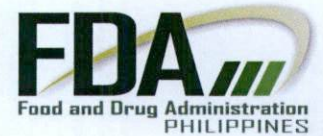




Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



FDA ADVISORY

No. **2020-1269**

JUN 26 2020

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Product Recall of Specific Lots of Ethyl Alcohol 70% Solution with Moisturizer (Alcostar)

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

DRUG PRODUCT	ETHYL ALCOHOL 70% SOLUTION WITH MOISTURIZER (ALCOSTAR) Net Content: 500 mL	
REGISTRATION NO.	DRHR-1959	
LOT NO./MFG. DATE	052070	MAY 2020
	062032	JUNE 2020
MANUFACTURER	Greatstar Laboratories – Sitio Calit, Banaoang, Calasiao, Pangasinan	
DISTRIBUTOR	Genace Pharma Distributor – #19 Diamond St., Greenheights Village, Brgy. San Isidro, Parañaque City	



Figure 1. Lot No. 052070 of Ethyl Alcohol 70% Solution with Moisturizer (Alcostar) for recall





Figure 2. Lot No. 062032 of Ethyl Alcohol 70% Solution with Moisturizer (Alcostar) for recall

Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected lots (052070 & 062032) do not contain Ethyl Alcohol, as labeled, but determined the presence of **Methanol, 78.4% & 76.5%**, respectively.

Methanol is a toxic alcohol that is used industrially as a solvent, pesticide, and alternative fuel source which can be absorbed into the body by inhalation, ingestion, skin contact, or eye contact. Effects of short-term exposure (less than 8-hours) may cause an accumulation of acid in the blood (metabolic acidosis), blindness, and death. Initial adverse health effects due to methanol poisoning include drowsiness, reduced level of consciousness (CNS depression), confusion, headache, dizziness, inability to coordinate muscle movement (ataxia), and heart and respiratory (cardiopulmonary) failure. Chronic poisoning from repeated exposure may produce inflammation of the eye (conjunctivitis), insomnia, stomach disturbances, visual failure, and irritation of the skin (dermatitis)¹.

Ethyl Alcohol (at 70% concentration) is used as a topical antiseptic and disinfectant. Ethyl Alcohol 70% Solution with Moisturizer (Alcostar) is packed in a translucent white HDPE plastic bottle with plastic flip-top cap.

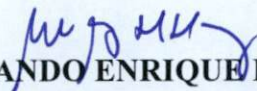
Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lots of the product are instructed to discontinue further distribution, sale, and use. Likewise, all consumers are advised not to use or purchase the affected product lots and may contact Greatstar Laboratories at mobile no. +639178558150 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.

¹ "METHANOL: Systemic Agent", 2011, <https://www.cdc.gov/niosh/ersbdb/emergencyresponsecard/29750029.html> (accessed May 2020)

For more information and inquiries, please e-mail us at cdr_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.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General



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