

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. Keep away from fire and flame.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product avoid contact with eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

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.

Directions

- Put enough on your palm to cover hand and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using the product.

Other information

- Store between 20-25C (68-77F)
- May discolor some fabrics or surfaces
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

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

Package Label - Principal Display Panel

The image shows the principal display panel of a Brady Hand Sanitizer Gel package. The label is white with teal accents. At the top, the Brady logo is displayed. Below it, the text 'HAND SANITIZER GEL' is written in large teal letters. Underneath, it says 'Kills 99.99% of Germs' and features a circular icon of a hand with stars. The main title 'HAND SANITIZER' is in large white letters, with 'Desinfectantes Para Manos' below it. The volume '32 FL.OZ.(1 QT) 946 ML' and code 'CM9507' are at the bottom. On the right side, there is a 'Drug Facts' panel with sections for Active ingredient, Use, Warnings, Directions, Other information, Inactive ingredients, and Questions?. At the bottom right, there is distributor information for Brady Industries, an American flag, and a barcode with the number 8 10037 73019 7.

946ml NDC: 79258-104-32

HAND SANITIZER			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79258-104
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		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
WATER (UNII: 059QF0K00R)			
GLYCERIN (UNII: PDC6A3C0OX)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
CARBOMER 934 (UNII: Z135WT9208)			

ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79258-104-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/30/2020	

Labeler - Brady Industries, Inc. (034932657)

Establishment

Name	Address	ID/FEI	Business Operations
McKenna Labs, Inc.		090631412	manufacture(79258-104)

Revised: 7/2020

Brady Industries, Inc.