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

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 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

- 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

Other Information

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

Inactive ingredients

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



HAND SANITIZER

ethyl alcohol gel

Product Type						
	ype HUMAN OTC DRUG Item (Item Code	(Source)	NDC:71927-001	
Route of Administr	ation	TOPICAL				
Active Ingredie						
Ingredient Name				Basis of Strength	strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)				ALCOHOL	62 mL in 100 mL	
Inactive Ingredi	ents					
Ingredient Name						Strengt
MALTO DEXTRIN (U	NII: 7CVR7L4A2	D)				
ALOE VERA LEAF (U	UNII: ZY8 1Z8 3H0	X)				
WATER (UNII: 059QF	F0KO0R)					
GLYCERIN (UNII: PD	C6A3C0OX)					
PROPYLENE GLYCO	DL (UNII: 6DC9C	(167V3)				
CARBOMER COPOI	YMER TYPE A	(ALLYL PENTAERYTHRITOL	CROSSLINKI	E D) (UNII: 71DD5V995I	L)	
FROLAMINE (UNII: 9	O3K93S3TK)					
Packaging						
# Item Code		Package Description		Marketing Start Date	Marketing End Date	
	30 mL in 1 BOTT Product	LE, PLASTIC; Type 0: Not a Com	binatio n	07/15/2020		
Marketing In	formation					
Marketing Catego	ory Applica	tion Number or Monograph C	itation M	arketing Start Date	Marketing	g End Dat
OTC monograph not f	inal part333E		0.7/	15/2020		

Labeler - Orazen Inc (080916640)

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Orazen Inc