

Client Alert

Environmental, Health & Safety Practice Group

March 3, 2016

California Adopts Additional Phthalate Proposition 65 Safe Harbor Limit

Agency Rejects Calls for Higher (and Lower) Limit

California's Office of Administrative Law has amended the list of regulatory safe harbor levels under Proposition 65 to include the chemical diisononyl phthalate (DINP), setting the limit at 146 micrograms per day (μ /day).¹

Background

California's Proposition 65 requires the Office of Environmental Health Hazard Assessment (OEHHA) to publish a list of chemicals known to the State to cause cancer or developmental or reproductive toxicity. The law requires businesses offering products or services in California that expose any person to a listed chemical above a threshold level to provide a "clear and reasonable" warning prior to such exposure.

A company selling a product that contains a chemical on the Proposition 65 carcinogen list is exempt from the statute's warning requirements if exposures to the product are so low as to create no significant risk of cancer.² OEHHA has established "no significant risk" levels (NSRLs) for roughly one quarter of the Proposition 65-listed substances. A Proposition 65 warning is not required if product exposure occurs at or below these levels.

The NSRL for DINP

DINP is a general purpose plasticizer used in a number of products including vinyl flooring, wire and cable insulation, stationary, gloves, toys, garden hoses, footwear, auto undercoatings, and roofing materials. OEHHA added DINP to California's Proposition 65 list of chemicals known to the state to cause cancer on December 20, 2013, triggering a deadline to provide warnings, if needed, after December 20, 2014.

The new regulation establishes a NSRL of 146 micrograms per day for DINP, adopting the level OEHHA proposed on January 2, 2015. Prior to the proposal, the American Chemistry Council and other manufacturing stakeholders requested a NSRL for DINP of 2664.00 μ g/day, and these stakeholders reiterated that recommendation during the comment period on the proposed rule. "Citizen enforcer" stakeholders recommended 70 μ g/day for the NSRL. These widely divergent recommendations reflect fundamental

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disagreement on the relevant scientific studies used to set the NSRL. Ultimately, while acknowledging the scientific arguments of all commenters, OEHHA decided to adopt the NSRL as proposed.³

Implications

Adoption of a NSRL provides certainty to affected businesses that products with lower exposure levels are not subject to Proposition 65 enforcement actions for failure to provide a warning. However, because the NSRL adopted by OEHHA is more than an order of magnitude lower than that requested by manufacturing stakeholders, the number of products that need to provide a Proposition 65 warning for DINP will substantially increase.

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¹ See <http://www.oehha.ca.gov/prop65/law/021916adoptnsrIDINP.html>.

² The NSRL is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70 year lifetime. In other words, a person exposed to the chemical at the NSRL for 70 years would not have more than a "one in 100,000" chance of developing cancer as a result of that exposure.

³ See Final Statement of Reasons, available at http://www.oehha.ca.gov/prop65/law/pdf_zip/DINP_NSRL_FSOR021916.pdf.