

HAND SANITIZER- alcohol gel
BioBarrier360 LLC

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.

BioBarrier360 Hand Sanitizer

Drug Facts

Active ingredients

Alcohol 70% v/v

Purpose

Antiseptic

Uses

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only.

Flammable. Keep away from heat or flame.

Do not use

- On children less than 2 months of age
- On open skin wounds

When using this product

- Keep out of eyes, ears and mouth. In case of contact with eyes rinse thoroughly with water.

Stop use and ask a doctor if

- Stop use and seek a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F).
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Carbomer, Glycerin, Triethanolamine, Iodopropynyl Butylcarbamate, Methylisothiazolinone.

Questions?

call (877) 458-1315

Company Information

Distributed By:

BioBarrier360 LLC

Austin, TX 78758

www.BioBarrier360.com

Made in Guatemala

Product Packaging - 500 ml

BIOBARRIER360

Hand Sanitizer

with moisturizing ingredients

Alcohol 70%

16.9 fl oz 500 ml

www.BioBarrier360.com



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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78426-001
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
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78426-001-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
2	NDC:78426-001-02	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
3	NDC:78426-001-03	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
4	NDC:78426-001-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
5	NDC:78426-001-05	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
6	NDC:78426-001-06	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - BioBarrier360 LLC (117535912)