SANICLEAN ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION GEL, UNSCENTED (HP2463)- 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.

Active Ingredient(s)

Alcohol 80% 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: 58039-102-01

SaniClean
Alcohol Antiseptic 80%
Topical Solution Gel
Unscented (HP2463)

Antiseptic Hand Rub
Non-Sterile Solution

1000L (265 gallons)

Caution: for manufacturing, processing, or repacking
NDC: 58039-102-01

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s]	***Purpose***
Alcohol 80% v/v	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings	
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Do not use	
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• on open skin wounds	
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Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
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alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58039-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 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)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58039-102-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	04/22/2020	
2	NDC:58039-102-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
3	NDC:58039-102-03	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
4	NDC:58039-102-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
5	NDC:58039-102-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	
6	NDC:58039-102-06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/22/2020	

Labeler - HPPE LLC (078769356)

Establishment

Name	Address	ID/FEI	Business Operations
HPPE, LLC		078769356	manufacture(58039-102)