

HAND SANITIZER- alcohol liquid
Solar Chemicals 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.

ACE 70% Alcohol Hand Sanitizer

Active Ingredient(s)

Ethanol 70% v/v.

Purpose

Topical Antimicrobial

Use

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.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- 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 40C (104F)

Inactive ingredients

water, glycerin, acrylate copolymer, fragrance

Package Label - Principal Display Panel

Drug Facts	Drug Facts (continued)
Active Ingredients Ethanol 70%Topical Antimicrobial	Purpose Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right way.
Use(s) • Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.
Warnings For external use only. Flammable. Keep away from fire or flame.	Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Do not use: • On children less than 2 months old • On open skin wounds	Inactive Ingredients Water, Glycerin, Acrylate Copolymer, Fragrance
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.	

Questions? 1-800-929-1321

DANGER: FLAMMABLE. EYE IRRITANT.

Manufactured for ATLANTIC CHEMICAL & EQUIPMENT CO. INC. 3471 Atlanta Industrial Pkwy – Ste 200 Atlanta, GA 30331 USA 333.50

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73831-107(NDC:78211-003)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	67.69 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.175 mL in 100 mL
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.058 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.776 mL in 100 mL
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	2.225 mL in 100 mL
WATER (UNII: 059QF0K00R)	28.076 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73831-107-01	236.59 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:73831-107-02	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

3	INDC: 73831-107-03	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Solar Chemicals Inc (030034888)

Registrant - Solar Chemicals Inc (030034888)

Establishment

Name	Address	ID/FEI	Business Operations
Solar Chemicals Inc		030034888	repack(73831-107)

Establishment

Name	Address	ID/FEI	Business Operations
INDUSTRIAL CHEMICALS INC.		113389170	manufacture(73831-107)

Revised: 6/2020

Solar Chemicals Inc