

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 20211846

28 JUL 2021

TO:

THE GENERAL PUBLIC

SUBJECT:

Product Information Safety Alert on Specific Neutrogena® and Aveeno® Aerosol Sunscreen Products Due to the

Presence of Benzene

The Food and Drug Administration (FDA) hereby informs the general public on the safety alert of the following sunscreen products:

- 1. NEUTROGENA® Beach Defense® aerosol sunscreen,
- 2. NEUTROGENA® Cool Dry Sport aerosol sunscreen,
- 3. NEUTROGENA® Invisible Daily™ defense aerosol sunscreen,
- 4. NEUTROGENA® Ultra Sheer® aerosol sunscreen, and
- 5. AVEENO® Protect + Refresh aerosol sunscreen.

On 14 July 2021, the U.S. Food and Drug Administration (USFDA) has issued a safety alert warning for consumers not to use certain cosmetic products tested with identified low levels of benzene. Accordingly, a voluntary recall was undertaken by Johnson and Johnson Consumer Inc. (JJCI) for all lots of five NEUTROGENA® and AVEENO® aerosol sunscreen product lines to the consumer level.

Benzene is classified as a human carcinogen, a substance that could potentially cause cancer depending on the level and extent of exposure. Benzene can be absorbed, to varying degrees, by repeated and chronic exposures of an individual via inhalation, through the skin, and oral ingestion. Based on exposure modeling and the US Environmental Protection Agency's (EPA) framework, daily exposure to benzene in these aerosol sunscreen products at the levels detected in the testing would not be expected to cause adverse health consequences. However, under the ASEAN Cosmetics Directive, benzene has been listed as a banned ingredient and should not form part of the composition of a cosmetic product that is sold in the ASEAN market.

In this regard, Johnson and Johnson Philippines Inc. has notified the FDA that they are voluntarily recalling all lots of NEUTROGENA® Cool Dry Sport with Micromesh Sunscreen Spray Broad Spectrum SPF 50 product that is notified and sold in the Philippine market. The rest of the products stated in the product recall notice by the USFDA are not sold in the country. Further, the company in its disclosure to the FDA stated that "benzene is not an ingredient in any of their sunscreen products, it was detected in some samples of the impacted aerosol sunscreen finished products. Currently, they are investigating the cause of this issue, which is limited to the above-mentioned aerosol sunscreen products.

To report any sale or distribution of the recalled health products to kindly email FDA via 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 information to all concerned is hereby requested.

DTN 20210715233044

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