

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2021-1694

0 6 JUL 2021,

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. ASEPSOTM PROFESSIONAL HAND SANITISER
- 2. WE¹¹ DAILY INSTANT HAND SANITISER
- 3. TP 706 HAND SANITISER 500 ML
- 4. SANIGEN GEL HAND REFRESHING GEL 600ML

The Food and Drug Administration (FDA) warns the public from purchasing and using the following violative health products, which were detected to contain ACETALDEHYDE and METHANOL 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 health products:

Product Details

1. AsepsoTM Professional Hand Sanitiser

Manufactured by/Local Company Responsible for Placing the Product in the Market:

Country of Manufacture: Not Indicated

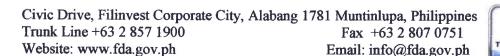
Lot/Batch Number: **B42M**

Manufacturing Date: Not Indicated

Expiration Date: FEB23

Product Image/s









Product Details

2. We¹¹ Daily Instant Hand Sanitiser

Manufactured by/Local Company Responsible for Placing the Product in the Market:

Country of Manufacture: Malaysia

Lot/Batch Number: Not Indicated Manufacturing Date: Not Indicated Expiration Date: 01-02-2022





3. TP 706 Hand Sanitiser 500 ML

Manufactured by/Local Company Responsible for Placing the Product in the Market:

Country of Manufacture: Malaysia

Lot/Batch Number: Not Indicated Manufacturing Date: Not Indicated Expiration Date: 10/03/2022



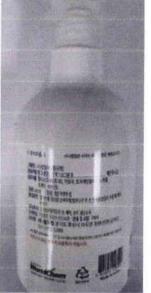
4. Sanigen Gel Hand Refreshing Gel 600ML

Manufactured by/Local Company Responsible for Placing the Product in the Market:

Country of Manufacture: Korea

Lot/Batch Number: WC082001 Manufacturing Date: Not Indicated Expiration Date: 20th Jan 2023





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 acceptable technical standards.

The aforementioned products were verified to contain Acetaldehyde and Methanol at levels above the acceptable limit. According to the U.S. Environment and Protection Agency (EPA), the primary acute effect of inhalation exposure to acetaldehyde is irritation of the eyes, skin, and respiratory tract in humans. At higher levels, erythema, coughing, pulmonary edema, and necrosis may also occur. Likewise, acute and chronic exposure of humans to methanol by inhalation or ingestion may result in visual disturbances, such as blurred or dimness of vision, leading to blindness, and neurological damage, specifically permanent motor dysfunction. Skin contact with methanol can also produce mild to severe dermatitis in humans.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to always check if a health product is registered/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 health 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.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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