

Dear ILMA:

Please see my responses to your questions below:

“(1) Our company has received several Safety Data Sheets ("SDS") with Prop. 65 warnings on them. The suppliers are including this information in section 16 of the OSHA-compliant SDS. We use a software package that produces both our labels and SDS. We have already updated our label format to properly present the warning and signal word. Do companies also need to use the triangle pictogram on our SDS? Currently, our software publishes the warning, but does not use the triangle pictogram.”

As OEHHA noted in the Questions and Answers for Businesses document available on the [Proposition 65 Warnings Website](#):

“Q43: 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.”

“(2) Sections 25607.24 and 25607.25 describe the Clear and Reasonable Warning requirements for Petroleum Product Warnings resulting from Environmental Exposures. ILMA Members routinely supply lubricant products either directly or through distributors to industrial users who otherwise utilize these products in occupational settings. In OEHHA's Petroleum Fact Sheet” (<https://www.p65warnings.ca.gov/fact-sheets/petroleum-productsenvironmental-exposure-industrial-operations-and-facilities>), one finds this answer to the question "What are petroleum products?" Petroleum products are made from crude oil, coal and natural gas. They include gasoline, diesel fuel, and lubricants (for automobiles, airplanes, trains, snowmobiles, cooking stoves, generators, and furnaces) and are used to make chemicals, plastics, and synthetic materials. [Emphasis added.] In addition to complying with the Clear and Reasonable Warning requirements for Occupational Exposures, do lubricant product users, such as customers of ILMA Members, also need to comply with the requirements of section 25607.25 by providing signage such as:

WARNING: Crude oil, gasoline, diesel fuel and other petroleum products can expose you to chemicals including toluene and benzene, which are known to the State of California to cause cancer and birth defects or other reproductive harm. These exposures can occur in and around oil fields, refineries, chemical plants, transport and storage operations such as pipelines, marine terminals, tank trucks and other facilities and equipment. For more information go to: www.P65Warnings.ca.gov/petroleum.”

The “tailored warnings” in Sections 25607.24 and 25607.25 are for *environmental exposures* to petroleum products from *industrial operations*. If there are occupational exposures, occupational warnings may also be required. As we noted in the Q&A for Businesses:

“Q37: 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.”

“(3) Many manufacturers, who are customers of ILMA members, utilize "straight oil" metalworking fluids, a subclass of the category of lubricants known as metalworking products (broadly, those formulated petroleum products utilized as processing aids for machining and grinding metal alloys including steel and alloy steel). Experience has shown that when such fluids are used to machine stainless steels which contain nickel or machine lead-containing alloys, are likely to see parts per million levels of those metals in their fluids. The OEHHA web pages which describe these metals are: lead: <https://oeh.ha.ca.gov/proposition-65/chemicals/lead-and-lead-compounds>, and nickel: <https://oehha.ca.gov/proposition-65/chemicals/nickel-metallic> In these cases, it is not the ILMA Members whose fluids contain lead or nickel, but it is the *process of machining* that can cause the metals to contaminate fluids. Is it required that ILMA Members who supply those fluids to their customers in California advise their customers of potential nickel or lead contamination?”

Proposition 65 only requires businesses to provide warnings for “knowing and intentional exposures” to listed chemicals. If a business is not causing an exposure, no warning is required. Additional information is available here: <https://www.p65warnings.ca.gov/frequently-asked-questions-businesses> .

“(4) Some ILMA members distribute biocidal products, whose labels are regulated by EPA, which may release formaldehyde under certain conditions. OEHHA published on April 23, 2018, a proposed amendment to the Clear and Reasonable Warning regulations that would allow substitution of the word "Warning" with "Attention" or "Notice" if the word "Warning" was already part of the EPA-required label. Does the original manufacturer of the biocidal product or does the distributor of the biocidal product (which may be an ILMA member) need to apply a label in compliance with the proposed amendment, should that amendment be adopted?”

The proposed amendment to Section 25603 is a narrow exception that provides the *option* of an alternate signal word for pesticide labels regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). For more information on the rulemaking, please visit the rulemaking page <https://oehha.ca.gov/proposition-65/crn/proposed-amendments-article-6-clear-and-reasonable-warnings-section-25603>.

In regard to the responsibility for providing warnings, see the discussion beginning on page 4 of this document: https://www.p65warnings.ca.gov/sites/default/files/art_6_business_qa.pdf

“(5) If a product contains, for example, five component parts that are all listed on Prop 65, how does a company correctly select what substance to list? May it simply choose whichever of the five listed? Must a company select the substance that is present at the highest concentration?”

