

PANROSA ALCOHOL FREE HAND SANITIZER ALOE VERA- 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, Aloe Vera

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 discolor fabrics.

Inactive ingredients

Water, Cetrimonium Chloride, Lauramine Oxide, Cocamide Methyl MEA, Sodium Chloride, Propanediol, Parfum (Fragrance), Aloe Barbadensis Leaf Juice, Methylchloroiso-thiazolinone, Methylisothiazolinone, FD&C blue No. 1, FD&C yellow No. 5.

Package Labeling:

<p>Drug Facts</p> <p>Active ingredients.....Purpose Benzalkonium Chloride 0.13%.....Antibacterial</p> <p>Uses ■ hand sanitizer to help decrease bacteria on the skin. when water, soap & towel are not available. ■ recommended for repeated use.</p> <p>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.</p>	<p>PANROSA® Alcohol-Free Hand Sanitizer Aloe Vera KILLS 99% OF GERMS! 16.9 FL OZ (500mL)</p>	<p>Directions ■ pump as need into your palms and thoroughly spread on both hands. ■ rub into skin until dry.</p> <p>Other information ■ store at 20°C (68°F to 77°F). ■ may discolor fabrics.</p> <p>Inactive ingredients Water, Cetrimonium Chloride, Lauramine Oxide, Cocamide Methyl MEA, Sodium Chloride, Propanediol, Parfum (Fragrance), Aloe Barbadensis Leaf Juice, Methylchloroiso-thiazolinone, Methylisothiazolinone, FD&C blue No. 1, FD&C yellow No. 5.</p> <p>PANROSA ENTERPRISES, INC. 550 Monica Circle Corona, CA 92880 www.panrosa.com</p> <p>6 51669 10444 0 MADE IN U.S.A.</p>
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PANROSA ALCOHOL FREE HAND SANITIZER ALOE VERA

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50302-005
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: 79GIT427CF)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPANEDIOL (UNII: 5965N8W85T)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50302-005-01	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(50302-005)

Revised: 3/2020

Panrosa Enterprises, Inc.