



02 JUL 2021,

FDA ADVISORY
No. **2021-1675**

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Violative Cosmetic Products as Reported in the ASEAN Post-Marketing Alert System (PMAS):

1. **UBERSUAVE CLASSIC POMADE**
2. **UBERSUAVE TEXTURING MATTE**

The Food and Drug Administration (FDA) warns the public from purchasing and using the following violative cosmetic products, which were detected to contain a mixture of **METHYLISOCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE (MCIT/MIT)** at levels above the acceptable limit, as reported in the ASEAN Post-Marketing Alert System (PMAS). The table below indicates the particulars of the violative cosmetic products:

Product Details	Product Image/s
<p>1. Ubersuave Classic Pomade</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Country of Manufacture: China</p> <p>Lot/Batch Number: B202004 Manufacturing Date: Not Indicated Expiration Date: APR 2023</p>	
<p>2. Ubersuave Texturing Matte</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Country of Manufacture: China</p> <p>Lot/Batch Number: A202004 Manufacturing Date: Not Indicated Expiration Date: APR 2023</p>	



The aforementioned products have been tested by the Health Sciences Authority, Singapore, as part of their post-marketing surveillance activities and results of the laboratory analyses show that these products are not compliant with the technical standards set forth by the ASEAN Cosmetic Directive (ACD).

Due to its skin sensitizing potential, the mixture of MCIT:MIT is restricted only for use as a preservative in finished cosmetic products up to a maximum authorized concentration of 0.0015% (of a mixture in the ratio 3:1) for rinse-off products. The aforementioned violative products, however, were found to contain high levels of MCIT:MIT mixture and are beyond the acceptable limit.

In light of the foregoing, the public is advised not to purchase the aforementioned violative product. Moreover, the public is advised to always check if a cosmetic product is notified with the FDA. The FDA website (www.fda.gov.ph) has a *Search* feature which may be used by typing in the name of the product before purchasing.

All concerned establishments are warned not to distribute violative cosmetic products.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

To report any sale or distribution, complaint and/or adverse event on the use of the violative cosmetic product, the online reporting facility, **eReport** can be accessed at ereport@fda.gov.ph, or call us at the Center for Cosmetics and Household/Urban Hazardous Substances Regulation and Research (CCHUHSRR) hotline **(02) 8857-1900 loc. 8113 or 8107**.

Dissemination of this advisory to all concerned is hereby requested.


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