FRESH PROTECT SKIN SANITIZER- benzalkonium chloride lotion Omega Tech Labs 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.

Fresh Protect Skin Sanitizer Product

DRUG FACTS

Active Ingredient

Benzalkonium chloride 0.13%

Purpose

Antiseptic

Uses

For hand sanitizing. To decrease bacteria on the skin.

Warnings

For external use only.

Do not use

in the eyes. In case of eye contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or redness develops, or if condition persists more than 72 hours.

Keep out of reach of children.

Instruct children on proper use. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply a small amount on your hands. Rub hands together until dry. When hands are visibly soiled, wash with soap and water.

Inactive Ingredients

Water, Emulsifying Wax NF, Behentrimonium Methosulfate, Centrimonium Chloride, Dimethicone, Aloe Barbadensis Leaf Extract, Tocopheryl Acetate E, Retinyl Palmitate A, Simmondsia Chinensis (Jojoba) Seed Oil, Glycerin, Hydrolyzed Soy Protein, Butylene Glycol, Avena Sativa (Oat) Extract, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Tetrasodium EDTA, Peppermint Essential Oil.

PRINCIPAL DISPLAY PANEL

Fresh Protect

96.9% Natural Skin Sanitizer Product Kills 99.99% of Germs No Alcohol 8 fl. oz. (237 ml)

Fresh Protect Skin Sanitizer Product

is an effective alternative to alcohol-based sanitizers. It is 96.9% natural & kills 99.99% of germs.

NO ALCOHOL NO PARABENS



Professional Formula
Used by Doctors & Nurses
Hands feel soft and refreshed.

Fresh Protect %.9% Natural

Skin Sanitizer Product

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OMEGA TECH LABS, LLC 5069 Alworth St. Boise, ID 83714 USA 1-208-375-5054 MADE IN USA www.freshprotect.com

DOM 4-20-2009

Kills 99.99% of Germs

No Alcohol

8 fl.oz. (237 ml)



FRESH PROTECT SKIN SANITIZER

benzalkonium chloride lotion

Product Information

Route of Administration

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:20802-1500

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)

TOPICAL

BENZALKONIUM CHLORIDE .0013 g in 1 mL

Inactive Ingredients

Ingredient Name

Strength

WATER (UNII: 059QF0KO0R)

BEHENTRIMO NIUM METHO SULFATE (UNII: 5SHP745C61)

CETRIMO NIUM CHLO RIDE (UNII: UC9 PE95IBP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERIN (UNII: PDC6 A3C0 O X)	
SOY PROTEIN (UNII: R44IWB3RN5)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
AVENA SATIVA LEAF (UNII: 206 PI19 V7R)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
SORBIC ACID (UNII: X045WJ989B)	
EDETATE SO DIUM (UNII: MP1J8420 LU)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:20802-1500-1	14 mL in 1 BOTTLE				
2 NDC:20802-1500-2	89 mL in 1 BOTTLE				
3 NDC:20802-1500-3	237 mL in 1 BOTTLE, PUMP				
4 NDC:20802-1500-4	473 mL in 1 BOTTLE, PUMP				
5 NDC:20802-1500-5	800 mL in 1BAG				
6 NDC:20802-1500-6	3785 mL in 1 BOTTLE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH NOT FINAL	part333A	12/16/2010			

Labeler - Omega Tech Labs Inc. (019313817)

Establishment						
Name	Address	ID/FEI	Business Operations			
Omega Tech Labs Inc		0 19 3 13 8 17	MANUFACTURE			

Revised: 1/2011 Omega Tech Labs Inc.