



Clifton Health Department Food Recall Notification



Food/Drug/Pet Recall: CorgioMed, LLC

CorgioMed, LLC is voluntarily recalling all lots of Leafree Instant Hand Sanitizer-Aloe Vera, within expiry to the consumer level. The products are being recalled because they are labeled as "EDIBLE ALCOHOL". Leafree Hand Sanitizer is an alcohol-based hand rub to be applied externally to reduce bacteria on the skin when soap and water are not available.

Risk Statement: Ingesting hand sanitizer, which is intended for topical use, may result in alcohol toxicity. Symptoms of alcohol toxicity may range from lack of coordination, slowed or slurred speech, drowsiness to coma, which can be fatal. Young children may experience a sharp decrease in blood sugar which may result in death. Pregnant women who ingest alcohol have experienced birth defects and developmental disabilities. Nursing mothers who ingest alcohol in above moderate levels may see developmental, growth and sleep pattern damages in their babies and may experience impaired judgement and ability to safely care for their child. Furthermore, ingesting alcohol can affect the brain and cause impaired driving or operating heavy machinery. Alcohol can also interact with numerous drugs which may result in serious adverse effects. Ingesting alcohol by people with alcohol addiction may interfere with maintaining abstinence. Additionally, people with alcohol addiction may seek large amounts of ethanol-based hand sanitizers as a substitute. The labeling of this product as 'edible alcohol' may promote this behavior.

The product is used as a hand sanitizer and is packaged in 100 ml (UPC #6970495860325), 300 ml (UPC #69705860318) and 500 ml (UPC #6970495860301) bottles. Product was distributed Nationwide via CorgioMed website.

CorgioMed LLC is notifying its distributors and customers by email and is arranging for return or disposal of all recalled products.

Distributors and Consumers with questions regarding this recall can contact CorgioMed LLC by emailing to: contact@corgiomed.com phone: 301-978-3898 from September 1st to September 30th, 2020.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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



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