RAW SPIRIT - MOISTURIZING ANTIMICROBIAL HAND- benzalkonium chloride lotion
Cosmetic Solutions LLC

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.

Raw Spirit - Moisturizing Antimicrobial Hand Lotion

DRUG FACTS:

ACTIVE INGREDIENTS

Benzalkonium chloride 0.13%

Purpose

Antiseptic

USES

To decrease bacteria on the skin.

WARNINGS

- For external use only: Hands only.
- **When using this product** avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. Avoid contact with broken skin.
- **Stop use and ask a doctor if** irritation or redness develops - condition persists for more than 72 hours.
- **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 and allow to dry without wiping - for children under 6, use only under adult supervision - not recommended for infants.

INACTIVE INGREDIENTS

Water (Aqua), Caprylic/Capric Triglyceride, Cetyl Alcohol, Behentrimonium Methosulfate, Carthamus Tinctorius Seed Oil, Dimethicone, Propanediol, Butylene Glycol, Calendula Officinalis Flower Extract, Citric Acid, Disodium Phosphate, Equisetum Arvense Extract, Ethylhexylglycerin, Fragrance, Geranium Maculatum Extract, Glycerin, Honey, Lactococcus Ferment Extract, Moringa Oleifera Seed Extract, Panax Ginseng Root Extract, Phenoxyethanol, Salvia Officinalis Leaf Extract, Sambucus Nigra Flower Extract, Sodium Hydroxide.

PRINCIPAL DISPLAY PANEL - 60 g Bottle Label

RAW
SPIRIT

moisturizing
antimicrobial
hand lotion

Net wt. 2.1 oz | 60g

RAW SPIRIT - MOISTURIZING ANTIMICROBIAL HAND

benzalkonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66163-2101
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 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Cetyl Alcohol (UNII: 936JST6JCN)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
Safflower Oil (UNII: 65UEH262IS)	
Dimethicone (UNII: 92RU3N3Y1O)	
Propanediol (UNII: 5965N8W85T)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Calendula Officinalis Flower (UNII: P0M7O4Y7YD)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Sodium Phosphate, Dibasic, Anhydrous (UNII: 22ADO53M6F)	
EQUISETUM ARVENSE BRANCH (UNII: 1L0VKZ185E)	
Ethylhexylglycerin (UNII: 147D247K3P)	
GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ)	
Glycerin (UNII: PDC6A3C0OX)	
Honey (UNII: Y9H1V576FH)	
Asian Ginseng (UNII: CUQ3A77YXI)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sambucus Nigra Flower (UNII: 07V4DX094T)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66163-2101-1	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333E	05/01/2020	

Labeler - Cosmetic Solutions LLC (807907928)

Revised: 7/2020 Cosmetic Solutions LLC