

SANICLEAN ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION GEL, LEMON SCENTED (HP2472)- 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, hypromellose, lemon fragrance, purified water USP

Package Label - Principal Display Panel

1000000 mL NDC: 58039-111-01



SaniClean
Alcohol Antiseptic 80%
Topical Solution Gel
Lemon Scented (HP2472)

Hand Sanitizer
Non-sterile Solution

1000 Liters (265 gallons)

Caution: for manufacturing, processing, or repacking
NDC: 58039-111-01

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s] Alcohol 80%v/v	PurposeAntiseptic
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, lemon fragrance, purified water USP	

SANICLEAN ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION GEL, LEMON SCENTED (HP2472)

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58039-111
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: 059QF0K00R)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LEMON (UNII: 24RS0A988O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-111-01	1000000 mL in 1 CONTAINER; Type 0: Not a Combination Product	06/26/2020	
2	NDC:58039-111-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
3	NDC:58039-111-03	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
4	NDC:58039-111-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
5	NDC:58039-111-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
6	NDC:58039-111-06	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

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

Labeler - HPPE, LLC (078769356)

Establishment			
Name	Address	ID/FEI	Business Operations
HPPE, LLC		078769356	manufacture(58039-111)

Revised: 7/2020

HPPE, LLC