

HAND SANITIZER- ethyl alcohol gel

Brady Industries, 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.

Drug Facts

Active Ingredient(s)

Ethyl Alcohol 65% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

For external use only. Flammable.

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 use 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.

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Directions

- Place enough product to cover hands and rub hands together briskly until dry.
- Supervise children under 6 years of age when using this product.

Other information

- Store between 20-25C (68-77F)
- May discolor some fabrics or surfaces

Inactive ingredients

Water, Glycerin, Propylene Glycol, Carbomer, Fragrance, Isopropyl Palmitate, Aminomethyl Propanol, Tocopheryl Acetate.

Package Label - Principal Display Panel



NDC:79258-103-16 16oz Hand Sanitizer Gel

HAND SANITIZER				
ethyl alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79258-103	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL	
Inactive Ingredients				
	Ingredient Name		Strength	
	ISOPROPYL ALCOHOL (UNII: ND2M416302)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	CARBOMER 940 (UNII: 4Q93RCW27E)			
	ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)			
	WATER (UNII: 059QF0KO0R)			
	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:79258-103	473 mL in 1 BOTTLE, PLASTIC, Type 0; Not a Combination		

1	NDC:79258-103-16	4.75 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/15/2020		

Labeler - Brady Industries, Inc. (034932657)

Establishment			
Name	Address	ID/FEI	Business Operations
Tonic Bath & Body Products Shenzhen Ltd		528197042	manufacture(79258-103)

Revised: 7/2020

Brady Industries, Inc.