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To Whomsoever it may concern

Antimony is regarded as a minor toxic metal. Food is the major route of environmental exposure, however exposure levels are usually very low. The average daily intake from food is estimated to be about 5 µg. Antimony mostly exists as the trivalent and pentavalent state, and has been used medically in the treatment of parasitic disease. (1)

Traces of antimony have been reported in certain colour cosmetics in Korea at levels ranging from 10.1 ppm to 14.3 ppm. Antimony is not directly added as a cosmetic ingredient, and these levels are marginally above the regulatory limit of 10 ppm for Antimony specified for cosmetics in Korea. It must be recognized that these limits are often set based on the technically unavoidable limits of manufacturing, in the industry, rather than quantitative risk assessment. This is the criterion adopted under the German cosmetic regulations (2), and the same criterion is adopted by Health Canada to set heavy metal limits for cosmetics (3). Based on an objective risk assessment, the aggregate exposure of Antimony from a range of colour cosmetics containing the theoretical maximum level of 10 ppm for antimony is of the order of 4.84×10^{-7} mg/kg bw/day (4). This exposure equals to a margin of safety which is thousands of time higher than the widely accepted factor of 100 for human exposure (NOAEL of 6 mg/kg/day). This exposure is also one thousand time lower than the highly conservative US EPA oral reference dose of 4×10^{-4} mg / kg bw/day (5). Hence those color cosmetics containing antimony as an impurity in the range of 10.1 ppm to 14.3 ppm are not expected to pose any safety concerns to consumers under intended product use conditions

In ASEAN, it must be recognized that the ASEAN Cosmetic Directive establishes a framework for regulation of cosmetic standards, which has established a robust safety assessment guideline for cosmetic products, including trace impurities.

There are also post-market surveillance mechanisms in place to monitor cosmetic product compliance. Moreover, cosmetic manufacturers already have in place control mechanisms to limit contaminants such as heavy metals via:

- proper supplier selection
- supplier quality control via CoA / TDS
- cosmetic GMP

References

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 4. Marinovich M et al, Regul Toxicol Pharmacol. 2014 Aug;69 (3): 416-24. doi: 10.1016/j.yrtph.2014.05.005. Epub 2014 May 20.
 5. Antimony, Evaluation of health hazards and proposal of a health based quality criterion for soil, Danish ministry of the Environment, Environment Project No. 1727, 2015
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