# SANICLEAN HP ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION GEL UNSCENTED (HP2502)- 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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#### SaniClean HP 75% IPA (HP2502)

#### **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, PEG-6 AMP-acrylates/vinyl isodecanoate crosspolymer, purified water USP

#### Package Label - Principal Display Panel

1000 L NDC: 58039-216-01

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isopropyl alcohol gel

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:58039-216

Route of Administration TOPICAL

## **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	750 L in 1000 L

#### **Inactive Ingredients**

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	Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)		14.5 L in 1000 L
WATER (UNII: 059QF0KO0R)		

ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPA.S NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-216-01	1000 L in 1 CONTAINER: Type 0: Not a Combination Product	08/13/2020	

# **Marketing Information**

	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part333A	08/13/2020	

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

# Registrant - HPPE LLC (078769356)

Establishment			
Name	Address	ID/FEI	Business Operations
HPPE LLC		078769356	manufacture(58039-216)

Revised: 8/2020 HPPE LLC