## SANI CLEAN PLUS- isopropyl alcohol gel HPPC 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.

-----

## Sani Clean Plus AMAZON lemon scent

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

## 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.

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.

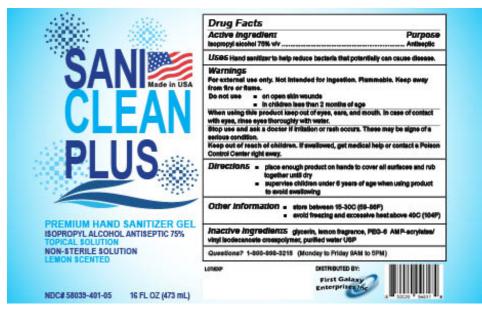
#### Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

#### **Inactive ingredients**

glycerin, purified water USP

#### Sani Clean Plus AMAZON lemon



Route of Administration TOPI	IAN OTC DRUG ICAL	Item Code (Sourc	e) NI	DC:58039-	-401					
Product Type HUM.   Route of Administration TOPI		Item Code (Sourc	e) NI	DC:58039-	-401					
Product Type HUM		Item Code (Sourc	e) Ni	DC:58039-	-401					
Route of Administration TOPI		Item Code (Sourc	e) NI	DC:58039-	-401					
	ICAL									
Active Ingredient/Active Moiety										
Active Ingredient/Active Moiety										
Active Ingredient/Active Moiety										
0										
Ingredie	Basis of Stren	igth S	Strength							
ISOPROPYL ALCOHOL (UNII: ND2M416302 UNII:ND2M416302)		ISOPROPYL ALCOHOL	75 n in 1	nL 100 mL						

**Inactive Ingredients** 

Ingredient Name								
LEMON (UNII: 24RS0A988O)								
	ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)							
G	GLYCERIN (UNII: PDC6A3C0OX)     1.45 mL       in 100 mL							
W	WATER (UNII: 059QF0KO0R)							
Packaging								
#	Item Code		Package DescriptionMarketing StartMarketing StartDate		larketing End Date			
1	NDC:58039-401- 04	236 i Prod	nL in 1 BOTTLE, PUMP; Type 0: Not a Combination uct	0 1/14/20 21				
2	NDC:58039-401- 05	473 r Prod	nL in 1 BOTTLE, PUMP; Type 0: Not a Combination uct	01/14/2021				
Marketing Information								
	Marketing Catego	ory	Application Number or Monograph Citation	Marketing Start Date	Marl	keting End Date		
0	TC monograph not f	final	part333A	01/14/2021				

# Labeler - HPPC LLC (078769356)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
HPPE LLC		078769356	manufacture(58039-401)		

Revised: 2/2021

HPPC LLC