

California Proposition 65 Compliance Assessment for Heavy-Duty Guardrail System

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Date: July 8, 2019

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INTRODUCTION

RegTox Solutions Inc. (RegTox) was requested by Cogan Wire & Metal Products Ltd. (Cogan) to provide a compliance assessment regarding its "Heavy-Duty Guardrail" system with California Proposition 65. This was conducted based on a review of provided technical and testing data.

PROPOSITION 65 REGULATORY BACKGROUND

The Safe Drinking Water and Toxic Enforcement Act of 1986, more commonly referred as Proposition 65, is a regulation of California that requires businesses to inform citizens of California, by way of a clear and reasonable warning, if the products they purchase contain chemicals that are considered by the State of California to cause cancer or birth defects or other reproductive harm. As required under Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency (Cal/EPA) updates the Proposition 65 list (most recently published in March 8, 2019¹) as new chemicals are added.

Proposition 65 warnings on a product are not required if exposure to a listed chemical from use of that product is below the applicable Safe Harbor Level (SHL) as established and published by OEHHA². SHL consist of No Significant Risk Levels (NSRLs) for carcinogens, which are associated with one excess case of cancer (above background) in an exposed population of 100,000, assuming a lifetime exposure, and Maximum Allowable Dose Levels (MADLs) for reproductive toxicants, based on a 1/1,000th safety factor applied to no-observable-adverse-effect level (NOAEL) or a benchmark dose for reproductive/developmental toxicity. If an SHL has not been derived by OEHHA, a company is required to derive one themselves.

Enforcement of Proposition 65 is under the jurisdiction of the State of California Department of Justice, Office of the Attorney General; however, under the provisions of the law, any private individual may bring a case against a defendant "in the public interest". In doing so, the individual or group (plaintiff) will file a "60-Day Notice of Violation" (NOV) with the Office of the Attorney General alleging a violation of the Act. The onus then falls on the defendant to clearly demonstrate that use of their product does not result in exposure to the violating chemical at levels that exceed the SHL. Companies issued an NOV can defend the compliance of their product in court, or can choose to settle, which typically includes paying settlement costs to the

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

² <https://oehha.ca.gov/proposition-65/general-info/current-proposition-65-no-significant-risk-levels-nsrls-maximum>

plaintiff group (can range from \$5,000 to \$100,000+/settlement) as well as agreeing to provide a warning or agreeing to reformulate the product.

EXPOSURE SCENARIO

The product (See Figure 1) consists of rails, brackets, columns, and hardware and is used primarily in an industrial setting to protect areas from collisions with forklifts. As such, the product would be primarily contacted during installation, with only incidental contact thereafter.

Figure 1: Heavy-Duty Guardrail System



The primary route of exposure would be dermal/skin contact, which would occur mainly during installation. The inhalation route of exposure is not considered relevant and hand-to-mouth exposure would be expected to be negligible based on the nature of the product.

SCREENING ASSESSMENT

The Proposition 65 list contains almost 900 chemicals; however, only a small number of chemicals from the list are expected to be relevant to any particular product. Also, it is not practical to test products, components or materials for every theoretically possible chemical from the Proposition 65 list. The decision of what specific chemicals to test for and the resources to allocate conducting comprehensive Proposition 65 compliance evaluations of a product is ultimately up to the company that is marketing the specific product based on relevant guidance they receive.

Cogan provided the following information:

- Heavy metal testing of the hardware: cadmium (found in all hardware: 6 to 12 ppm); arsenic³ (1 nut: 109 ppm); chromium⁴ (all hardware: 129 to 622 ppm); no lead detected (detected heavy metals are all listed);
- Mill tests for the hardware, tubing, and steel components;
- SDS for the yellow thermoset powder-coating, containing up to 30% bisphenol A/epichlorohydrin polymer resin (may contain low levels of residual epichlorohydrin and BPA, both are listed chemicals).
- Post caps are made of a hard, plastic resin.

A search of the Proposition 65 NOV database⁵ was conducted to gauge enforcement risk for similar products/materials.

As the steel is powder-coated completely, exposure for installers is limited to contact with the powder coated materials, the hardware, and post caps.

