

SANI CLEAN PLUS- isopropyl alcohol gel
First Galaxy Enterprises, 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.

Sani Clean Plus 70% IPA lemon scented acrylates AMAZON

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.

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

- 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, lemon fragrance, PEG-6 AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, purified water USP

Package Label - Principal Display Panel

Drug Facts	
Active Ingredient	Purpose
Isopropyl alcohol 70% v/v	Antiseptic
Uses Hand sanitizer to help reduce bacteria that potentially can cause disease.	
Warnings	
For external use only. Not intended for ingestion. Flammable. Keep away from fire or flame.	
Do not use	
<ul style="list-style-type: none"> on open skin wounds in children less than 2 months of age 	
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 and rub together until dry supervise children under 6 years of age when using 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, lemon fragrance, PEG-6 AMP-acrylates/vinyl isodecanoate crosspolymer, purified water USP	
Questions? 1-800-888-3216 (Monday to Friday 9AM to 5PM)	
LENSEP DISTRIBUTED BY: First Galaxy Enterprises Inc.	

SANI CLEAN PLUS

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90082-382
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
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	

LEMON (UNII: 24RS0A988O)

GLYCERIN (UNII: PDC6A3C00X)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90082-382-08	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/10/2020	
2	NDC:90082-382-16	437 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/10/2020	

Labeler - First Galaxy Enterprises, Inc. (114966288)

Establishment

Name	Address	ID/FEI	Business Operations
HPPE LLC		078769356	manufacture(90082-382)

Revised: 10/2021

First Galaxy Enterprises, Inc.