



FDA ADVISORY
No. **2018-047**

15 FEB 2018

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

SUBJECT: ASEAN Advisory Statement on Talc

The Food and Drug Administration hereby disseminates the Association of Southeast Asian Nations (ASEAN) Advisory Statement on Talc to provide the general public with information on talc safety to ease the public's fear in using cosmetic products containing the ingredient. Below is the full text of the statement.

“Cosmetic products which are sold or supplied in the ASEAN countries must comply with the applicable prohibitions or restrictions on cosmetic ingredients as well as the product labelling stipulated under the ASEAN Cosmetic Directive (ACD) which has been adopted by all the ASEAN Member States (AMS).

Talc is allowed for use as an ingredient in cosmetic products under the ACD and EU Cosmetic Regulation. It is also allowed as a cosmetic ingredient in many countries. Talc is a naturally occurring mineral, composed mainly of magnesium, silicon and oxygen. It is used as an abrasive, absorbent, anticaking, bulking or opacifying agent in products such as body powder, eye shadow and face powder.

Talc is divided into two grades: Industrial-grade and Pharmaceutical/Food/Cosmetic-grade. Cosmetic-grade talc must not contain contaminants such as asbestos, a prohibited substance under the ACD. Cosmetic grade talc is generally regarded to be a safe ingredient in cosmetic products worldwide.

There have been concerns about a possible link between talcum powder and ovarian cancer. The ASEAN Cosmetic Scientific Body (ACSB) has assessed that the available evidence globally remains inconclusive in establishing such a link to date. In this regard, the ACSB has advised that talc is allowed to be used in cosmetic products with the current requirements on the product labelling.

At present, talcum powders used in children must be labelled with a warning that states “Keep powder away from children’s nose and mouth” to avoid inhalation. This is in line with the product labelling requirements in the European Union (EU) and Canada.



ASEAN countries will continue to monitor closely any new safety data related to the use of talc in cosmetic product and will take appropriate action and inform the public if necessary."

The ASEAN Advisory Statement on Talc has been approved by the ASEAN Cosmetic Scientific Body (ACSB) for release during the 27th ACSB Meeting on 14 to 15 November 2017 in Bandung Indonesia pending final formatting check. As agreed as well during said meeting, the full copy of the Statement is also accessible in the ASEAN website through the link - <http://asean.org/storage/2012/05/ASEAN-Advisory-Statement-on-Talc.pdf>.

Dissemination of the information to all concerned is requested.


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