ASEAN Cosmetic Committee (ACC) Statement on Antimony in Cosmetics

The ASEAN Cosmetic Directive established a framework for regulation of cosmetic standards, which is based on a robust safety assessment guideline for cosmetic products, including trace impurities. There are also post-market surveillance mechanisms in place to monitor cosmetic products compliance. Moreover, cosmetic manufacturers already have in place control mechanisms to limit contaminants such as heavy metals via:

- proper raw material supplier selection
- supplier quality control via Certificate of Analysis/Technical Data Sheet
- cosmetic Good Manufacturing Practices (GMP)

Antimony, one of such possible trace impurities, is a naturally occurring heavy metal. Antimony is a prohibited ingredient in ASEAN cosmetics and included in Annex II of the ACD. Thus it should not be intentionally added into cosmetic products. The presence of antimony as trace impurity is subject to the condition that it is technically unavoidable in good manufacturing practice and that it is does not pose a safety risk to consumers.

As an example, based on an objective risk assessment, the aggregate exposure of Antimony from a range of colour cosmetics containing up to 10 ppm for antimony is one thousand times lower than the conservative estimates of the US EPA oral reference dose*[1]. Hence, trace levels of antimony in cosmetics is not expected to pose any safety concerns to consumers.

In countries like Germany[2] and Canada[3], the criterion of trace limit in cosmetic product was adopted as a guideline to encourage industrial efforts. It must be recognized that these limits are set based on the technically unavoidable limits of manufacturing in the industry, rather than quantitative risk assessment.

ASEAN Regulatory Authorities and ASEAN Cosmetics Association (ACA) will continue to review and monitor closely any emerging safety data related to antimony as trace impurity in cosmetic products and will take appropriate action when necessary to protect the health and welfare of consumers.

* *A reference dose is the United States Environmental Protection Agency's maximum acceptable oral dose of a toxic substance for humans.*

References

1. US EPA, (1993) Reference Dose (RfD): Description and Use in Health Risk Assessments. Background Document 1A.
2. Bund, B. J Consum Prot Food Saf (2017) 12: 51. https://doi.org/10.1007/s00003-016-1044-2
3. Guidance on Heavy Metal Impurities in Cosmetics, Government of Canada, https://www.canada.ca/en.html