

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 fire and flame.

Stop use and ask a doctor if

- irritation or redness develops
- condition persists for more than 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, use only under adult supervision
- not recommended for infants

Inactive ingredients

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

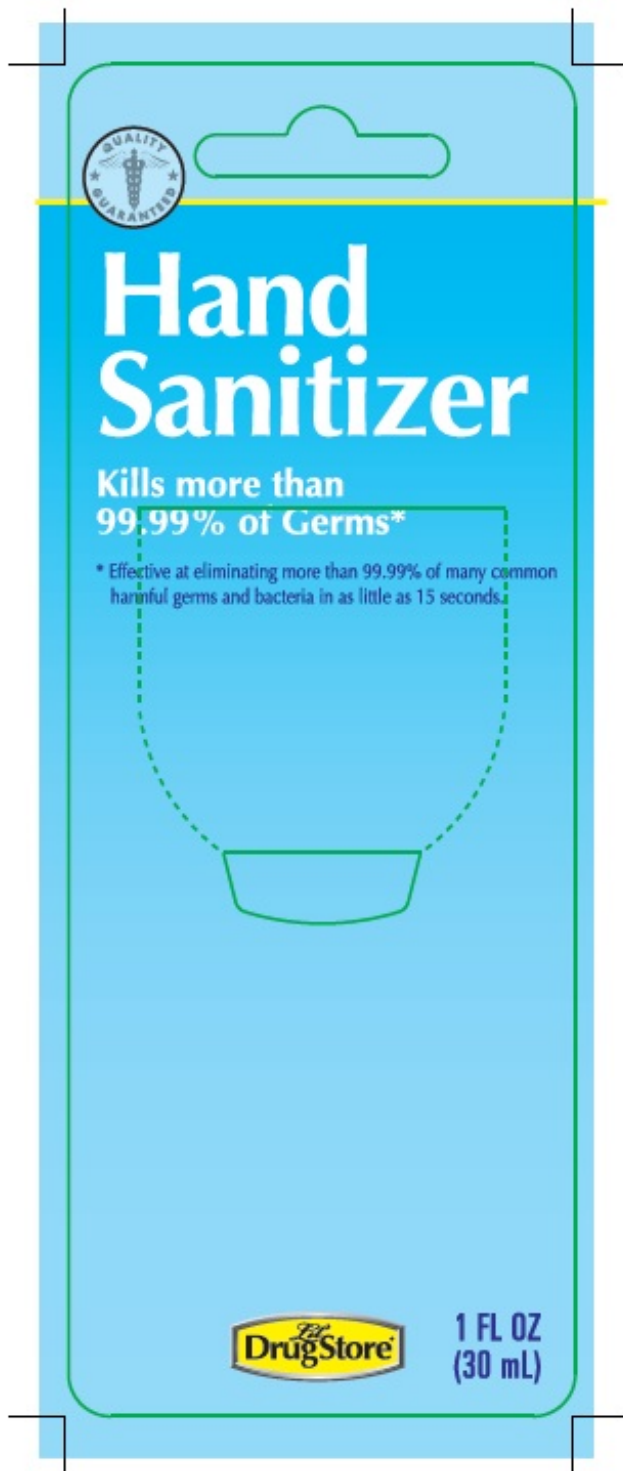
Other Information

- 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 Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-008
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: 059QF0K00R)				
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:71927-008-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/31/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	12/31/2019		

Labeler - Orazen Inc (080916640)

Revised: 12/2019

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