regulatory affairs, Sagentia Regulatory supports innovation and compliance across sectors including crop protection, antimicrobials, biocides, industrial, consumer goods, and more.

For further information visit us at:
sagentia.com/regulatory or
email info@sagentiaregulatory.com



Sagentia Regulatory

1150 18th St NW
Suite 475
Washington DC
20036
USA

sagentia

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