

HAND SANITIZER ISOPROPYL ALCOHOL ANTISEPTIC 70% TOPICAL GEL- isopropyl alcohol gel

Solugen Blending LLC

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.

Hand Sanitizer Isopropyl Alcohol Antiseptic 70% Topical Gel

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This is a hand sanitizer manufactured according to the part333A of the OTC monograph. The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentag formulation)

- a. Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.5% v/v).
- c. Hydroxymethyl Cellulose (1.3% v/v) .
- d. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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

glycerin, methylcellulose, purified water USP

Hand Sanitizer Isopropyl Alcohol Antiseptic 70% Topical Gel



LOT #: _____

Hand Sanitizer Liquid

Isopropyl Alcohol Antiseptic 70% Topical Gel

Hand Sanitizer
Non-sterile Solution



Drug Facts	
Active ingredient(s) Isopropyl alcohol 70% v/v	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
Do not use	
<ul style="list-style-type: none"> • 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. There 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, methylcellulose, purified water USP	

Made in USA

Before handling this material, read accompanied Safety Data Sheet for more detailed safety, health, and environmental data.

Net Weight:
DOT: UN1993, 3, III, Flammable Liquid, 0,8,3 (n-propanol, isopropanol)
Percent Active Alcohol: 70 % (v/v)

14549 Minetta St. Houston, TX 77035
PHONE: (713) 380-2134

18927000 ml NDC: 79975-004-01

HAND SANITIZER ISOPROPYL ALCOHOL ANTISEPTIC 70% TOPICAL GEL			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79975-004

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	1.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79975-004-01	18927000 mL in 1 TANK; Type 0: Not a Combination Product	08/31/2020	
2	NDC:79975-004-02	1249000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	08/31/2020	
3	NDC:79975-004-03	208198 mL in 1 DRUM; Type 0: Not a Combination Product	08/31/2020	
4	NDC:79975-004-04	18927 mL in 1 DRUM; Type 0: Not a Combination Product	08/31/2020	
5	NDC:79975-004-05	3785 mL in 1 PAIL; Type 0: Not a Combination Product	08/31/2020	
6	NDC:79975-004-09	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/31/2020	

Labeler - Solugen Blending LLC (117590261)

Establishment

Name	Address	ID/FEI	Business Operations
Solugen Blending LLC		117590261	manufacture(79975-004)

Establishment

Name	Address	ID/FEI	Business Operations
Solugen Blending LLC		117605218	manufacture(79975-004)