

California Proposition 65

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Clear and Reasonable Warnings

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Modifications to Article 6 Clear and Reasonable Warnings

- In August 2016 OEHHA adopted amended regulations for the provision of “clear and reasonable” Proposition 65 warnings in Title 27, California Code of Regulations, section 25600, et seq.
- In December 2017, OEHHA adopted clarifications to the regulations.
- The new regulations will be effective on August 30, 2018, although businesses can begin using warnings that conform with the new regulations at any time.
 - Article 6, Subarticle 1 consists of mandatory provisions including definitions of terms that are applicable to all warnings provided under Proposition 65.
 - Article 6, Subarticle 2 provides non-mandatory, “safe harbor” methods and content for giving “clear and reasonable” warnings under Proposition 65.

When is a Warning required?

- The product or activity exposes the persons in California:
 - to chemicals known to the State to cause cancer or reproductive harm;
 - at a level of exposure above the Safe Harbor Level established by OEHHA; or
 - for which a Safe Use Determination has not been established.
- The warnings regulations do not address the question of whether a warning is required; rather, the regulations provide guidance on how to provide a warning once a business has made a determination that a warning is required.

Is testing required?

- The warning regulations do not require a business to perform any testing.
- HOWEVER, The manufacturer, importer, and distributor of the Product are responsible for determining if a warning is required.

What is a Safe Harbor Warning?

- The safe harbor warning methods and content in Article 6 are deemed by OEHHA to be clear and reasonable, and provide a “safe harbor” against enforcement actions for businesses that choose to use them.
- A business can choose to use other warning methods and content; however, the business might have to defend the warning in legal proceedings if it were challenged by a public or private enforcer as not being clear and reasonable.
- A consumer product covered by a court-approved settlement can continue to use any warning methods and content contained in that settlement.

Who is responsible to provide the warning?

- OEHHA's new regulations place primary responsibility for providing warnings on product manufacturers, producers, packagers, importers, suppliers or distributors.
- For consumer product exposures, businesses in the above categories must either
 - provide a warning on the product, or
 - provide notice and warning materials to “the authorized agent” for a retail seller and receive an acknowledgment that the notice and materials were received.
- The retail seller is responsible for placement and maintenance of the warning materials he/she receives from the product manufacturer, producer, packager, importer, supplier or distributor.

How do the new regulation effect component manufactures

- A company that manufactures component parts or ingredients that include listed chemicals can comply with the obligation to warn persons who can be occupationally exposed to the bulk product by providing warnings consistent with Section 25606.
- The company would only have responsibility for a consumer warning if it has knowledge that the end use of the component part or ingredient can expose a consumer to a listed chemical.

Safe Harbor Warning Methods and Content - Size

- Type size requirements depend on the category of exposure covered by the safe harbor warning.
 - Consumer product exposure warnings must generally be prominently displayed on a label, labeling, or sign, and must be displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use.
 - Some safe harbor warnings, such as on-product warnings for consumer products (Section 25602), environmental exposure warnings (Sections 25604, 25605), and several “tailored warnings” (Section 25607.1, et seq.), have specific minimum type-size requirements.
 - You should refer to the safe harbor methods corresponding to the exposure category for which you are providing a warning to determine if there are any applicable type size requirements.

Safe Harbor Warning Methods and Content - Consumer Products

- The safe harbor methods and content for providing a warning can be found in Sections 25602 and 25603. Section 25602(a) describes four safe harbor warning methods:
 - A product-specific warning provided on a posted sign, shelf tag, or shelf sign, at each point of display of the consumer product.
 - A product-specific warning provided via any electronic device that automatically provides the warning to the purchaser before purchase without requiring the purchaser to seek out the warning.
 - A warning on the label that complies with the content requirements in Section 25603(a); namely, the warning symbol, the signal word, “WARNING:”, and the applicable warning message.
 - An on-product “short-form” warning on the label that complies with the content requirements in Section 25603(b); namely, the warning symbol, the signal word, “WARNING:”, and the applicable truncated warning message. The warning must be in a type size no smaller than the largest type size used for other consumer information on the product and in no case in a type size smaller than 6-point type.

