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

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 fire or 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 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 recommented for infants.

Other information. do not store above 105°F may discolor some fabics. harmful to wood finished and plastics

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

HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71927-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-009-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

Labeler - Orazen Inc. (080916640)

Revised: 4/2020 Orazen Inc.