

**SANICLEAN ISOPROPYL ALCOHOL 75% TOPICAL SOLUTION GEL, UNSCENTED  
(HP2468)- isopropyl 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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**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.

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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.
- 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, purified water USP

# Package Label - Principal Display Panel

1000000 ml NDC: 58039-201-01



**SaniClean**  
**Isopropyl Alcohol Antiseptic 75%**  
**Topical Solution Gel**  
**Unscented (HP2468)**

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

**1000 Liters (265 gallons)**

**Caution: for manufacturing, processing, or repacking**  
**NDC: 58039-201-01**

## DRUG FACTS LABEL

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Isopropyl Alcohol 75% 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 <b>Do not use</b> <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, purified water USP	

# SANICLEAN ISOPROPYL ALCOHOL 75% TOPICAL SOLUTION GEL, UNSCENTED (HP2468)

isopropyl alcohol gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58039-201
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58039-201-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/26/2020	
2	NDC:58039-201-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
3	NDC:58039-201-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
4	NDC:58039-201-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
5	NDC:58039-201-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
6	NDC:58039-201-06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	06/26/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
HPPE, LLC		078769356	manufacture(58039-201)

Revised: 7/2020

HPPE, LLC