

SANIPURE HAND SANITIZER- isopropyl alcohol gel
SCARLETH RESEARCH 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.

Active Ingredient(s)

Isopropyl Alcohol 75% 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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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.
- 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

purified water USP, glycerin, carbomer, triethanolamine

Package Label - Principal Display Panel

120 ml NDC: 77876-3729-4




SaniPure
HAND SANITIZER
4 fl oz

SANITIZING STRENGTH
Kills 99.99%
of germs causing illness

Life100

Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% 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 • in children less than 2 months of age • on open skin wounds	
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MANUFACTURED BY
SCARLETH RESEARCH LLC
MIAMI FL 33157
MADE IN U.S.A



SaniPure
HAND SANITIZER

DISTRIBUTED BY
LIFE100 LLC
MIAMI FL 33157

240 ml NDC: 77876-3729-8



SaniPure
HAND SANITIZER
8 fl oz

SANITIZING STRENGTH
Kills 99.99%
of germs causing illness

Life100

Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% 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	
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SaniPure
HAND SANITIZER

DISTRIBUTED BY
LIFE100 LLC
MIAMI FL 33157

473 ml NDC: 77876-3729-6



Drug Facts	
Active ingredient(s) Isopropyl alcohol 75% 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. 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 <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 purified water USP, glycerin, carbomer, triethanolamine.	

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946 ml NDC: 77876-3729-2



Drug Facts	
Active ingredient(s) Isopropyl alcohol 75% 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. 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 <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 purified water USP, glycerin, carbomer, triethanolamine.	

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SANIPURE HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77876-3729
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77876-3729-4	120 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	05/20/2020	
2	NDC:77876-3729-8	240 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	05/20/2020	
3	NDC:77876-3729-6	473 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	05/20/2020	
4	NDC:77876-3729-2	946 mL in 1 BOTTLE, WTH APPLICATOR; Type 0: Not a Combination Product	05/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

Labeler - SCARLETH RESEARCH LLC (025450667)

Registrant - KHELY SANCHEZ (025450667)

Establishment

Name	Address	ID/FEI	Business Operations
SCARLETH RESEARCH LLC		025450667	manufacture(77876-3729)

Revised: 1/2022

SCARLETH RESEARCH LLC