

PROPOSITION 65¹
CLEAR AND REASONABLE WARNINGS
QUESTIONS AND ANSWERS FOR BUSINESSES



Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

July 2017

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¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65, codified at Health and Safety Code section 25249.5 *et seq.* Hereafter referred to as “Proposition 65” or “the Act”.

Modified Article 6 Clear and Reasonable Warnings

Has the Office of Environmental Health Hazard Assessment (OEHHA) issued new regulations concerning the provision of warnings?

Yes, 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.*² 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.

I have determined that I need to provide a warning. How do I do so?

Guidance for providing a clear and reasonable warning is available in OEHHA’s [warning regulations](#). Warnings can be given by a variety of methods depending on the type of exposure (consumer product, environmental, or occupational). You may find it helpful to refer to the [side-by-side comparison](#) of the September 2008 and August 2018 (“new”) regulations to consider your options, as either can be used until August 30, 2018.

What kind of testing does a business have to do in order to meet the safe harbor warning requirements?

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. The warning regulations do not require a business to perform any testing.

To guide businesses in determining whether a warning is necessary, OEHHA has developed over 300 regulatory [safe harbor levels](#) for 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 is not required 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.

² All further references are to sections of Title 27, California Code of Regulations unless indicated otherwise.

Subarticle 1. General

When do the new regulations take effect?

To allow for a reasonable transition period for businesses to begin providing warnings under the new regulatory provisions, businesses can use either the [September 2008](#) or [new regulations](#) until August 30, 2018, at which time the new regulations will become operative and the September 2008 regulations will no longer be available as a safe harbor compliance option.

If I have to provide a warning, am I required to use the safe harbor warning methods and content described in Article 6?

No. 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.

When do I need to provide the new warnings?

The new warnings become operative on August 30, 2018, at which time the September 2008 safe harbor warning methods and content will no longer be operative. The exceptions involve consumer products manufactured prior to August 30, 2018 and labeled in compliance with the September 2008 warning regulations, and products covered by court approved settlements (Section 25600).

Does a product available for retail purchase before August 30, 2018 require a new warning?

A consumer product that is *manufactured* prior to August 30, 2018 and labeled with a warning that is compliant with the September 2008 version of the regulations is deemed to be compliant with the new regulations (Section 25600(b)). In other words, such a product does not require a new warning. The date the product is available for purchase does not determine whether the product should have a new warning.

Does a product covered by a court-approved warning require a new warning?

A consumer product covered by a court-approved settlement can continue to use any warning methods and content contained in that settlement.

Can a product that is similar to one covered by a court-approved warning use the court-approved warning instead of the new warning in the regulation?

The new regulations do not prohibit a business that is not a party to a settlement from using warning methods and content incorporated into the settlement. However, if the

warning methods or content differ from those in the regulations, the business would not be able to claim safe harbor protection. The business could still defend an enforcement action by arguing such a warning is “clear and reasonable.”

Can a business replace the September 2008 warnings and provide the new warnings immediately?

Yes, during the two-year phase-in period from August 30, 2016 to August 30, 2018, a business can follow the safe harbor methods and content from either the September 2008 regulations or the new regulations (Section 25600(b)).

Responsibility to Provide Warnings

Who should provide a warning?

Consistent with the Act, 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. Businesses should carefully review the new [requirements](#) (Section 25600.2).

Can retail sellers rely on new Section 25600.2(e) now?

No. Section 25600.2(e) of the new regulations does not become operative until August 30, 2018. The phase-in period for the new regulations allows a business to provide *warnings* using the new safe harbor methods and content prior to the operative date of August 30, 2018. However, Section 25600.2(e) is not operative until August 30, 2018.

If a company is a manufacturer or producer, but does not sell directly to retailers, how can it comply with the requirement to provide warnings to retail sellers?

A company that does not sell directly to retailers has two options for compliance: (1) Label the product with the required warning; or (2) Provide the warning notice and offer to provide the warning materials to the packager, importer, supplier or distributor. The second option is only acceptable if the warning is passed along the supply chain and ultimately reaches the consumer. A manufacturer or producer may choose to enter into a contract with other businesses along the commerce chain of their product to ensure that the warning is appropriately transmitted to the retailer and end consumer.

