

**SANICLEAN ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION GEL, LEMON SCENTED (HP2513)- ethanol 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.*

-----  
**HP2513 Lemon 70% ethanol**  
**NDC: 58069-322-01**

**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.

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, hydrogen peroxide, lemon fragrance, PEG-6 AMP-acrylates/vinyl isodecanoate crosspolymer, purified water USP

**Package Label - Principal Display Panel**

1000000 ml NDC: 58039-322-01



**SaniClean**  
**Alcohol Antiseptic 70%**  
**Topical Solution Gel**  
**Lemon Scented (HP2513)**

**Hand Sanitizer**  
**Non-sterile Solution**

**1000 Liters (265 gallons)**

**Caution: for manufacturing, processing, or repacking**  
**NDC: 58039-322-01**

**DRUG FACTS LABEL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70%v/v	Antiseptic
<b>Use[s]</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> </ul>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Store between 15-30C (59-86F)</li> <li>Avoid freezing and excessive heat above 40C (104F)</li> </ul>	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, lemon fragrance, PEG-6 AMP-acrylates/vinyl isodecanoate crosspolymer, purified water USP	

## SCENTED (HP2513)

ethanol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58039-322
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-322-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	08/06/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/06/2020	

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

### Establishment

Name	Address	ID/FEI	Business Operations
HPPE LLC		078769356	manufacture(58039-322)

Revised: 8/2020

HPPE, LLC