# HAND SANITIZER- ethyl alcohol gel Ultra Distributors 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.

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#### **HAND SANITIZER Princess**

## Active ingredient

Ethyl Alcohol 62%

#### Purpose

Antiseptic

#### Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

# **Warnings**

For external use only: hands

Flammable. Keep away from fire or flame

# When using this product

- keep out of eyes. In case of contact with eyes, flush thoroughly with water.
- avoid contact with broken skin.
- do not inhale or ingest.

## Stop use and ask a doctor if

- irritation or redness develops.
- condition persists for more than 72 hours

**Keep out of reach of children**. If swallowed, get medical help or contact a poison control center(1-800-222-1222)right away.

#### Directions

- wet hands thoroughly with product and allow to dry without wiping.
- for children under 6, use only under adult supervision.
- not recommended for infants.

# Other information

- do not store above 105°F
- may discolor some fabics
- harmful to wood finished and plastics

#### **Inactive ingredients**

water, glycerin, propylene glycol, acrylates/C10-C30 alkyl acrylate crosspolymer, triethanolamine, aloe barbadensis leaf juice, maltodextrin





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# Drug Facts (continued)

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# HAND SANITIZER

ethyl alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78495-001

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) ALCOHOL 62 mL in 100 mL

# Inactive Ingredients Ingredient Name Strength MALTO DEXTRIN (UNII: 7CVR7L4A2D) CARBO MER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L) ALOE VERA LEAF (UNII: ZY8 1Z83H0 X) TROLAMINE (UNII: 9O3K93S3TK) WATER (UNII: 059QF0 KOOR) GLYCERIN (UNII: PDC6A3C0OX) PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:78495-001- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/04/2020		

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333E	09/04/2020				

# Labeler - Ultra Distributors Inc (007160073)

Revised: 9/2020 Ultra Distributors Inc