SANITIZING HAND- alcohol gel
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

Ethyl Alcohol 70% V/V

Purpose

Antimicrobial Agent

Use

for cleaning 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, Glycerin, Carbopol, Tocopherol, Aloe Vera Barbadensis Leaf Juice[1], Chamomilla Recutita (Matricaria) Flower Extract[1], Camelia Sinensis Leaf Extract[1], Vitis Vinifera (Grapeseed) Extract[1], Helianthus Annuus (Sunflower) Seed Oil[1], Fragrance (Naturally Derived), Sodium Hydroxide

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[1] Organic Ingredient

Directions for Use

- Press dispensing pump to release product into hand, 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 Gel

- Kills 99.9% of Germs
- Safe for Sensitive Skin
- 70% Alcohol Formula

Paraben Free
No Artificial Fragrance
Made with Organic Ingredients

13.5 fl oz (400 ml)

SANITIZING HAND

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80994-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Alcohol (UNII: 3K9958V90M) (Alcohol - UNII:3K9958V90M)	Alcohol	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
carbomer homopolymer, unspecified type (UNII: 0A5MM307FC)	
Tocopherol (UNII: R0ZB2556P8)	

Chamomile (UNII: FGL3685T2X)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Vitis Vinifera Seed (UNII: C34U15ICXA)	
Sunflower Oil (UNII: 3W1JG795YI)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80994-001-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:80994-001-02	400 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3	NDC:80994-001-03	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
4	NDC:80994-001-04	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(80994-001)

Revised: 11/2020 BELLA BRANDS INC