

INSTANT HAND SANITIZER- ethyl alcohol gel
Rejoice International Corp.

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

Ethyl Alcohol 62.0%

Antimicrobial

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

Directions

- wet hands thoroughly with product
- briskly rub hands together until dry
- supervise children under 6 years in the use of this product

Use:

- for handwashing to decrease bacteria on the skin
- recommended for repeated use

Warnings:

For external use only.

Flammable. Keep away from heat and flame.

Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

Inactive Ingredients: water, carbomer, triethanolamine, glycerin, propylene glycol, fragrance, tocopheryl acetate (Vitamin E), fd&c blue no. 1, fd&c yellow no. 5.



INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-083-01	53 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/25/2017	

Labeler - Rejoice International Corp. (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(57337-083)

Revised: 9/2019

Rejoice International Corp.