

Comments on OEHHA Notice of Intent to List Antimony (Trivalent Compounds)

Contents

Contents

1. Background.....	3
2. Concerns with OEHHA Approach.....	3
2.1. Antimony (Trivalent Compounds)	3
2.2. Routes of Exposure.....	4
3. Conclusions.....	4
4. Who are i2a	4

1. Background

On 30th September 2022, the Office of Environmental Health Hazard Assessment (OEHHA) published the notice of Intent to List Chemical by the Labor Code Mechanism: Antimony (Trivalent Compounds)¹. OEHHA has proposed listing antimony (trivalent compounds) based on the International Agency for Research on Cancer's (IARC) Lancet Oncology summary of the outcome of the classification of "trivalent antimony." IARC made this classification at an IARC Working Group meeting on 2nd-18th March 2022. The IARC Monograph (131) for trivalent antimony has not been published and at the time of writing is stated on the IARC website as being "in preparation²." The International Antimony Association (I2a) understands that OEHHA has, in several highly analogous cases, waited until after the publication of the IARC Monograph before proposing to list chemicals classified by IARC. In certain of these cases, the detailed information in the IARC Monograph has allowed OEHHA to more accurately identify how a substance should be listed under Proposition 65.

On April 7th, 2022, The Lancet Oncology's published a summary³ of IARC's decision.

2. Concerns with OEHHA Approach

On review of the Lancet summary, it is the opinion of i2a there is not sufficient information to allow OEHHA to accurately determine whether:

- 1) IARC will list all or only certain trivalent antimony compounds as Group 2A, and
- 2) If any such listing should be limited to a particular route of exposure or other relevant limitation.

As this information is not yet known i2a believes that OEHHA should and must analyze the detailed IARC Monograph before proposing any listing of antimony (trivalent compounds) or trivalent antimony.

2.1. Antimony (Trivalent Compounds)

IARC Monograph 131 and the following Lancet article discuss trivalent antimony and pentavalent antimony; it does not summarize or discuss "antimony (trivalent compounds)".

The Lancet article stated, "*Trivalent antimony was classified as 'probably carcinogenic to humans' (Group 2A), based on 'limited' evidence for cancer in humans, 'sufficient' evidence for cancer in experimental animals, and 'strong' mechanistic evidence in human primary cells and in experimental system.*"

¹ OEHHA (2022) [Notice of Intent to List Chemical by the Labor Code Mechanism: Antimony \(Trivalent Compounds\) - OEHHA](#)

² IARC (2022) [List of Classifications – IARC Monographs on the Identification of Carcinogenic Hazards to Humans \(who.int\)](#)

³ Karagas MR, Wang A, Dorman DC, Hall AL, Pi J, Sergi CM, et al. (2022) Carcinogenicity of cobalt, antimony compounds, and weapons-grade tungsten alloy. The Lancet Oncology 23(5):577-578. May 1, 2022. Published April 7, 2022.

31 October 2022

The OEHHA's Notice proposes listing antimony (trivalent compounds). The Notice does not provide a reason for the difference in wording that led to the proposal to list antimony (trivalent compounds) as opposed to trivalent antimony. The Lancet Summary provides no support for the proposition that IARC reviewed and classified antimony (trivalent compounds).

There are multiple trivalent antimony compounds with different hazard classifications⁴. As it is not clear how IARC classified trivalent antimony i2a is of the opinion that OEHHA delay the listing to avoid making presumptions and thus potentially incorrectly listing some trivalent antimony compounds prior to the publication of the monograph.

2.2. Routes of Exposure

Some IARC classifications are qualified by a range of factors, including the route of exposure. From the Lancet article it is not possible to know if IARC qualified its classification of trivalent antimony. This is of importance as there is little or no evidence that oral exposure to antimony compounds is carcinogenic. Indeed, the Lancet article bases its sufficient evidence finding on inhalation studies in animals, suggesting that the IARC monograph will be limited to the inhalation exposure route.

I2a is of the opinion that this uncertainty on whether the IARC monograph will be qualified is another reason to delay the listing.

3. Conclusions

I2a believes that the Lancet Summary does not provide sufficient information to allow:

- OEHHA to accurately determine whether all or certain trivalent antimony compounds should be listed; and
- Determine whether IARC's classification supports a qualified listing of any kind.

As such, OEHHA should withdraw its current proposal to list antimony (trivalent compounds), evaluate the IARC Monograph in full upon publication, and then take appropriate action.

4. Who are i2a

The International Antimony Association (i2a) is the Brussels-based organization representing the producers, importers, and users of multiple Antimony substances. i2a's aim is the sustainable and responsible production, use and recycling of Antimony.

⁴ <https://www.antimony.com/antimony/>

31 October 2022

Our vision is a sustainable and responsible Antimony industry, where Antimony substances continue to be the material of choice for many technology-enabling applications. At i2a we want to ensure the safe use and responsible management of Antimony substances throughout their lifecycle and to inspire positive product stewardship throughout the Antimony value chain, from classification to sustainability profiling.

i2a aims to:

- Address knowledge gaps weakening the safe use and positive image of Antimony substances;
- Make sure that the most up to date evidence is used in any regulatory scrutiny of Antimony substances;
- Determine the most relevant, proportionate, and efficient risk management measures applicable to each use of Antimony substances; and
- Support the Antimony industry in implementing responsible product stewardship practices