




FDA ADVISORY
No. **20213069**

17 NOV 2021

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Violative Cosmetic Product PUTERI RATU TREATMENT CREAM WHITENING CREAM as Reported in the ASEAN Post-Marketing Alert System (PMAS)

The Food and Drug Administration (FDA) warns the public from purchasing and using the violative cosmetic product **PUTERI RATU TREATMENT CREAM WHITENING CREAM** which tested positive for the presence of **MERCURY** as reported in the ASEAN Post-Marketing Alert System (PMAS). This ingredient is not allowed to be part of a cosmetic product as per ASEAN Cosmetic Directive (ACD). The table below indicates the particulars of the violative cosmetic product:

Product Details	Product Image/s
<p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Malaysia</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: Not Indicated Expiration Date: Not Indicated</p>	

The aforementioned product has been tested by the Department of Pharmaceutical Services, Ministry of Health, Brunei Darussalam, as part of their post-marketing surveillance activities and results of the laboratory analyses show that the aforementioned product is not compliant with the technical standards set forth by the ACD.



The aforementioned product was verified to contain Mercury, a naturally occurring heavy metal which is known to be severely hazardous to health even in small amount. According to World health Organization (WHO), the main adverse effect of exposure to inorganic mercury (e.g. ammoniated mercury) is kidney damage. Mercury may also cause skin rashes, skin discoloration and scarring, as well as reduction in the skin's resistance to bacterial and fungal infections. Exposed pregnant women and nursing mothers transfer the mercury to their fetuses, which can later result in neurodevelopmental deficits in the children.

In light of the foregoing, the public is advised not to purchase the aforementioned violative cosmetic product. Always check if a product is notified with the FDA by using the FDA Verification Portal feature accessible at <https://verification.fda.gov.ph> which may be used by typing in the name of the product before the purchase and/or using the cosmetic products.

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 their jurisdiction.

To report any sale, 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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Director General

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