FOAMING HAND- benzalkonium chloride lotion
OptiSource International, Inc

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.

Optical 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

Distributed by:

OptiSource International, Inc

40 Sawgrass Drive, Bellport, NY 11713

principal display panel

Optical

Soap

- Hypoallergenic
- Antibacterial
- Fragrance Free

Sanitizing Foaming Hand Soap

7.5 FL OZ (221 mL)

FOAMING HAND

benzalkonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75447-224
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)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	

LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
MYRISTAMIDOPROPYLAMINE OXIDE (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:75447-224-96	222 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/01/2020	

Labeler - OptiSource International, Inc (849200159)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(75447-224)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture(75447-224)

Revised: 4/2022 OptiSource International, Inc