# SANICLEAN PLUS ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION GEL, CITRUS FLORAL SCENTED (HP2489)- alcohol gel HPPE 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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HP2489 70% ethanol citrus floral

NDC code: 58039-307-01

#### **Active Ingredient(s)**

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**

citrus floral fragrance, glycerin, hydrogen peroxide, hypromellose, purified water USP

### Package Label - Principal Display Panel

1000000 mL NDC: 58039-307-01



### SaniClean Plus Alcohol Antiseptic 70% Topical Solution Gel Citrus Floral Scented (HP2489)

Hand Sanitizer Non-sterile Solution

1000 Liters (265 gallons)

Caution: for manufacturing, processing, or repacking

NDC: 58039-307-01

#### DRUG FACTS LABEL

#### Drug Facts

Active ingredient[s] Alcohol 70%v/v ..... Purpose Antisantic

#### Use[s]

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Inactive ingredients citrus floral fragrance, glycerin, hydrogen peroxide, hypromellose, purified water USP

236 mL NDC: 58039-307-04



473 mL NDC: 58039-307-05



Drug Facts
Active ingredientsPurpose
Alcohol 70% v/vAntiseptic
Nses
Hand Sanitizer Gel topical solution hand rub to help reduce bacteria that potentially can cause disease.
Warnings
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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 wa
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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.
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Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
Inactive ingredients citrus floral fragrance, glycerol, hydrogen peroxide, hypromellose, purified water USP
Manufacturer:
8 50202 94664

## SANICLEAN PLUS ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION GEL, CITRUS FLORAL SCENTED (HP2489)

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58039-307	
Route of Administration	TOPICAL			

I	Active Ingredient/Active Moiety			
I	Ingredient Name	Basis of Strength	Strength	
I	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6 A3C0 OX)			
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)			
WATER (UNII: 059QF0KO0R)			
METHYL DIHYDRO JASMO NATE (SYNTHETIC) (UNII: 3GW44CIE3Y)			

## HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) DIHYDROMYRCENOL (UNII: 46L1B02ND9)

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58039-307- 01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/06/2020		
2	NDC:58039-307- 02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020		
3	NDC:58039-307- 03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020		
4	NDC:58039-307- 04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020		
5	NDC:58039-307- 05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020		
6	NDC:58039-307- 06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/06/2020	

## **Labeler - HPPE LLC (078769356)**

Establishment				
Name	Address	ID/FEI	Business Operations	
HPPE LLC		078769356	manufacture(58039-307)	

Revised: 7/2020 HPPE LLC