

FOAMING HAND- benzalkonium chloride lotion
Vi-Jon

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Germ-X Foaming Hand Sanitizer 224.000/224AA

Active ingredient

Benzalkonium chloride 0.13%

Purpose

Antiseptic

Use

- to decrease bacteria on the skin that could cause disease

Warnings

for external use only: hands

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- irritation or redness develop
- condition persists for more than 72 hours

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions

- wet hands thoroughly with product and allow to dry without wiping
- for children under 6, use only under adult supervision
- not recommended for infants

Inactive ingredients

water, cocamidopropyl betaine, lauramidopropylamine oxide, lauramine oxide, myristamidopropylamine oxide, glycerin, citric acid, tetrasodium EDTA, sodium benzoate

Rear label text

Product is NSF registered for use as a hand sanitizer in and around food processing areas.

Manufactured By: Vi-Jon, Inc.

8515 Page Ave., St. Louis, Mo 63114

vijonprofessional.com

principal display panel

NDC 11344-224-96

germ-X

Professional

ANTIBACTERIAL

FOAMING

HAND SOAP

Helps kill harmful germs

NSF

Nonfood Compounds

Program Listed (Code E2)

7.5 FL OZ (221 mL)



FOAMING HAND

benzalkonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-224
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CO CAMIDO PROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURAMIDO PROPYLAMINE O XIDE (UNII: I6KX160QTV)	
LAURAMINE O XIDE (UNII: 4F6FC4MI8W)	
MYRISTAMIDO PROPYLAMINE O XIDE (UNII: 3HSF539C9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-224-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2018	
2	NDC:11344-224-96	222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/08/2018	
3	NDC:11344-224-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2018	
4	NDC:11344-224-04	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2018	
5	NDC:11344-224-45	1150 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/08/2018	
6	NDC:11344-224-20	44 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	02/08/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/08/2018	

Labeler - Vi-Jon (150931459)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		150931459	manufacture(11344-224)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(11344-224)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(11344-224)