Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2024

09 AUG 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Product Recall of Specific Lot of Isopropyl Alcohol 70% (v/v) Solution (Zach)**

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

DRUG PRODUCT	**ISOPROPYL ALCOHOL 70% (v/v) SOLUTION (ZACH)** **Net Content: 500 mL**	
REGISTRATION NO.	**HRP-268**	
LOT NO./EXP. DATE	**G2005005**	**MAY 2022**
MANUFACTURER	**Azarias Pharmaceutical Laboratories, Inc. – 001 Service Road, Zone 1, Pandayan, Meycauayan, Bulacan**	

Figure 1. Isopropyl Alcohol 70% (v/v) Solution (Zach) for recall

Based on the results of the laboratory analyses conducted by the FDA, it was found that the affected lot contains only 58.9% of Isopropyl Alcohol which is less than 70%, as labeled, and determined the presence of Methanol.

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 (Central Nervous System 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].

Isopropyl Alcohol at 70% concentration is used as a topical antiseptic and disinfectant. Isopropyl Alcohol 70% (v/v) Solution (Zach) is packed in an opaque white HDPE plastic bottle with blue flip top cap.

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected lot 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 lot and may contact Azarias Pharmaceutical Laboratories, Inc. at telephone number **+632 8475-9119** or mobile no. **+639616342868** 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 lot 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.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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[1] "METHANOL: Systemic Agent", 2011, https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750029.html