



FDA ADVISORY

No. 2023-0088

09 JAN 2023

TO: THE GENERAL PUBLIC

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

1. KT NIGHT CREAM
2. BEWILD PETITE STICK (CORAL BROWN)
3. LOVELY PLUS HERBAL HAIR COLOR (7.3 BROWN)
4. LOVELY PLUS HERBAL HAIR COLOR (7.4 GOLDEN BROWN)
5. P.U. LIGHT AURA BRIGHT
6. NP SKIN IDEAL SKIN CARE TURMERIC NIGHT REPAIR TREATMENT
7. NP SKIN IDEAL SKIN CARE CM-II ARBUTIN NIGHT CREAM
8. LIGHT WHITE CREAM
9. LIGHT WHITE BODY CREAM
10. MIRACLE PINK

The Food and Drug Administration (FDA) warns the public from purchasing and using the following adulterated cosmetic products which tested and found to contain, **HYDROQUINONE, BETAMETHASONE VALERATE 17, CLOBETASOL PROPIONATE, MERCURY COMPOUNDS, CI 15585, and o-AMINOPHENOL** 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
Product Name: KT NIGHT CREAM Manufactured by/Local Company Responsible for Placing the Product in the Market: KT BRAND Country of Manufacture: Thailand Lot/Batch Number: L:25 Manufacturing Date: 20/02/64 Expiration Date: 20/02/67	 <p><i>*found to contain Mercury compounds</i></p>



Product Details	Product Image/s
<p>Product Name: BEWILD PETITE STICK (CORAL BROWN)</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Guangzhou Aise Cosmetics Co., LTD.</p> <p>Country of Manufacture: China</p> <p>Lot/Batch Number: 0LA Manufacturing Date: 201230 Expiration Date: 231229</p>	 <p><i>*found to contain CI 15585</i></p>
<p>Product Name: LOVELY PLUS HERBAL HAIR COLOR (7.3 BROWN)</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Chemi Sale laboratory Private Co., LTD</p> <p>Country of Manufacture: India</p> <p>Lot/Batch Number: 143 Manufacturing Date: 03/2021 Expiration Date: Not Indicated</p>	 <p><i>*found to contain o-Aminophenol</i></p>
<p>Product Name: LOVELY PLUS HERBAL HAIR COLOR (7.4 GOLDEN BROWN)</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Chemi Sale laboratory Private Co., LTD</p> <p>Country of Manufacture: India</p> <p>Lot/Batch Number: 128 Manufacturing Date: 03/2021 Expiration Date: Not Indicated</p>	 <p><i>*found to contain o-Aminophenol</i></p>

Product Details	Product Image/s
<p>Product Name: P.U. LIGHT AURA BRIGHT</p> <p>Manufactured by/Local Company Responsible for Placing the Product in the Market: Not Indicated</p> <p>Country of Manufacture: Thailand</p> <p>Lot/Batch Number: Not Indicated Manufacturing Date: 18/01/21 Expiration Date: Not Indicated</p>	 <p><i>*found to contain Mercury compounds & Betamethasone -17- Valerate</i></p>
<p>Product Name: NP SKIN IDEAL SKIN CARE TURMERIC NIGHT REPAIR TREATMENT</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: 002149 Manufacturing Date: 220264 Expiration Date: 220265</p>	 <p><i>*found to contain Mercury compounds & Betamethasone -17- Valerate</i></p>
<p>Product Name: NP SKIN IDEAL SKIN CARE CM-II ARBUTIN NIGHT CREAM</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: 002143 Manufacturing Date: 110863 Expiration Date: 110864</p>	 <p><i>*found to contain Mercury compounds</i></p>

Product Details	Product Image/s
<p>Product Name: LIGHT WHITE CREAM</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: 09/12/63 Expiration Date: 08/12/64</p>	 <p><i>*found to contain Clobetasol propionate</i></p>
<p>Product Name: LIGHT WHITE BODY CREAM</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: 09/12/63 Expiration Date: 08/12/64</p>	 <p><i>*found to contain Mercury compounds</i></p>
<p>Product Name: MIRACLE PINK</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 Hydroquinone</i></p>

The aforementioned cosmetic products have been tested by the Thailand, 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.

Hydroquinone, Betamethasone Valerate 17 and Clobetasol Propionate are not allowed to be part of cosmetic product as these are classified as drug products in the Philippines because of their multiple serious adverse effects, such as sensitivity to light, skin redness and permanent skin discoloration, when used indiscriminately.

The ingredients **CI 15585** and **o-Aminophenol** are included in the list of substances which must not form part of the composition of cosmetic products as per Annex II of the ASEAN Cosmetic Directive.

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.

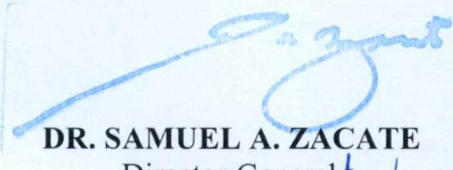
In light of the foregoing, the public is advised not to purchase the aforementioned violative cosmetic product. Always check if a product is notified with the FDA by using the FDA Verification Portal feature accessible at <https://verification.fda.gov.ph> which may be used by typing in the name of the 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. 8107**.

Dissemination of this advisory to all concerned is hereby requested.



DR. SAMUEL A. ZACATE
Director General

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