HAND SANITIZER- ethyl alcohol gel
Orazen 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:
Ethyl alcohol 62%

Purpose

Antiseptic

Warnings

For external use only: hands

Flammable. Keep away from heat and flame.

Stop use and ask a doctor if
- irritation or redness develops
- condition persists for more that 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, ues only under adult supervision
- not recommended for infants

Inactive ingredients

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

Other Information
- do not store above 105F
- may discolor some fabrics
- harmful to wood finishes and plastics

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

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

HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71927-002
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**
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71927-002-01	37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/06/2018	

Labeler - Orazen Inc (080916640)

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