



FDA ADVISORY
No. **2020-1300**

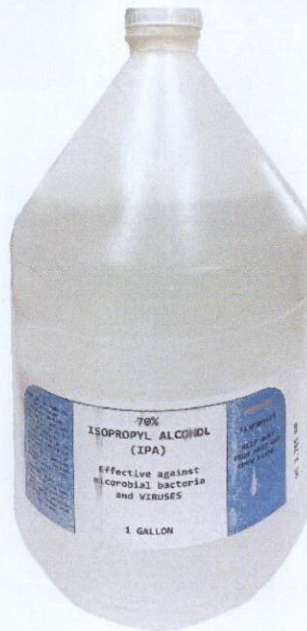
JUN 24 2020

TO : THE GENERAL CONSUMING PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of Adulterated, Misbranded, and Unregistered Health Product "70% Isopropyl Alcohol (IPA) 1 Gallon"

The Food and Drug Administration (FDA) warns the public against the purchase and use of the following adulterated, misbranded, and unregistered health product which poses potential danger or injury to health:

PRODUCT IMAGE



70% ISOPROPYL ALCOHOL (IPA) 1 Gallon

Figure 1. Adulterated, Misbranded, and Unregistered Health Product.

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned health product has not gone through the registration process of the Agency and been issued with proper market authorization, e.g., Certificate of Product Registration.

The FDA laboratory analysis showed that the product contains only 14.37% 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 (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.

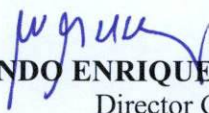
In light of the foregoing, the public is advised to always check if a health product has been registered with the FDA before purchasing it by making use of the embedded Search feature at the FDA website (www.fda.gov.ph). You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to manufacture, distribute, sell, or offer for sale the adulterated/misbranded/unregistered health product. Pursuant to Section 11, subsections (a) and (b) of Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the following acts and the causing thereof: (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; and (b) the adulteration or misbranding of any health product are prohibited.

All Law Enforcement Agencies (LEAs) and Local Government Units (LGUs), are requested to ensure that this product is not sold or made available in their localities or areas of jurisdiction.

For more information or inquiries, please e-mail us at cdr_postmarketsurveillance@fda.gov.ph. To report any 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 (CDRR) at telephone number **(02) 8809-5596**. Any suspected adverse reaction experienced from the use of the product 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 this advisory to all concerned is hereby requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General



¹“METHANOL: Systemic Agent”, 2011, https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750029.html (accessed May 2020)