SUMMIT HAND SANITIZER- alcohol gel
IMO SOURCE (PTY) LTD

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.

Summit Soap Hand Sanitizer

Drug Facts

Active ingredient(s)

Ethyl Alcohol 70% (V/V%)

Purpose

Antiseptic

Use[s]

- To help minimize bacteria on the skin that could cause disease
- Recommended for repeated use

Warnings

For external use only

• Flammable

• Keep away from fire or flame

Do not use

- On children less than 2 months of age
- On open skin wounds

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, rash or redness develops and persists

Keep out of reach of children

- If swallowed, seek medical help or contact a Poison Control Center immediately

Directions

- Apply enough product to cover all areas of hands
- Rub hands together briskly until dry
- Children under 6 years of age require supervision when using this product

Other information

- Do not store above 105°F
- May cause fabric discoloration
- May harm plastics and wood finishes

Inactive Ingredients

Purified water USP, Glycerol, Hydroxyethylcellulose , Tocopheryl Acetate (Vitamin E), Benzalkonium Chloride, Tetrasodium EDTA, Citric Acid.

Package Labeling

SUMMIT SOAP
& COMPANY
OUTDOOR PURE

ANTISEPTIC GEL

HAND SANITIZER

70% ALCOHOL ANTISEPTIC
KILLS **99.9%** OF GERMS

+VITAMIN E

5 LITER (169 OZ, 1.32 GALLON)

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PRO: ----/--/--
EXP: ----/--/--

LEARN MORE AT:
SUMMITSOAP.COM

DISTRIBUTED BY
SUMMIT SOAP & COMPANY
DENVER, COLORADO

CUSTOMER SERVICE:
1.888.662.9166

QUESTIONS OR COMMENTS:
INFO@SUMMITSOAP.COM

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SUMMIT HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79190-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79190-000-01	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/30/2020	

Labeler - IMO SOURCE (PTY) LTD (557388658)

Revised: 6/2020 IMO SOURCE (PTY) LTD