There is no requirement that the chemical named be the highest concentration in the product. As OEHHA noted in the Q&A for Business:

“Q27: 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.”

“(6) What guidance does OEHHA have on the "only one ingredient required rule"(Section 25605)? Why did OEHHA do this in the first place? Why not require all?”

The amended regulations were intended to further the “right-to-know” purposes of the statute and provide more specificity for the content of safe harbor warnings for a variety of exposure situations, and corresponding methods for providing those warnings. More information regarding the reasoning behind this provision of the regulations can be found in the Initial Statement of Reasons for the rulemaking. See:

<https://oehha.ca.gov/media/downloads/cmr/112715warningreg20isor.pdf>

For guidance on the safe harbor warning requirement to include “one or more chemical names”, please see excerpt above from the Q&A for Business. Also in the Final Statement of Reasons (FSOR) for the Article 6 Clear and Reasonable Warnings rulemaking OEHHA noted:

“Where a warning is being provided for more than one endpoint (cancer and reproductive toxicity) the warning must include the name of one or more chemicals for each endpoint unless the chemical is listed as known to cause both cancer and reproductive toxicity and this is stated in the warning. As an example, if a warning is being provided for Proposition 65-listed carcinogens A and B and Proposition 65-listed reproductive toxicants C and D, the warning may specify either carcinogen A or B, or both; and must include either reproductive toxicant C or D, or both.”

“(7) Should we list the most toxic, most prevalent, most likely in terms of exposure route, or should we use another guiding principle?”

There is no requirement in the regulation for identifying one listed chemical over another. The business is free to make that determination on their own.

“(8) There is the standard Environmental Exposure language at 25605. There is a specific Petroleum Products Warnings (Environmental Exposures) at 25607.25. If a product, as sold, does not contain any of the ingredients 25607.25 mentions is it still required, or can the manufacturer use the general warning?”

As noted above, the “tailored warnings” in Sections 25607.24 and 25607.25 are for *environmental exposures* to petroleum products from *industrial operations*. If there are occupational exposures, occupational warnings may be required for the safe harbor (see Section 25606). If there are consumer product exposures, consumer product exposure warnings may be required for the safe harbor (see sections 25602 and 25603).

“(9) If a manufacturer introduces metallic nickel or lead into our products as part of their processes, which sign is required? Where must it be placed: at the entrances, or in the specific areas where the lead and nickel are present?”

If the manufacturer is causing occupational exposures to a listed chemical, warnings can be provided consistent with Section 25606. If there are consumer product exposures to a listed chemical, the manufacturer can provide warnings consistent with Sections 25602 and 25603. If there are environmental exposures to petroleum products from industrial operations, the manufacturer can provide warnings consistent with Sections 25607.24 and 25607.25.

“(10) Section 25604 (1) refers to "public entrances" (25607.25 also defaults to this sub section). If there is a separate employee entrance not accessible to the "public," are signs at those entrances also required?”

If members of the public will not be accessing the facility through the entrance, warnings can be provided consistent with the occupational exposure warnings in Section 25606.

“(11) Does OEHHA have a recommendation for labeling if an item does not contain chemicals that would initiate the Prop. 65 warning statement? Technically, a manufacturer would not have to do anything, but the concern is that many of a company's products will require warnings, so does that company run risk of getting "picked up" if a product does not have anything related to Prop 65 on a label? As a corollary, for OSHA's Hazard Communication Standard 2012 (HCS 2012) we put on our bottles a statement that indicated the product was not hazardous under HCS 2012, so there was never a question if the product had been examined to meet HCS 2012 labeling requirements.”

Warnings are not required where a product does not cause an exposure to a listed chemical at a level that requires a warning. Providing a statement that an item will not cause an exposure to a listed chemical should be discussed with legal counsel.

“(12) Many companies distribute products manufactured by other companies. What responsibilities and/or liabilities does the distributor have if the original manufacturer fails to properly label the product they make?”

Section 25600.2 places the primary responsibility to provide warnings for listed chemicals in consumer products on the manufacturer. As described in the Q&A for Businesses:

“Q11: 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).”

“(13) Even though OEHHA does not require warnings on SDS, do companies incur any liabilities if they choose not to mention Prop 65 on their SDS?”

OEHHA cannot prescribe warning methods and content for other agencies’ laws and regulations. If a person in California can be exposed to a Proposition 65 listed chemical a warning may be required. Methods for providing occupational warnings are discussed in Section 25606.

Best regards,

Mario

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