

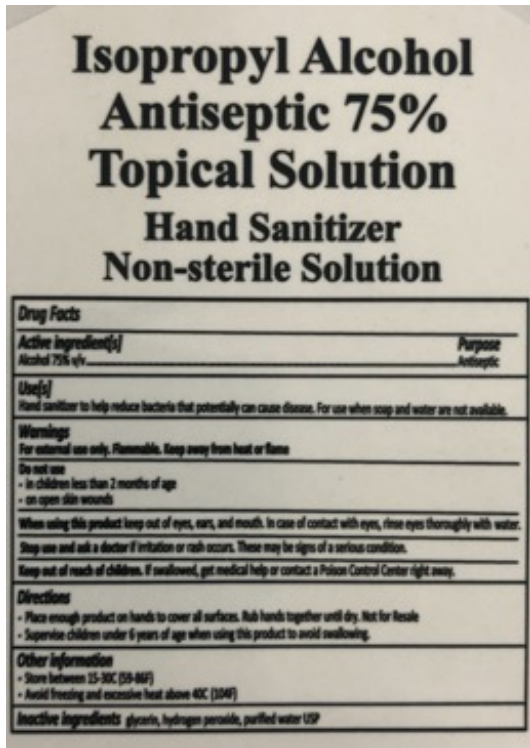
HAND SANITIZER- hand sanitizer liquid
Elevation Gourmet, Inc.

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 Ingredients & Label

Active Ingredient(s)

Isopropyl alcohol 75% v/v.....Antiseptic



Purpose & Use

Use(s)

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Isopropyl Alcohol Antiseptic 75% Topical Solution Hand Sanitizer Non-sterile Solution

Drug Facts	
Active ingredient(s) Alcohol 75% v/v	Purpose Antiseptic
Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
Do not use - in children less than 2 months of age - on open skin wounds	
When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions - Place enough product on hands to cover all surfaces. Rub hands together until dry. Not for Resale - Supervise children under 6 years of age when using this product to avoid swallowing.	
Other information - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 43C (109F)	
Inactive ingredients: glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER

hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73874-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCEROL FORMAL (UNII: 3L7GR2604E)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	23.425 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73874-0001-1	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
2	NDC:73874-0001-2	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2020	
3	NDC:73874-0001-3	3785.41 mL in 1 JUG; Type 0: Not a Combination Product	03/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/27/2020	

Labeler - Elevation Gourmet, Inc. (097452447)

Establishment

Name	Address	ID/FEI	Business Operations
Elevation Gourmet, Inc.		097452447	manufacture(73874-0001)

Revised: 3/2020

Elevation Gourmet, Inc.