

California Limits New Prop 65 Listing to Soluble Nickel Compounds

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California has added a new chemical to the list of substances known to the state to cause reproductive toxicity under Proposition 65, though the listing is not as broad as originally proposed. While the Office of Environmental Health Hazard Assessment (OEHHA) is adding "Nickel (soluble compounds)" to the reproductive toxin list, at an October 11 meeting, the expert panel that reviews proposed listings (the Developmental and Reproductive Toxicant Identification Committee or DARTIC) rejected a proposed broader listing that would have included metallic nickel and insoluble nickel compounds.

Extensive comments submitted by the nickel industry detailed how the available scientific information, summarized in a 347-page "hazard information" document released in August, did not support a listing beyond certain soluble compounds of nickel. The DARTIC agreed, voting unanimously against listing "Nickel and Nickel Compounds" broadly for any of the three reproductive toxicity endpoints the Committee reviews (developmental toxicity and male/female reproductive toxicity).

The decision to limit the listing to only soluble nickel compounds is significant for industries that produce nickel-containing materials, such as stainless steel and other metal alloys, as well as companies that use such materials to manufacture consumer and industrial products. While metallic nickel and other nickel compounds currently are listed as carcinogens under Proposition 65, the regulations exclude nickel exposures via the route of ingestion. OEHHA also has stated that the carcinogen listing for nickel does not include "nickel alloys" within its scope. Perhaps most notably, a series of cases and settlement agreements have determined that stainless steel and other nickel-containing alloys do not require a Proposition 65 warning when used in a variety of "high contact" products, such as jewelry, body piercings, and medical and dental implants. These "no warning" determinations have been based on a conclusion that the potential exposure to nickel from various metal alloys -- in which nickel is entrained within the alloy matrix and not readily released -- is minimal and below the threshold required for warnings under Proposition 65.

A broader reproductive toxicity listing that included metallic nickel would have triggered a review of the "no warning" determinations for these materials, as well as the need to develop a maximum allowable dose level (MADL) to define the safe threshold level for exposure.

OEHHA staff now are charged with the task of defining the scope of the soluble nickel compounds listing.