PANROSA ALCOHOL FREE HAND SANITIZER- benzalkonium chloride gel
Panrosa Enterprises, 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.

Panrosa Alcohol Free Hand Sanitizer

Drug Facts

Active ingredients

Benzalkonium Chloride 0.13%

Purpose

Antibacterial

Uses

- hand sanitizer to help decrease bacteria on the skin. when water, soap & towel are not available.
- recommended for repeated use.

Warnings

For external use only.

Flammable. Keep away from fire or flame.

Do not apply around eyes.

Do not use

in ears & mouth.

When using this product,

avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if

redness or irritation develop and persist for more than 72 hours.

Keep out of reach of children.

Children must be supervised in use of this product.

Directions

- pump as need into your palms and thoroughly spread on both hands.
- rub into skin until dry.

Other information

- store at 20°C (68°F to 77°F).
- may dscolor fabrics.

Inactive ingredients

Water, Cetrimonium Chloride, Lauramine Oxide, Cocamide Methyl MEA, Sodium Chloride, Propanediol, Parfum (Fragrance), Aloe Barbadensis Leaf Juice, Methylchloroisothiazolinone, Methylisothiazolinone.

Package Labeling: 50302-004-00

Package Labeling: 50302-004-01

PANROSA ALCOHOL FREE HAND SANITIZER

benzalkonium chloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50302-004
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 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCOYL METHYL MONOETHANOLAMINE (UNII: 79G1T427CF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:50302-004-00	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	
2	NDC:50302-004-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/09/2020	

Labeler - Panrosa Enterprises, Inc. (859957578)

Establishment

Name	Address	ID/FEI	Business Operations
Panrosa Enterprises, Inc.		859957578	manufacture(50302-004)

Revised: 3/2020 Panrosa Enterprises, Inc.