



FDA ADVISORY
No. **2021-3613**

28 DEC 2021

TO: GENERAL CONSUMING PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of Misbranded and Adulterated Health Product "MARKLENE ETHYL ALCOHOL 70% SOLUTION"

The Food and Drug Administration (FDA) warns the public from purchasing and using the misbranded and adulterated health product "**MARKLENE ETHYL ALCOHOL 70% SOLUTION**". (Refer to the image below.)

PRODUCT DETAILS	PRODUCT IMAGE/S
<p>Manufactured by/ Local Company Responsible for Placing the Product in the Market: MARKLENE FABRICATE CORPORATION</p> <p>Address: 31 Iglesia ni Kristo St., Sta. Rosa I, Marilao, Bulacan</p> <p>Country of Manufacture: Philippines</p> <p>Lot/Batch Number: 1210012 Mfg. Date: 12-2020 Exp. Date: 12-2022</p>	

The FDA laboratory analysis showed that the product contains only 4.3% of Ethyl Alcohol which is less than 70% as labeled, and presence of Methanol.

As Per Section 11, subsections (a) and (b) of R.A. 3720 as amended by Republic Act No. 9711 "Food and Drug Administration (FDA) Act of 2009", Section 10 subsection (a) and (b), prohibits the following: (a) The manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is adulterated, unregistered or misbranded; (b) The adulteration or misbranding of any health product.



The aforementioned misbranded and adulterated product is found to be non-compliant with the existing standards, and, thus pose potential hazards to the consuming public. 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. Neurological damage, specifically permanent motor dysfunction, may also result. Contact of skin with methanol can produce mild to severe dermatitis in humans.

In light of the foregoing, the public is advised not to purchase the aforementioned misbranded and adulterated product. Always check if a health product is notified and/or registered 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 misbranded and adulterated health product/s.

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, 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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