Powder Coating

Exposure to residual BPA and epichlorohydrin would be insignificant under the context of this application for this product, if it even occurred at all. Thermoset epoxy powder-coatings are cross-linked and cured to make the final coating highly durable and resistant to wearing, combined with the fact that the primary resin prior to curing would contain very low levels of BPA/epichlorohydrin (likely <0.1% each)^{6,7,8}, such that limited handling of the products during installation at ambient temperatures would not result in any significant surface migration or exposure. These chemicals would be either bound within cured polymer matrix or driven off during the curing process. This lack of exposure is supported by the fact that despite widespread use of these types of epoxy resins, no NOV resulting in any settlements or judgements have been issued for resins over the ~30 years of this regulation.

Hardware

The hardware contained heavy metals, including cadmium (maximum of 12 ppm or 0.0012%; listed for cancer and reproductive toxicity), arsenic (109 ppm or ~0.011%; listed for cancer), and chromium (for the purposes of this assessment it will be assumed to hexavalent chromium as a

³ Speciation of arsenic unknown - only inorganic arsenic and inorganic oxides listed.

⁴ Speciation of chromium is unknown (III vs. VI) – only hexavalent (VI) chromium is listed.

⁵ Last accessed June 4, 2019: <https://oag.ca.gov/prop65/60-day-notice-search> (Notice of Violation is a publicly filed document that outlines the specifics of the alleged non-compliant product).

⁶ https://oshwiki.eu/wiki/Occupational_exposure_to_epoxy_resins

⁷ <https://epoxy-europe.eu/safety/assessment-of-potential-bpa-emissions-from-epoxy-applications/>

⁸ <https://oehha.ca.gov/media/downloads/cnr/eubisphenolareport325.pdf>

worst-case scenario, which is listed for reproductive toxicity and cancer; maximum of 622 ppm or ~0.062%).

For exposure to occur, the metals must migrate from the hardware (wherein only a certain proportion of the total amount of detected metals would be accessible on the surface to migrate onto the skin), there must be sufficient contact made with the components, and for an adequate amount of time for the chemicals to move from the component to the skin. Finally, the metal must actually be absorbed through the skin in order to constitute a hazard.

The dermal absorption of cadmium is generally not considered a significant route of exposure, as it is very poorly absorbed through the skin (below 0.5%)^{9,10}. Arsenic and chromium VI are also expected to be absorbed through the skin only to a limited extent (<6% and ~1%, respectively)^{11,12}. The parts themselves are relatively small, especially the nuts and washers, providing only limited surface area of contact.

Therefore, given that the hardware has a very small surface area of potential skin contact, the duration of exposure is very limited (actual direct skin contact with the hardware would likely be only a few minutes total if that much), the metals have generally very low dermal absorption, and the concentrations of the chemicals is very low, even if some of the metals were to migrate from the hardware onto the skin, the overall systemic exposure would be insignificant and therefore, not trigger Proposition 65 warnings.

Finally, these metals have not been frequently targeted for similar type products (*i.e.*, screws, bolts, washer, nuts, *etc*), in comparison to lead, which was not detected in Cogan's hardware.

Post Caps

The exact composition of the post caps was not disclosed; however, it was relayed that they are a hard resin. These types of materials (typically ABS or similar) are manufactured to be generally very durable and chemically resistant under ambient conditions. Therefore, due to the limited contact with the post caps and the durable nature of these types of materials, no significant exposures to any listed chemicals would be anticipated during installation.

CONCLUSION

RegTox has reviewed relevant data related to Cogan's "Heavy-Duty Guardrail" product and concludes that the product complies with California Proposition 65 without the need for warnings.

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1578573/>

¹⁰ <https://www.atsdr.cdc.gov/csem/csem.asp?csem=6&po=9>

¹¹ https://echa.europa.eu/documents/10162/13641/asernic_nov13_en.pdf/c144cc3e-bf48-d6d6-cb6a-b90ece3e4ba5

¹² <https://oehha.ca.gov/media/downloads/cnr/apendf.pdf>

The listed chemicals that may be theoretically present in the resins, and heavy metals that were detected in hardware would be expected to result in insignificant exposures for the reasons stated herein and therefore not trigger a need for warnings.

It should be noted that there are no guaranteed ways to ensure products are not targeted for enforcement action, even for compliant products (except for providing warnings); however, having conducted due-diligence investigations clarifies the level of product risk and would provide a stronger defense against any actions that may occur. Companies that are prepared with supporting data, have increased potential for reducing or even eliminating potential settlements.

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