#### 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.

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## 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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## 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)

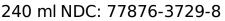
## **Inactive ingredients**

purified water USP, glycerin, carbomer, triethanolamine

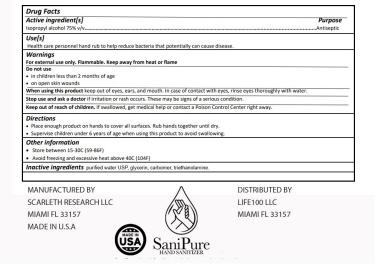
## Package Label - Principal Display Panel

120 ml NDC: 77876-3729-4









Active ingredient[s] Isopropyl alcohol 75% v/v	Purpose Antiseptic
Use[s] Health care personnel hand rub to help reduce bacteria that poten	·
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Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive ingredients purified water USP, glycerin, carbomer, triv MANUFACTURED BY	ethanolamine. DISTRIBUTED BY
Other information 5 Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Inactive ingredients purfied water USP, glycerin, carbomer, tri MANUFACTURED BY SCARLETH RESEARCH LLC	ethanolamine. DISTRIBUTED BY LIFE100 LLC

473 ml NDC: 77876-3729-6



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DISTRIBUTED BY LIFE100 LLC MIAMI FL 33157

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SANIPURE HAND SA	NITIZER				
sopropyl 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 o Strengt		Strength
ISOPROPYL ALCOHOL (UNII: ND2 UNII:ND2M416302)			ISOPROPYL ALCOHOL		75 mL in 100 mL
Inactive Ingredients					
	Ingredient Name			S	trength

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 903K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

## Packaging

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

# Labeler - SCARLETH RESEARCH LLC (025450667)

# Registrant - KHELY SANCHEZ (025450667)

## Establishment

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

Revised: 1/2022

SCARLETH RESEARCH LLC