

**SANICLEAN PLUS ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION GEL, LEMON SCENTED (HP2491)- 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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**HP2491 Lemon 70% ethanol**  
**NDC: 58069-308-01**

**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, hypromellose, lemon fragrance, purified water USP

**Package Label - Principal Display Panel**

1000000 mL NDC: 58039-308-01



**SaniClean Plus**  
**Alcohol Antiseptic 70%**  
**Topical Solution Gel**  
**Lemon Scented (HP2491)**

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

**1000 Liters (265 gallons)**

**Caution: for manufacturing, processing, or repacking**  
**NDC: 58039-308-01**

**DRUG FACTS LABEL**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 70%v/v	<b>Purpose</b> 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>	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> 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, hypromellose, lemon fragrance, purified water USP	

# SANI CLEAN PLUS



**PREMIUM HAND SANITIZER GEL**  
**ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION**  
**LEMON SCENT**  
**NDC# 58039-308-04**      **8 FL OZ/ 236 mL**

<b>Drug Facts</b>
<b>Active ingredients</b> ..... <b>Purpose</b> Alcohol 70% v/v.....Antiseptic
<b>Uses</b> Hand Sanitizer Gel topical solution hand rub used to help reduce bacteria that potentially can cause disease.
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>
<b>Do not use</b> - in children less than 2 months of age - on open skin wounds
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> - 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.
<b>Other information</b> - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)
<b>Inactive ingredients</b> glycerol, hydrogen peroxide, hypromellose, lemon fragrance, purified water USP



**Manufacturer:**  
**HPPE** 6906 Dixie St.,  
 Columbus, GA 31907



**Distributed by:**  
**First Galaxy Enterprises Inc**  
**Contact:**  
**1-800-998-3215**

473 mL NDC: 58039-308-05

# SANICLEAN PLUS



Made in USA



**PREMIUM HAND SANITIZER GEL**  
**ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION**  
**LEMON SCENT**  
**NDC# 58039-308-05      16 FL OZ/ 473 mL**

<b>Drug Facts</b>
<b>Active Ingredients</b> ..... <b>Purpose</b> Alcohol 70% v/v.....Antiseptic
<b>Uses</b> Hand Sanitizer Gel topical solution hand rub used to help reduce bacteria that potentially can cause disease.
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b>
<b>Do not use</b> - in children less than 2 months of age - on open skin wounds
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> - 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.
<b>Other information</b> - Store between 15-30C (59-86F) - Avoid freezing and excessive heat above 40C (104F)
<b>Inactive ingredients</b> glycerol, hydrogen peroxide, hypromellose, lemon fragrance, purified water USP

**Manufacturer:**  
**HPPE** HIGH PERFORMANCE PRODUCT CORPORATION  
 6906 Dixie St.,  
 Columbus, GA 31907

**Distributed by:**  
**First Galaxy Enterprises Inc**

**Contact:**  
 1-800-998-3215



**SANICLEAN PLUS ALCOHOL ANTISEPTIC 70% TOPICAL SOLUTION GEL, LEMON SCENTED (HP2491)**

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58039-308
<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)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
LEMON (UNII: 24RS0A988O)	

**HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)**

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-308-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/06/2020	
2	NDC:58039-308-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020	
3	NDC:58039-308-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020	
4	NDC:58039-308-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020	
5	NDC:58039-308-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/06/2020	
6	NDC:58039-308-06	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(58039-308)

Revised: 7/2020

HPPE, LLC