If a company manufactures component parts or ingredients that are sold in bulk to other manufacturers or formulators, how can it comply with the requirement to

provide a warning, especially if the need for a warning depends on the concentration or the manner of use of the listed chemical in the final product?

A company that manufactures component parts or ingredients that include listed chemicals can comply with the obligation to warn persons who may be occupationally exposed to the bulk product by providing warnings consistent with Section 25606. Such a company would only have responsibility for a consumer warning if it has knowledge that the end use of the component part or ingredient will expose a consumer to a listed chemical at a level that requires a warning. For example, if a manufacturer of a food ingredient knows that the ingredient is typically used at high enough concentrations to require a warning in certain types of prepared foods and could thereby result in an exposure under the Act, then the ingredient manufacturer should provide the warning notice to the product manufacturer. An ingredient manufacturer in such a situation may choose to work with the product manufacturer to evaluate whether the product should have a warning and may enter into a contract with product manufacturers to ensure that the warning is appropriately transmitted to the retailer and ultimately the consumer.

Subarticle 2. Safe Harbor Methods and Content

What are the type size requirements for safe harbor warnings?

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.

Consumer Product Exposure Warning Methods

What are the ways to provide safe harbor warnings for consumer product exposures?

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.

If a consumer product has exterior packaging, is a warning label required on both the packaging and on the product itself?

No. A “label” is defined as a display of written, printed or graphic material that is affixed to a product or its immediate container or wrapper (Section 25600.1). The warning label should be placed in a manner to ensure that consumers receive the warning prior to exposure. A warning must be visible on exterior packaging that is opaque if an exposure requiring a warning can occur upon opening the package. A business may also choose to provide a warning on both the exterior packaging and the product itself.

Can an owner’s manual be used for providing a safe harbor warning?

No. 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).

Can a sign combine two different safe harbor warnings?

It is possible to provide two or more warnings on a single sign. However, combining the content of multiple warnings into one warning message would not comply with the safe harbor requirements. If a business provides a warning in this manner, it would not benefit from the safe harbor protections of the regulations. For example, if a vehicle repair facility allowed smoking at its facility such that warnings were required both for the environmental exposure to petroleum products and tobacco smoke, the required warning elements for each situation must be included. A combined sign would need to be 8 ½ by 11 inches in dimension (designated smoking area requirement), posted at each public entry of the repair facility as well as within the area in which smoking occurred, printed in no smaller than 32-point type (repair facility requirement) with the

messages enclosed in boxes to satisfy the safe harbor requirements. (Sections 25607.26, 25607.27, 25607.28, and 25607.29)

Can a business provide a general Proposition 65 warning at each public entrance to a store instead of providing warnings for specific consumer products?

No. 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 and Catalog Warnings

Must warnings be provided for internet purchases? Must a product sold over the internet have a warning in order to meet the safe harbor requirements?

Yes, under the safe harbor provisions of the regulations, 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, *and* a 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. In addition, if an on-product (short-form) warning is provided on the product label, the website warning may use the same content.

Must warnings be provided for catalog purchases? Must a product sold through a catalog also have a warning in order to meet the safe harbor requirements?

Yes, under the safe harbor provisions of the regulations, warnings meeting the requirements of Section 25602(c) are required to be provided for purchases made through catalogs prior to completing the purchase, *and* a warning must be provided via any one of the four methods for consumer products in Section 25602, subsections (a)(1)-(4). In addition, if an on-product (short-form) warning is provided on the product label, the catalog warning may use the same content.

Instead of displaying the entire consumer product warning content on the product page of a catalog or webpage, can a business place the warning symbol next to the product and use it as a reference to a full consumer product warning provided elsewhere in the catalog or website and still claim safe harbor protection?

No. 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 insure that the warning is “clearly associated” with the item being purchased. This approach would not meet the safe harbor requirements in the regulations.

