

**SANICLEAN ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION GEL,
UNSCENTED (HP2473)- 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.

HP2473 75% IPA Unscented Gel

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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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: 58039-203-01



**SaniClean
Isopropyl Alcohol Antiseptic 75%
Topical Solution Gel
Unscented (HP2473)**

**Hand Sanitizer
Non-sterile Solution**

1000 Liters (265 gallons)

**Caution: for manufacturing, processing, or repacking
NDC: 58039-203-01**

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s] Isopropyl Alcohol 75% v/v	Purpose Antiseptic
Use[s] 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 <ul style="list-style-type: none"> 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.	
Directions <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, hypromellose, purified water USP	

GEL, UNSCENTED (HP2473)

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58039-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-203-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	07/09/2020	
2	NDC:58039-203-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
3	NDC:58039-203-03	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
4	NDC:58039-203-04	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
5	NDC:58039-203-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	
6	NDC:58039-203-06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/09/2020	

Labeler - HPPE, LLC (078769356)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 7/2020

HPPE, LLC