Disapproved Safe Harbor Warning Methods and Content

- Owner's Manual
 - A standalone warning in an owner's manual is not a safe harbor warning method for consumer product exposures.
 - For some products (specifically diesel engines, passenger vehicles and recreational vessels), owner's manuals are included as part of a safe harbor warning method used in conjunction with another warning method (Sections 25607.14, 25607.16, and 25607.18).
- General Warnings
 - A standalone warning at public entrances purporting to cover all possible consumer product exposures would not meet the requirements for safe harbor warnings under the new regulations.

Internet Warnings

- Warnings are required for purchases made over the internet following the methods in Section 25602(b).
 - Warnings must be provided to the consumer prior to completing the purchase.
 - The warning must be provided via any one of the four methods for consumer products in Section 25602, subsections (a)(1)-(4).
 - For a website warning, 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.
 - If an on-product (short-form) warning is provided on the product label, the website warning may use the same content.

Catalog Warning

- Warnings meeting the requirements of Section 25602(c) are required to be provided for purchases made through catalogs prior to completing the purchase.
 - The warning must be provided via any one of the four methods for consumer products in Section 25602, subsections (a)(1)-(4).
 - If an on-product (short-form) warning is provided on the product label, the catalog warning may use the same content.
- A warning symbol provided near a product in a catalog or on a webpage separate from a consumer product warning which is located elsewhere in the catalog or website is unlikely to ensure that the warning is “clearly associated” with the item being purchased. This approach would not meet the safe harbor requirements in the regulations.

Warning Symbols



Warning Symbol Requirements

- The regulations only require that the warning symbol be “yellow.”
 - If a business does not use the color yellow for other information printed on the label or sign, the business may print the warning symbol in black and white (Section 25603(a)).

Warning Type Size

- For a consumer product exposure safe harbor warning provided on a label pursuant to Section 25602(a)(3), there is no specific type size requirement.
 - Section 25601(c), however, requires that safe harbor consumer product exposure warnings on a label be prominently displayed with such conspicuousness as compared with other words, statements, designs or devices on the label, labeling, or sign, as to render the warning likely to be read and understood by an ordinary individual under customary conditions of purchase or use.
- A “short-form” warning may be provided on a product in accordance with Section 25602(a)(4).
 - This section requires that the entire warning be in a type size no smaller than the largest type size used for other “consumer information” on the product, and in any case the warning must not be in a type size smaller than 6-point type.
 - “Consumer information” is defined in Section 25600.1(c), and includes warnings, directions for use, ingredient lists, and nutritional information, but does not include the brand name, product name, company name, location of manufacture, or product advertising.

Warning and Chemical Names

- If a business chooses to follow the safe harbor methods and content in Section 25601(b), the business must include the name of one or more chemicals for which it is providing a warning.
- Where a business is providing a warning for both cancer and reproductive toxicity, the warning must include the name of one or more chemicals for each endpoint.

Short Form Warnings

- Must be applied directly to the product or its immediate packaging or label
- Does not require identification of specific chemicals
- No limitation of product size
- The warning content on the short-form warning must be in a type size no smaller than the largest type size used for other consumer information on the product label and in no case smaller than 6-point type.

Warning in Languages other than English

- Safe harbor consumer product warnings (Section 25602), environmental warnings (Section 25604), and “tailored” warnings (Section 25607.1, et seq.) require warning content to be provided in other languages under certain circumstances.
- If a consumer product label or packaging contains consumer information in a language other than English, the warning must be provided in that language in addition to English.
- If signage at a business or facility is in a language other than English, then an environmental warning provided by that business or facility must be in that other language in addition to English.

Environmental Exposure Warnings and Methods

- If a business has determined that a visitor to the facility can be exposed to a listed chemical at a level that requires a warning, then an additional Proposition 65 warning for those exposures may be required.
 - The methods and content for providing safe harbor environmental warnings are located in Sections 25604 and 25605.
 - The “map” referenced in the regulations at 25604(a)(2)(B)) showing where exposures are likely to occur is required.
 - The warning should be provided close enough to the source of exposure for the person seeing the warning to determine where and how they may be exposed

Occupational Exposure Warnings and Methods

- If a business has determined that the only exposures to a listed chemical that require a warning will be occupational, then the business can follow the methods and content described in Section 25606 (Occupational Exposure Warnings). The term “occupational exposure” is defined in Section 25600.1(k) as an exposure to any employee at his or her place of employment.
- Safety Data Sheets may be used to provide occupational exposure warnings, they are not a safe harbor warning method for other exposure types such as consumer product or environmental exposures covered by Article 6.

Questions?

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