Consumer Product Exposure Warning Content

Warning Symbol

Which American National Standards Institute (ANSI) International Organization for Standardization (ISO) number is required for the yellow warning symbol?

The Article 6 regulations did not adopt the ANSI standards for warning symbols, and there is no requirement that the warning symbol color correspond to a specific ISO number. The regulations only require that the warning symbol be “yellow.” OEHHA provides [sample compliant warning symbols](#) that a business may download and use.

If a business does not have the ability to print in color, can the business print the warning symbol in black and white?

Yes, 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)).

Type Size

What is the minimum type size for consumer product exposure warnings?

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.

Chemical Names

Section 25601(b) requires a safe harbor warning to identify “one or more” of the chemicals for which the warning is being provided. What if a business determines that there are five listed chemicals requiring a Proposition 65 warning? Do *all* five chemicals need to be named in the warning?

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. Additionally, 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.

If, for example, there are five possible chemical exposures from a given product, and all five chemicals are listed only as carcinogens, then the business would only be required to name one of those five chemicals in the warning. However, the business may identify any or all of the remaining four chemicals if it chooses to do so. If there are exposures to both carcinogens and reproductive toxicants, a business would be required to name one of the chemicals that is a carcinogen and one of the chemicals that is a reproductive toxicant, but the business could choose to identify more chemicals in the warning. If the warning covers exposure to a chemical that is listed as both a carcinogen and a reproductive toxicant, the warning would only need to name that one chemical, however both endpoints would need to be included in the warning. The business could choose to identify more chemicals covered by the warning.

Is it acceptable to use chemical acronyms in a warning? As an example, if a product requires a warning for "diethylhexyl phthalate," is it acceptable to identify "DEHP" instead of the full chemical name in the warning?

The full chemical name as it appears on the Proposition 65 list needs to be included in the first mention of the listed chemical in the warning. If the abbreviation is included as part of the full chemical name in a warning, the abbreviation alone can be used for subsequent references to the chemical name.

On-Product ("Short-Form") Warnings

When can a business use the on-product or short-form label?

Section 25603, subsections (a) and (b) provide options for safe harbor warning content for consumer products. Subsection (a) is the standard warning content, while subsection (b) allows a business to use truncated, "short-form" warning content on a product label. A business may use either the standard or short-form warning content on a label for a consumer product exposure. The short-form warning cannot be used on a sign.

Can a short-form warning be placed on the packaging or does it have to be on the product itself?

The short-form warning can be affixed to or printed on a product or its immediate container or wrapper.

Can a short-form warning label be used on any size product?

OEHHA's intent in adding the short-form, truncated warning to the safe harbor methods and content was to provide an alternative that could be used on small products or where space was limited. There is no express prohibition, however, on using the short-form warning on larger products. 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.

If the space on a product label is too small and the short-form warning cannot be placed in one line, can the short-form warning be placed in two/three lines?

Yes, there is no requirement that the short-form warning content fit on one line, though the warning must be legible.

If a business provides a short-form warning on the consumer product, can the same warning be provided on a website?

Yes, a consumer product warning provided on a website pursuant to Section 25602(b) can use the same short-form warning content that the business is providing on the product. The business may also use a picture of the label on the product for the website warning.

Warnings in Languages Other Than English

When are warnings required to be provided 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. Specifically, 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.

How can I access warning content in different languages – Spanish, Chinese, French, etc.?

OEHHA has provided [warnings translations for businesses](#) on the [Proposition 65 Warnings Website](#), including translations in Spanish, Chinese, French, Tagalog, Korean and Vietnamese.

Is a product name considered "consumer information"?

No, a product name is not considered "consumer information" for purposes of determining whether a language needs to be provided in a language other than English.

“Consumer information” includes warnings, directions for use, ingredient lists, and nutritional information; it does not include the brand name, product name, company name, location of manufacture, or product advertising (Section 25600.1(c)).

