



30 JUN 2017

**FDA ADVISORY**  
No. **2017-191**

**TO: ALL COSMETIC MANUFACTURERS, TRADERS, DISTRIBUTORS, COSMETIC SAFETY ASSESSORS, FORMULATORS, RESEARCHERS, OTHER CONCERNED PARTIES AND THE GENERAL CONSUMING PUBLIC**

**SUBJECT: Safety Issues of Talc-Containing Body Powder Used in the Perineal Area of the Body**

Talc, otherwise known as talcum or hydrated magnesium silicate, is a naturally occurring mineral mined from the earth. Due to its very soft texture, it has long been used in the formulation of loose body powders. Presently, there is a growing concern in the United States due to a series of suits/claims of ovarian cancer among women attributed to a long-term history of talc use/application in the perineal area. A review of related literature showed that the potential hazard is significantly different from that posed by talc contaminated with asbestos, a known carcinogen which has already been addressed by the enforcement of stringent quality control in talc mining and processing since the 1970s.

Based on the review of existing studies, the International Agency for Research on Cancer (IARC), the World Health Organization's (WHO's) specialized cancer agency, has considered that "there is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder". However, the IARC Working Group found a modest, but unusually consistent excess in risk in case-control studies.

More recent evaluation/review of talc safety in cosmetic products such as that of the Cosmetic Ingredient Review (CIR) Panel, an independent council based in the United States of America (U.S.A.), showed that talc in its current practice of use is considerably safe

Accordingly, to protect the public health and safety, the Food and Drug Administration (FDA) has undertaken the following public health interventions:

1. Issued letters to talc-containing cosmetic product manufacturers, traders, distributor/importers and distributor/wholesalers to provide proof or certifications of asbestos-free products sold in the market.
2. Continuous implementation of the ASEAN Cosmetic Directive (ACD), pursuant to Administrative Orders 2005-0015 and 2005-0025, which required product owners or local companies placing talc-containing cosmetic powders intended to be used for children under three (3) years of age in the market to indicate a warning in the product label – "*keep powder away from children's nose and mouth.*"
3. Coordinated with the Philippine Cancer Control Program under the Disease Prevention and Control Bureau (DPCB) for the review of the cancer registry relative to this issue.


The ASEAN Cosmetic Committee (ACC), during its 24<sup>th</sup> meeting last 26 and 27 May 2016, proposed the formation of a task force comprised of Singapore, Philippines and Thailand to conduct more research and literature review on the association between talc and ovarian cancer and to come up with a harmonized ASEAN statement regarding the subject. As of the 26<sup>th</sup> ACC and its related meetings on 1-5 May 2017, the draft ASEAN Joint Opinion Statement on Talc is undergoing final revisions.

In light of the above, FDA, being the National Regulatory Authority (NRA) ensuring the safety and quality of cosmetic products made available in the market, hereby advises the public to be more cautious and vigilant in purchasing cosmetic products such as talc-containing body powders that **did not go through the verification process of the agency**. Further, the general public is advised to use cosmetic products in accordance with the written instructions/directions for use found in the immediate and/or secondary packaging label. For more safety tips on the purchase and use of cosmetic products, visit the FDA website ([www.fda.gov.ph](http://www.fda.gov.ph)) and download the Consumer Manual on Online Shopping which is issued together with FDA Advisories 2016-048 (English version) and 2016-048A (Filipino version).

Lastly, the public is requested to report to FDA any adverse effects experienced when using cosmetic products. Reports can be made through any of the following channels:

1. FDA's online reporting facility, **eReport** at [www.fda.gov.ph](http://www.fda.gov.ph)
2. Send an email to [report@fda.gov.ph](mailto:report@fda.gov.ph)
3. Contact the FDA Center for Cosmetics Regulation and Research (CCRR) Customer Service Hotline at **(02) 857-1979** or **(02) 857-1984**.

Dissemination of the information to all is requested.

  
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