

HAND SANITIZER- alcohol gel

J. A. Cosmetics U.S. 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.

Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- For Hand Sanitizing

Warnings

For external use only - hands.

Flammable. Keep away from heat and 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 skin irritation develops.

Keep out of reach of children.

If swallowed, get medical help or call a Poison Control Center 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 fabrics.

Inactive Ingredients

Carbomer, Fragrance, Glycerin, Propylene Glycol, Tocopheryl Acetate, Triethanolamine, Water.

Package Labeling:

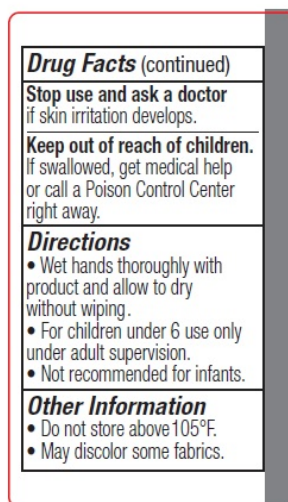


FRONT LABEL

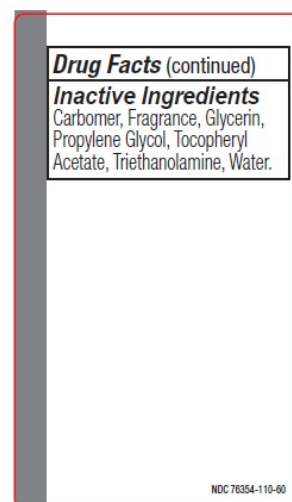
First layer front side



First layer back side



Second layer



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76354-194
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.62 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76354-194-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

Labeler - J. A. Cosmetics U.S. INC (186705047)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Ayan Biotech Co.,Ltd.		544377996	manufacture(76354-194)

Revised: 4/2020

J. A. Cosmetics U.S. INC