

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 20201766 SEP 2 5 2020

TO:

ALL HEALTHCARE PROFESSIONALS AND THE

**GENERAL PUBLIC** 

SUBJECT:

Product Recall of Specific Batch of Ethyl Alcohol

70 mL/100 mL (70% v/v) Solution (Alcoplus)

All healthcare professionals and the general public are hereby warned by the Food and Drug Administration (FDA) that the affected batch of the subject product is being recalled from the market. The details of the product are as follows:

DRUG PRODUCT	ETHYL ALCOHOL 70 mL/100 mL (70% v/v) SOLUTION (ALCOPLUS) Net Content: 150 mL	
REGISTRATION NO.	DRHR-1692	
BATCH NO./EXP. DATE	020180	052223 / 22 May 2023
MANUFACTURER	Ocean Deep Industries – 116 Tandang Sora St., Barangay 136, Caloocan City	
TRADER	Skintec Advance Incorporated – Bypass Road, Brgy. Bulihan, Plaridel, Bulacan	





Figure 1. Batch No. 020180 of Ethyl Alcohol 70 mL/100 mL (70% v/v) Solution (Alcoplus) for recall

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Management System ISO 9001:2015



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Based on the results of the laboratory analyses conducted by the FDA, aside from Ethyl Alcohol (as labeled), it was found that the affected batch (020180) also contains 3.4% of Isopropyl Alcohol which presents quality issues due to the adulteration.

Ethyl Alcohol (at 70% concentration) is used as a topical antiseptic and disinfectant. Ethyl Alcohol 70 mL/100 mL (70% v/v) Solution (Alcoplus) is packed in a 150 mL PET Clear Bottle.

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batch of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product batch and may contact Ocean Deep Industries at telephone nos. (02) 363-2381 and (02) 364-7390 or send an e-mail to oceandeep1995@gmail.com for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product lots are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at cdrr\_postmarketsurveillance@fda.gov.ph. To report continuous sale or distribution of the abovementioned, kindly e-mail us via ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: https://primaryreporting.whounc.org/Reporting/Reporter?OrganizationID=PH and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

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Director General



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