Environmental Exposure Warning Methods

If a business has determined that occupational exposure warnings are required, and is providing Proposition 65 occupational warnings that are compliant with the Article 6 safe harbor methods and content, does a business also need to provide warnings to visitors for exposures to listed chemicals at the facility?

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 “environmental exposure” definition states all exposures that are not consumer product or occupational exposures are environmental exposures. It is not clear what type of warning is required when there are combinations of exposures. Are multiple types of warnings required when multiple types of exposures are occurring?

Proposition 65 requires warnings for exposures to listed chemicals. When the regulations were first adopted, exposures were divided into three general categories: consumer product exposures, occupational exposures and environmental exposures. These categories have worked well over the years. It is true that in some circumstances warnings will need to be provided that do not fit neatly into a single category. In that case, more than one warning may be provided for exposures to a listed chemical in a given location. As an example, the regulations for amusement park warnings require a warning to be posted at each public entrance, but also require warnings to be provided separately for consumer products, alcoholic beverages, food, and enclosed parking facilities where such exposures occur on the premises in order for the amusement park to receive full safe harbor protection (Section 25607.22).

The regulations for environmental exposures require the warning to include a map. Does that mean a floor plan of the property or a map of the area showing the location?

The “map” referenced in the regulations (now in Section 25604(a)(2)(B)) could be a floor plan delineating the affected area(s), a map of the facility showing where exposures are likely to occur, or a map of a community showing the geographic area affected.

Businesses should determine where exposures are likely to occur and place the warnings at or near that location.

Environmental Exposure Warning Content

How specific must the description be in an environmental warning? Must a specific area be described for each source of exposure or for each chemical present, or only for the chemical listed in the warning?

The specific area must be described in the warning only for the chemical or chemicals for which the warning is being provided. 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.

Examples of how a warning can identify the source of the exposure and be provided in a manner that clearly associates it with the exposure can be found in the tailored warning section of the regulation (see Sections 25607.20 and 25607.21 (enclosed parking facilities), Sections 25607.24 and 25607.25 (petroleum products), Sections 25607.26 and 25607.27 (service stations and repair facilities), and Sections 25607.28 and 25607.29 (designated smoking areas).

Where a warning is being provided for multiple chemicals and/or multiple exposures, the warning should describe the area in which an exposure to those chemicals can occur. It may be appropriate in some circumstances to provide warnings in more than one location in a facility so that the warning will be clearly associated with the source(s) of exposure. For example, posting a sign at the entry of a facility that purports to provide a warning for an exposure that is only likely to occur in one area of the facility, such as in an art studio on the third floor of a building, would not be sufficiently associated with the source of the exposure. Such a warning should be posted at entrances to that area of the third floor. On the other hand, if a particular chemical exposure can occur throughout a facility, for example exposures to a solvent from paint used throughout a large freestanding art studio, a warning at the studio entrance naming the chemical and the source (paint) may be appropriate.

Occupational Exposure Warnings

Are professional or industrial use-only products covered by this regulation?

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.

Section 25606(a) states that a warning is not required on products that meet the requirements of the Hazard Communication Standard (HCS). If a product contains a Proposition 65 chemical, but the quantity is not enough to trigger classification as a carcinogen or reproductive toxicant under the HCS, does it still require a Proposition 65 warning?

Proposition 65 imposes separate warning requirements from the HCS. Section 25606 provides that a business can comply with Proposition 65 by complying with state and federal occupational training and warning requirements *when a warning is required* under the federal or California HCS, or the California Pesticides and Worker Safety requirements. In the event that there is an occupational exposure to a Proposition 65 listed chemical with no warning requirement for the chemical under these laws, *a Proposition 65 warning may still be required*. Section 25606(b) provides businesses the option to use safe harbor warning methods and content for an exposure to a Proposition 65 listed chemical in an occupational setting.

Can a business place the Proposition 65 warning on a Safety Data Sheet (SDS)?

Safety Data Sheets (SDS) are outside the scope of this regulation, as OEHHA cannot prescribe the content of forms under the authority of a federal or other state agency. While SDS 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.