

October 31, 2022

**Comment to
California Environmental Protection Agency
Office of Environmental Health Hazard Assessment
Regarding
Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop 65)
Notice of Intent to List Chemical by the Labor Code Mechanism: Antimony
(Trivalent Compounds)**

The PET Resin Association (PETRA) is the industry association representing the North American producers of PET (polyethylene terephthalate) resin. PET is widely used around the globe to package foods and beverages, especially soft drinks and water, as well as other foodstuffs, personal care items and pharmaceuticals. The use of antimony and antimony compounds in food-contact and medical applications (such as PET) is evaluated and regulated for safety by the U.S. Food and Drug Administration, as well as the European Food Safety Authority in Europe, Health Canada, and sister agencies around the world. For more information about PETRA and PET resin, please see www.PETresin.org.

The OEHHA Notice does not meet the requirements for listing antimony (trivalent compounds), also known as “trivalent antimony compounds,” as known to cause cancer under Proposition 65.

Prop 65 listing is premature as the relevant IARC Monograph has not yet been published
The Labor Code mechanism requires that substances identified as human or animal carcinogens by the International Agency for Research on Cancer (IARC) be listed as known to cause cancer under Proposition 65. The Notice references a list of IARC classifications.¹ However, Prop 65 Listing is premature as the IARC Monograph which documents the classification has not yet been published.²

The Notice also cites a published summary (Karagas et al., 2022³, referred to herein as “the Lancet Summary”) which references “limited evidence for cancer in humans, sufficient evidence of carcinogenicity in experimental animals and strong mechanistic evidence in human primary cells and in experimental systems.”

¹ International Agency for Research on Cancer (IARC), 2022. Agents classified by the IARC Monographs, Vols. 1-132. IARC, World Health Organization, Lyon, France. <https://monographs.iarc.who.int/list-of-classifications>. Accessed October 27, 2022

² [Monographs available – IARC Monographs on the Identification of Carcinogenic Hazards to Humans \(who.int\)](#), accessed October 31, 2022.

³ Karagas MR, et al. Carcinogenicity of cobalt, antimony compounds, and weapons-grade tungsten alloy. *Lancet Oncol.* 2022 May;23(5):577-578. doi: 10.1016/S1470-2045(22)00219-4. Epub 2022 Apr 7.

The Lancet Summary does not provide an appropriate or adequate basis for listing trivalent antimony compounds as known to cause cancer under Proposition 65.

The Lancet Summary is unclear as to which trivalent compounds have been assessed

Regarding occupational studies, it has not been established that trivalent antimony compounds are causative due to possible bias from co-exposure to arsenic and other lung carcinogens in smelting processes, as noted in the Lancet Summary. Furthermore, the Summary does not indicate which trivalent compounds were present, or provide any characterization of particle size or the exposure route.

The two rodent studies tested antimony trioxide. No other antimony trivalent compounds were reported in the Summary to have been tested in animal studies.

The Summary of the mechanistic studies is unclear as to which compounds were tested and whether or not the routes of exposure were relevant to the occupational and/or the animal studies.

Without information on which compounds have been assessed, the available data is inadequate to support the listing of trivalent antimony compounds.

Where the route of exposure is evident, this data is limited to inhalation exposures

The evidence cited for cancer in humans is based on occupational exposures. Exposure is presumably via inhalation, although the potential routes of exposure are not discussed in the Summary. The evidence cited for cancer in experimental animals is based on inhalation studies. The mechanistic evidence cited does not provide data on routes of exposure.

In short, the available data do not meet the requirements for listing trivalent antimony compounds as known to the state to cause cancer for purposes of Proposition 65.

Sincerely,

John E. Heinze, Ph.D.
Kellen Company
On Behalf of PETRA