

HAND SANITIZER 80 ALCOHOL- alcohol gel
Aruba Aloe Balm NV

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.

Hand Sanitizer 80% Alcohol

DRUG FACTS

Active Ingredients

Alcohol 80%

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

- In 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 eyes thoroughly with water.

Stop using and ask 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 (Aqua/Eau), Glycerin, Propylene Glycol, Aloe Barbadosensis Leaf Juice (Aloe Vera Gel from Aruba), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum), Tocopheryl Acetate (Vitamin E Acetate), Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Sodium Hydroxide.

Package Labeling:



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Made in Aruba by Aruba Aloe Balm Inc. Pitastraat 115, Aruba, Dutch Caribbean. Distributed in the USA by Aruba Aloe of North America LLC, Plainfield, IN 46168. Toll Free 1-800-95-ARUBA. NL, P.O. Box 531, 7300 AM, Apeldoorn



HAND SANITIZER 80 ALCOHOL

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53675-185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.8 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53675-185-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

Labeler - Aruba Aloe Balm NV (855442273)

Establishment

Name	Address	ID/FEI	Business Operations
Aruba Aloe Balm NV		855442273	manufacture(53675-185)

Revised: 4/2020

Aruba Aloe Balm NV