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 Juice¹, Chamomilla Recutita (Matricaria) Flower Extract¹, Camelia Sinensis Leaf Extract¹, Vitis Vinifera (Grapeseed) Extract¹, Helianthus Annuus (Sunflower) Seed Oil¹, Fragrance (Naturally Derived), Sodium Hydroxide

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

PURIGENTM

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)

Drug Facts: Active Ingredient Purpose Ethyl Akohol 70% V/V Antimicrobial Agent Use for cleaning hands and decreasing bacteria on the skin. Intervention on the skin. Warning: - 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 27 bours. - Keep out of reach of children. If swallowed, get medical help or visit a Poison Control Center right away. Inactive Ingredients: Water, Glycerin, Carbopal, Tocopherol, Aloe Vera Barbadensis Leaf Juice*, Chemomilia Recruita.	È PURIGEN™ Sanitizing Hand Gel • Kills 99.9% of Germs • Safe for Sensitive Skin • 70% Alcohol Formula	Pure. Clean. Healthy. Purigen Sanitizing Hand Gel is both effective and moisturizing. Formula includes organic aloe vera, grapeseed extract and sunflower seed oil to keep skin soft and moisturized. Also available: Purigen Hand Sanitizing Lotion, Spray, Soap and Wipes.	
(Matricaria) Hower Extract*, Camelia Sinensis Leaf Extract*, Vitis Vinifera (Grapesed) Extract*, Helianthus Annuus (Sunflower) Seed Ol*, Fragrance (Naturally Derived), Sodium Hydroxide *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.	Paraben Free No Artificial Fragrance Made with Organic Ingredients	Bella Brands Inc. Aliso Viejo, California MADE IN THE USA www.PurigenCare.com	
For adults and children 2 years and over. For children under 2 years of age, consult a doctor before use.	13.5 fl oz (400 ml)	41786 12912	

SANITIZING HAND

alcohol gel					
Product Information					
Product Type	e HUMAN OTC DRUG Item Code (Source) NDC:80994		30994-001		
oute of Administration TOPICAL					
Active Ingredient/Active Mo	ety				
Ingred	ent Name		Basis of Strength		Strength
Alcohol (UNII: 3K9958V90M) (Alcoho	l - UNII:3K9958V90M)		Alcohol	70	mL in 100 mL
Inactive Ingredients					
Ingredient Name					Strength
Water (UNII: 059QF0KO0R)					
Glycerin (UNII: PDC6A3C0OX)					
carbomer homopolymer, unspecifie	d type (UNII: 0A5MM307FC)				
Tocopherol (UNII: R0ZB2556P8)					

Chamomile (UNII: FGL3685T2X)					
G	reen Tea Leaf (UNII:	W2ZU1RY8B0)			
Vitis Vinifera Seed (UNII: C34U15ICXA)					
Sı	unflower Oil (UNII: 3	W1JG795YI)			
Se	dium Hydroxide (U	NII: 55X04QC32I)			
Packaging					
P	аскадінд				
		Package Description	Marketing Start Date	Marketing End Date	
#	Item Code	Package Description 250 mL in 1 BOTTLE; Type 0: Not a Combination Product	Marketing Start Date 05/01/2020	Marketing End Date	
# 1	Item Code NDC:80994-001-01	5 K		Marketing End Date	
# 1 2	Item Code NDC:80994-001-01 NDC:80994-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 5/0 1/20 20 0 5/0 1/20 20	Marketing End Date	
# 1 2 3	Item Code NDC:80994-001-01 NDC:80994-001-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product 400 mL in 1 BOTTLE; Type 0: Not a Combination Product 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 5/0 1/20 20 0 5/0 1/20 20	Marketing End Date	
# 1 2 3	Item Code NDC:80994-001-01 NDC:80994-001-02 NDC:80994-001-03	250 mL in 1 BOTTLE; Type 0: Not a Combination Product 400 mL in 1 BOTTLE; Type 0: Not a Combination Product 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 5/0 1/20 20 0 5/0 1/20 20 0 5/0 1/20 20	Marketing End Dat	

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