Ohio | Department of Health

Mike DeWine, Governor
Jon Husted, Lt.Governor

Lance D. Himes, Interim Director

DATE: August 18, 2020

TO: Health Commissioners, Directors of Environmental Health, and Interested Parties

RE: Recall Announcement ODH 2020-019

Albek de Mexico S.A. de C.V. Issues Voluntary Nationwide Recall of All Hand Sanitizers Due to Potential Presence of Undeclared Methanol.

SAN JUAN del RIO QUERETARO, Mexico -- ALBEK de Mexico S.A. de C.V. is voluntarily recalling all lots and all brands of hand sanitizer currently in US distribution to the consumer level. The products were manufactured between November 7, 2019 and June 28, 2020.

This recall is being initiated out of an abundance of caution due to detection of methanol in hand sanitizer samples manufactured by Albek when product was presented for import into the United States.

Risk Statement: Substantial methanol exposure could result in serious health effects (including nausea, diarrhea, vomiting, severe abdominal pain, headache, blurred vision, permanent blindness, seizures, coma, nervous system damage) or death. Persons using methanol-based products on their hands may be at risk. Young children who accidently ingest them and adolescents and adults who drink such products are most at risk for methanol poisoning. To date, there have been no reports of serious adverse events related to the products in the scope of this recall.

Recalled Products: The products are labeled for use as a hand sanitizer (or "antiseptic") and are packaged for several nationwide distributors in a variety of formats as indicated in the table as follows:

Product Name	NDC	Size	UPC	Affected Lots
Nuuxsan Instant Hand Sanitizer	72758-005-02 72758-001-08	8 fl oz	713620000175	All Lot #s
Modesa Hand Sanitizer with Moisturizers and Aloe Vera	72758-011-23	8 fl oz	32251380426	1931104AL
Assured Hand Sanitizer Vitamin E and Aloe	72758-010-23	8 fl oz	639277928597	1931101AL
Assured Hand Sanitizer Aloe Vera	72758-009-23	8 fl oz	639277928610	1931102AL
Next Hand Sanitizer	50066-605-08	8 fl oz	650240053573	The affected lots end in: 1001, 1002, 1003, 1004, 1005

These products were distributed nationwide in the United States beginning on November, 15 2019.

Albek is partnering with its distributors, who will help notify their customers by phone calls, emails, and/or mailed letters and is arranging for return of all recalled products. Consumers, distributors, and retailers that have product which is being recalled should stop use or distribution and return to place of purchase.

Consumers with questions regarding this recall can contact Albek de Mexico S.A. de C.V. during the business hours business hours: 9:00am – 5:00pm (CT)

Email: contact@albek.com.mx

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.