



FDA ADVISORY

No. **2023-0086**

09 JAN 2023

TO: THE GENERAL PUBLIC

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

1. **O WHITE EXTRA CREAM**
2. **SKY & PEARL COLLAGEN WHITENING MOISTURIZING DAY & NIGHT**
3. **COMFOR BEAUTY MATTE LIP STICK (12)**

The Food and Drug Administration (FDA) warns the public from purchasing and using the following adulterated cosmetic products which tested and found to contain **MERCURY** and **RHODAMINE B** as reported in the ASEAN Post-Marketing Alert System (PMAS). These ingredients are 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/s:

Product Details	Product Image/s
<p>Product Name: O WHITE EXTRA CREAM</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: OK Cosmetics Limited Partnership</p> <p>Country of Manufacture: Thailand</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: 11/2020 Expiration Date: Not Indicated</p>	 <p style="text-align: center;"><i>*found to contain Mercury</i></p>



Product Details	Product Image/s
<p>Product Name: SKY & PEARL COLLAGEN WHITENING MOISTURIZING DAY & NIGHT</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: 8/5/2021 Expiration Date: 7/5/2023</p>	 <p><i>*found to contain Mercury</i></p>
<p>Product Name: COMFOR BEAUTY MATTE LIP STICK (12)</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Not Indicated</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: Not Indicated Expiration Date: Not Indicated</p>	 <p><i>*found to contain Rhodamine B</i></p>

The aforementioned cosmetic products have been tested by Myanmar, Department of Food and Drug Administration, as part of their post-marketing surveillance activities and results of the laboratory analyses show that the aforementioned products are not compliant with the technical standards set forth by the ACD.

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.

Rhodamine B is a fluorescent dye used as a tracer in water and air flow studies, and in molecular and cell biology studies. It presents as a red to violet powder. It has been shown to be carcinogenic in mammalian models.


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. 8107**.

Dissemination of this advisory to all concerned is hereby requested.


DR. SAMUEL A. ZACATE
Director General

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