

MOISTURIZING HAND SANITIZER- benzethonium chloride lotion
Vi-Jon, 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.

Germ-X Moisturizing Hand Sanitizer Lotion
478

Active ingredient

Benzethonium chloride 0.2%

Purpose

Antimicrobial

Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

For external use only - hands only

When using this product

- Keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands thoroughly with product
- briskly rub hands together until absorbed
- apply to hands as needed
- for children under 6, use only under adult supervision
- not recommended for infants

Inactive ingredients

water, dimethicone, cetyl alcohol, cyclopentasiloxane, stearyl alcohol, polyquaternium-37, cocamidopropyl PG-dimonium chloride phosphate, glyceryl laurate, butylene glycol, Vitis vinifera (grape) seed oil, tocopheryl acetate, Butyrospermum parkii (shea) butter extract, Chamomilla recutita (matricaria) flower extract, Aloe barbadensis leaf juice, Camellia oleifera leaf extract, Thymus vulgaris (thyme) flower/leaf oil, Melaleuca alternifolia (tea tree) leaf oil, Litsea cubeba fruit oil, Origanum vulgare oil, cholecalciferol, ascorbic acid, retinyl palmitate, glycerin, glyceryl caprylate/caprate, propylene glycol, glyceryl stearate SE, steareth-2, steareth-21, polysorbate 20, beeswax, ethylhexylglycerin, ethylhexyl palmitate, tetrasodium EDTA, phenoxyethanol, methylparaben,

ethylparaben, imidazolidinyl urea, DMDM hydantoin, potassium sorbate, sodium benzoate, citric acid

*Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds

Distributed By: Vi-Jon, Inc.

8515 Page Ave

St. Louis, MO 63114

www.germx.com

478.001/988AC

Principal display panel

germ-X Moisturizing Hand Sanitizer Lotion

2 in 1 moisturize & sanitize hands

KILLS 99.99% OF GERMS

Fragrance Free

Alcohol Free

Dermatologist Tested

NET WT 2 OZ (59 g)



MOISTURIZING HAND SANITIZER

benzethonium chloride lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-478
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	1.98 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
POLYQUATERNIUM-37 (10000 MPA.S) (UNII: 41QWS48DFN)	
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)	
GLYCERYL LAURATE (UNII: Y98611C087)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SHEA BUTTER (UNII: K49155WL9Y)	
CHAMOMILE (UNII: FGL3685T2X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
THYME OIL (UNII: 2UK410MY6B)	
TEA LEAF OIL (UNII: VC855RRT77)	
LITSEA CUBEBA FRUIT (UNII: R3617MQA5Z)	
LITSEA OIL (UNII: 2XIW34BN6O)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
GLYCERIN (UNII: PDC6A3C0OX)	
glyceryl caprylate/caprate (UNII: G7515SW10N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
STEARETH-2 (UNII: V56DFE46J5)	
Steareth-21 (UNII: 53J3F32P58)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
Ethylhexylglycerin (UNII: 147D247K3P)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
IMIDUREA (UNII: M629807ATL)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-478-16	56 g in 1 TUBE; Type 0: Not a Combination Product	05/03/2016	

2	NDC:11344-478-26	113 g in 1 TUBE; Type 0: Not a Combination Product	05/03/2016	
3	NDC:11344-478-32	340 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/03/2016	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/03/2016	

Labeler - Vi-Jon, Inc (150931459)

Registrant - Vi-Jon, Inc (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc		088520668	manufacture(11344-478)