SANITIZING HAND- benzethonium chloride lotion
BELLA BRANDS 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.

Sanitizing Hand

Drug Facts:

Active Ingredient

Benzethonium Chloride, 0.1%

Purpose

Antimicrobial Agent

Use

for moisturizing hands and decreasing bacteria on the skin.

Warnings

- For external use only.
- Do not use if you are allergic to any of the ingredients.
- When using this product, do not get into eyes. If contact occurs, rinse thoroughly with water.
- Stop use and consult a doctor if irritation or rash develops and continues for more than 72 hours.
- Keep out of reach of children. If swallowed, get medical help or visit a Poison Control Center right away.

Inactive Ingredients

Water, Ethyl Alcohol, Helianthus Annuus (Sunflower) Seed Oil, Butylene Glycol, Caprylic/ Capric Triglyceride, Potassium Cetyl Phosphate, Sorbitan Isostearate, Diheptyl Succinate & Capryloyl Glycerin/Sebacic Acid Copolymer, Stearic Acid, Chlorohexidine Gluconate, Carbomer, Polysorbate 20, Aminomethyl Propanol, Tetrasodium EDTA, Camellia Sinensis (Green Tea) Extract[1], Glycirrhiza Glabra (Licorice) Root Extract[1], Aloe Vera Barbadensis Leaf Juice[1], Chamomilla Recutita (Matricaria) Flower Extract[1], Phenoxyethanol, Ethylglycerin, Fragrance (Naturally Derived)

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[1] Organic Ingredient

Directions For Use

- Press dispensing pump to release product into hands, and rub thoroughly around both sides of hands and between fingers. Do not wipe off. Let air dry.
- For adults and children 2 years and over.
- For children under 2 years of age, consult a doctor before use

PRINCIPAL DISPLAY PANEL - 400 ml Bottle Label

PURIGEN™

Sanitizing
Hand Lotion

- Kills 99.9% of Germs
- Safe for Sensitive Skin
- Dual Use Sanitizer & Moisturizer

Paraben Free
No Artificial Fragrance
Made with Organic Ingredients

13.5 fl oz (400 ml)

SANITIZING HAND

benzethonium chloride lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80994-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**

WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
EDETATE SODIUM (UNII: MP1J8420LU)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LICORICE (UNII: 61ZBX54883)	
CHAMOMILE (UNII: FGL3685T2X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-AMINOBUTYRIC ACID, L- (UNII: 0QAJ5KN9IM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80994-002-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:80994-002-02	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3	NDC:80994-002-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
4	NDC:80994-002-04	150 in 1 BOX	05/01/2020	
4		1.2 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part333A	05/01/2020	

Labeler - BELLA BRANDS INC (034908755)

Establishment

Name	Address	ID/FEI	Business Operations
BELLA BRANDS INC		034908755	MANUFACTURE(80994-002)

Revised: 11/2020 BELLA BRANDS INC