

16.9OZ HAND SANITIZER- ethyl alcohol gel
MCURE HEALTH SOLUTIONS 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.

Active Ingredient(s)

Alcohol 75% v/v.

Purpose: Antibacterial

Purpose

Antiseptic, Hand Sanitizer

Use

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 do not use in or near the eyes.

In case of contact, 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.

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 below 30°C (86°F)

Inactive ingredients

glycerin, Carbome, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

500ML Hand Sanitizer



Size: 6.2x12.9cm

Dieline: —

Date: 04/07/2020

500 mL NDC: 52486-426-01

16.9OZ HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52486-426
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52486-426-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/26/2020	

Labeler - MCURE HEALTH SOLUTIONS INC. (053034873)

Revised: 4/2020

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