
Subject: Ascent Consumer Products Inc. Issues Voluntary Nationwide Recall of SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System Due to Microbial Contamination

Summary

Company Announcement Date:

February 25, 2025

FDA Publish Date:

February 25, 2025

Product Type:

Drugs

Reason for Announcement:

Microbial contamination of the product with *Staphylococcus aureus* (*S. aureus*)

Company Name:

Ascent Consumer Products Inc.

Brand Name:

SinuCleanse

Product Description:

Soft Tip Squeeze Bottle Nasal Wash System

Company Announcement

FOR IMMEDIATE RELEASE: 02/25/2025 Melville, NY. Ascent Consumer Products Inc. is voluntarily recalling one lot of SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System to the consumer level. The recall is being initiated due to a confirmed test result of microbial contamination of the product with *Staphylococcus aureus* (*S. aureus*).

Risk Statement:

Use of the SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System, contaminated with *S. aureus*, can result in blood infections in users whose nasal mucosa may be compromised due to inflammation and mechanical injuries, caused by nasal irrigation. Resulting secondary infections may occur, such as endocarditis (infection of the heart's inner lining), bone and joint infections, splenic abscesses or meningitis, and bacterial sinusitis which may lead to eye tissue infections, vision problems, cranial nerve damage, or meningitis. These infections are serious and potentially life-threatening. To date, no adverse events have been reported to Ascent Consumer Products, Inc. related to this recall.

SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System is used as a nasal wash of the nasal passages to help temporarily relieve symptoms associated with sinusitis, cold, flu, or allergies. The only affected product lot includes the following:

| Product Name | Lot Number | Expiration Date |
|---|-------------|-----------------|
| SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System | 024122661A1 | 12-31-2027 |

The SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System is packaged in a carton, containing the squeeze bottle and 30 Saline Packets. The lot number and expiration date can be identified on the side of the carton or on the back of the Saline Packets within the carton. The affected lot was distributed in January 2025 nationwide through retail and online outlets.

Ascent Consumer Products Inc. is notifying its distributors and customers by electronic mail. Distributors and retailers in possession of the affected lot should immediately cease distribution and remove the recalled SinuCleanse Soft Tip Squeeze Bottle Nasal Wash System lot from inventory. Consumers who have this product should discontinue use immediately and return it to the place of purchase or discard it.

Consumers with questions regarding this recall can contact Ascent Consumer Products Inc. by email at cs@ascentconsumerproducts.com Monday-Friday from 9am-5pm ET. Consumers should contact their physician or healthcare provider if they experience any problems related to the use of this product.

Reporting Adverse Reactions

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program:

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download a form at www.fda.gov/MedWatch/getforms.htm 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.

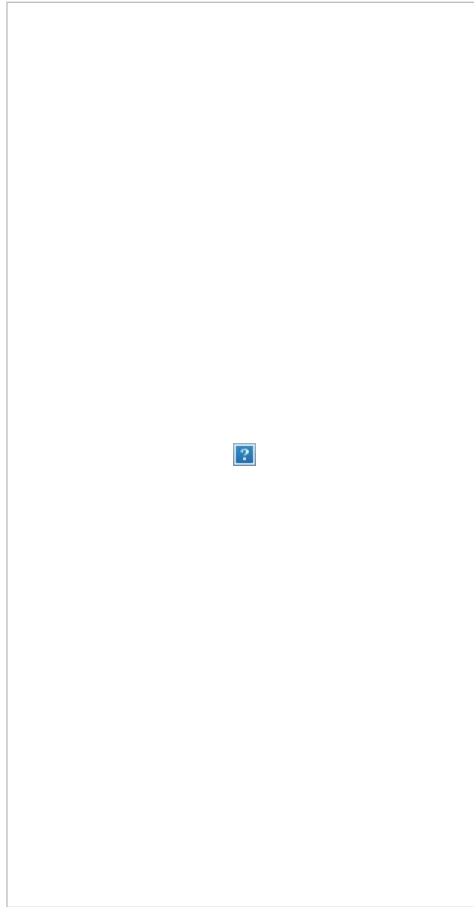
Company Contact Information

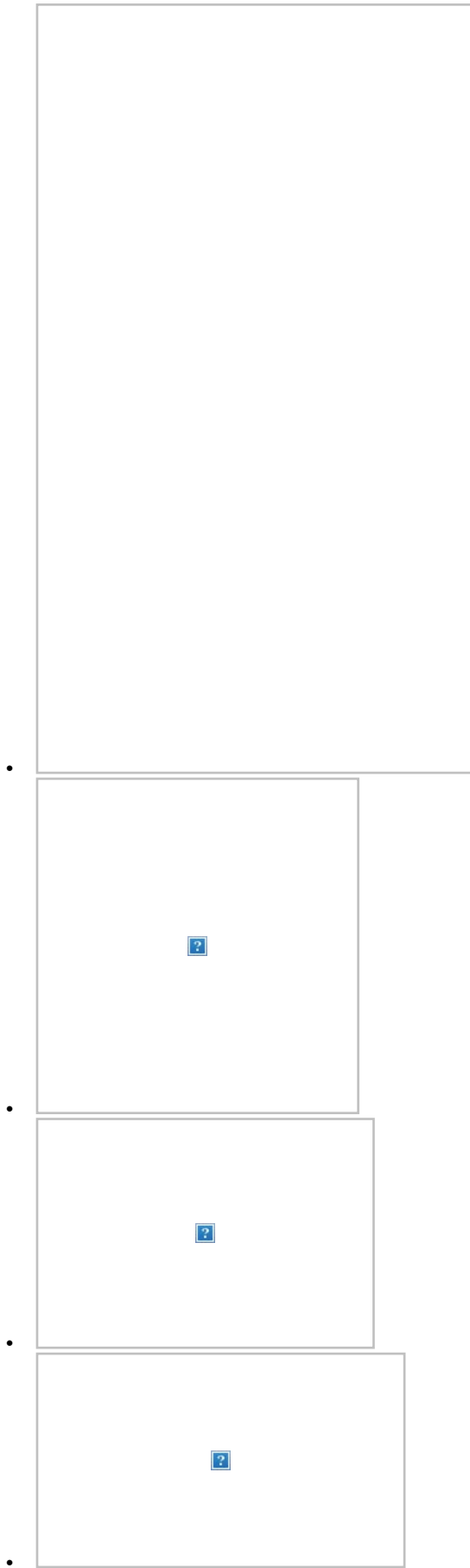
Consumers:

Ascent Consumer Products, Inc.

cs@ascentconsumerproducts.com

Product Photos





* We believe that none of the product being recalled were processed or offered through the national office

* We strongly encourage you to notify your agencies within one business day from receipt of this notice.

* ALL cased and uncased inventories, both at the member level and agency level, need to be checked. This product may have entered member and agency warehouses through salvage, local donations, TEFAP, local purchases, retail pickups, food drives, or other avenues.

* For additional local details, please contact the Health Department(s) for the area(s) your food bank serves.

About Feeding America Recall Notices

The Feeding America national office issues notifications of all national Class I and II recalls--those involving a health hazard situation in which there is reasonable probability that eating the food will cause health problems or death--and other recalls that may affect the safety of food supplied to network members.

The national office strongly encourages all member product solicitors, operations managers, and others involved in food and grocery distribution to regularly consult resources provided by the United States Food and Drug Administration (FDA) at <http://www.fda.gov/opacom/7alerts.html>, and the United States Department of Agriculture (USDA) at http://www.fsis.usda.gov/Fsis_Recalls/index.asp. Additionally, members can often receive information on national, state, and local recalls by contacting their local health departments.

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