

**SANICLEAN ALCOHOL ANTISEPTIC 77% TOPICAL SOLUTION GEL, UNSCENTED
(HP2464)- 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.

**HP2454 77% Ethanol, Unscented
NDC: 58039-116**

Active Ingredient(s)

Alcohol 77% 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, methylcellulose, purified water USP

Package Label - Principal Display Panel

1000000 mL NDC: 58039-116-01



**SaniClean
Alcohol Antiseptic 77%
Topical Solution Gel
Unscented (HP2464)**

**Antiseptic Hand Rub
Non-Sterile Solution**

1000L (265 gallons)

**Caution: for manufacturing, processing, or repacking
NDC: 58039-116-01**

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 77%v/v	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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, methylcellulose, purified water USP	

UNSCENTED (HP2464)

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58039-116
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	77 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)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-116-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/23/2020	

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

Name	Address	ID/FEI	Business Operations
HPPE LLC		078769356	manufacture(58039-116)

Revised: 4/2020

HPPE LLC