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 70%

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

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

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 T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:71927-004		
Route of Administration	TOPICAL					
Active Ingredient/Active Moi	ety					
Ingred		Basis of Strength	h Strength			
ALCOHOL (UNII: 3K9958V90M) (ALC	A	LCOHOL	70 mL in 100 mL			
Inactive Ingredients						
Ingredient Name						
MALTO DEXTRIN (UNII: 7CVR7L4A2D)						
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)						
WATER (UNII: 059QF0KO0R)						
GLYCERIN (UNII: PDC6A3C0OX)						

PF	ROPYLENE GLYC	0L (U	NII: 6 DC9 Q 16 7 V3)					
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)								
AMINO METHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)								
Packaging								
#	Item Code		Package Description	Marketing Start Date	Marketing End Date			
	NDC:71927-004- 01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		11/27/2018				
Marketing Information								
Marketing Category		ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final		final	part333E	11/27/2018				

Labeler - Orazen Inc (080916640)

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Orazen Inc