HAND SANITIZER- ethyl alcohol gel Audy Global Enterprises 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)

Ethyl Alcohol 75% v/v.

Purpose: Antimicrobial

Use

Place product in a dispenser if desired

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

Inactive ingredients

Water (Aqua), Glycerin, Carbomer, Phenoxyethanol, Aminomethyl propanol

Package Label - Principal Display Panel

500 ml NDC: 75778-003-50



5 L NDC: 75778-003-55

KEY





HAND SANITIZER GEL

KILLS 99.99% OF GERMS 75% ALCOHOL



DRUG FACTS

Active Ingredient

Purpose Ethyl Alcohol 75% v/v -----Antimicrobial

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- 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 eyes thoroughly with water.

Inactive Ingredients:

Water, Propylene, Glycol Glycerin, Carbomer, Triethanolamine

Keep the lid of this container tightly closed.

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

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.

Distrubuted by:

Audy Global Enterprises Inc. 1457 VFW Pkwy, West Roxbury, MA 02132, United States

For Any Concerns Contact Us at: (617) 379-0023 customerservice@audyglobal.com







MADE IN MEXICO

NET CONTENT **5 LITRES**

BATCH NO. EXPIRATION DATE

HAND SANITIZER

ethyl alcohol gel

Product Information

HUMAN OTC DRUG NDC:75778-003 Product Type Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

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

Inactive Ingredients

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Ingredient Name	Strength			
POLYACRYLIC ACID (800000 MW) (UNII: D016NSZ87U)	0.5 mL in 100 mL			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	3 mL in 100 mL			
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	20.2 mL in 100 mL			
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL			

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:75778-003- 50	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020			
	NDC:75778-003- 55	$5000\ mL$ in $1BOTTLE,$ DISPENSING; Type 0: Not a Combination Product	03/30/2020			

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	03/28/2020					

Labeler - Audy Global Enterprises Inc. (079171473)

Establishment						
Name	Address	ID/FEI	Business Operations			
Ecodeli Comercial, S.A. de C.V.		588530951	manufacture(75778-003)			

Revised: 5/2020 Audy Global Enterprises Inc.