

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No.* 2021-1697 (0 9 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. CUTICURA HAND SANITIZER
- 2. EPI KLLENGEL HAND SANITIZER GEL
- 3. GUARDIAN LAVENDER & PASSION FLOWER ANTIBACTERIAL HAND SANITISER
- 4. GUARDIAN ALOE & KOREAN-MINT ANTIBACTERIAL HAND SANITISER
- 5. KUNDAL FRESH WATER HAND SANITIZER+
- 6. <u>SANITELLE® INSTANT HAND SANITIZER</u> ANTISEPTIC GEL KIDS
- 7. CATH KIDSTON® MOISTURIZING HAND SANITISER
- 8. REDMOON BACTERIOSTAT WASH FREE HAND WASH GEL
- 9. <u>COOL DAY'S PEPPERMINT INSTANT HAND</u> SANITIZER
- 10. WALCH® INSTANT HAND SANITIZER
- 11. LIFEBUOY INSTANT HAND SANITIZER
- 12. FAIRPRICE HAND SANITISER LAVENDER
- 13. <u>GERM-X ADVANCED HAND SANITIZER ORIGINAL</u> <u>SCENT</u>
- 14. YURI® HAND GEL GREEN TEA EXTRACT

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



1. Cuticura Hand Sanitiser

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

Country of Manufacture: Not Indicated

Lot/Batch Number: **OB01BS**Manufacturing Date: 10/02/2020
Expiration Date: 09/02/2023

Product Image/s



2. Epi KleenGel Hand Sanitizer Gel

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

Country of Manufacture: Israel

Lot/Batch Number: 621003 Manufacturing Date: 12/02/2020 Expiration Date: 12/02/2023





3. Guardian Lavender & Passion Flower Antibacterial Hand Sanitiser

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

Country of Manufacture: Malaysia

Lot/Batch Number: 9K28DF Manufacturing Date: 11/10/2019 Expiration Date: 10/10/2022





4. Guardian Aloe & Korean-Mint Antibacterial Hand Sanitiser

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

Country of Manufacture: Malaysia

Lot/Batch Number: **0D32DF**Manufacturing Date: **16/04/2020**Expiration Date: **15/04/2023**

Product Image/s



5. Kundal Fresh Water Hand Sanitizer+

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

Country of Manufacture: Not Indicated

Lot/Batch Number: BN227d

Manufacturing Date: Not Indicated

Expiration Date: 20230218



6. Sanitelle® Instant Hand Sanitizer Antiseptic Gel Kids

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

Country of Manufacture: Not Indicated

Lot/Batch Number: 24.02.23.A Manufacturing Date: Not Indicated

Expiration Date: 24.02.23.A



7. Cath Kidston® Moisturizing Hand Sanitiser

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

Country of Manufacture: China

Lot/Batch Number: 01204

Manufacturing Date: Not Indicated Expiration Date: Not Indicated

8. Redmoon Bacteriostat Wash Free Hand Wash Gel

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

Country of Manufacture: China

Lot/Batch Number: Not Indicated Manufacturing Date: 20200212 Expiration Date: 20220211

9. Cool Day's Peppermint Instant Hand Sanitizer

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

Country of Manufacture: China

Lot/Batch Number: Not Indicated Manufacturing Date: 12/02/2020 Expiration Date: 11/02/2022

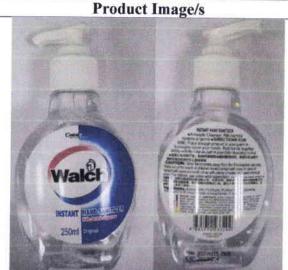


10. Walch® Instant Hand Sanitizer

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

Country of Manufacture: Not Indicated

Lot/Batch Number: **TG01**Manufacturing Date: **20200215**Expiration Date: **20220214**



11. Lifebuoy Instant Hand Sanitizer

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

Country of Manufacture: Not Indicated

Lot/Batch Number: **OD13UL**Manufacturing Date: **02/0402020**Expiration Date: **01/04/2023**



12. FairPrice Hand Sanitiser Lavender

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

Country of Manufacture: Malaysia

Lot/Batch Number: 201251-001 Manufacturing Date: Not Indicated

Expiration Date: 05/2022





13. germ-X® Advanced Hand Sanitizer Original Scent

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

Country of Manufacture: USA

Lot/Batch Number: 0466510

Manufacturing Date: Not Indicated

Expiration Date: 02/2022

germ2/

Product Image/s

14. Yuri® Hand Gel Green Tea Extract

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

Country of Manufacture: Indonesia

Lot/Batch Number: EB 26043

Manufacturing Date: Not Indicated Expiration Date: 02 24



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 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.

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 products, 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

DTN: 20210630103610