HAND SANITIZER- 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.

HP2469 Lemon Product 58039-105

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, lemon fragrance, methylcellulose, purified water USP

Package Label - Principal Display Panel

1000 L NDC: 58039-105-01



SaniClean Alcohol Antiseptic 80% Topical Solution Gel Lemon Scented (HP2469)

Hand Sanitizer Non-sterile Solution

1000 Liters (265 gallons)

Caution: for manufacturing, processing, or repacking NDC: 58039-105-01

DRUG FACTS LABEL

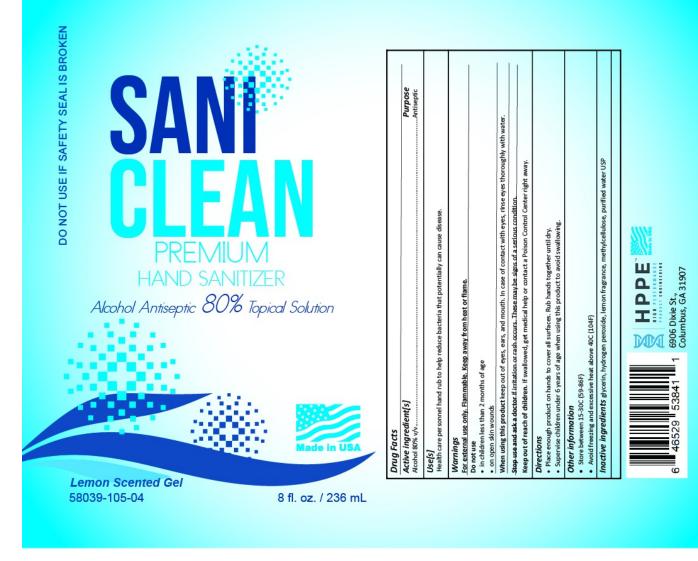
| Antisept Use [5] Iand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Warnings for external use only. Flammable. Keep away from heat or flame No not use in children less than 2 months of age on open skin wounds When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. Itop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Geep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 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. Dther information Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) | Drug Facts | |
|--|---|----------------------------|
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| | Inactive ingredients glycerin, hydrogen peroxide, lemon fragrance, methylcellulose, purifier | d water LICD |



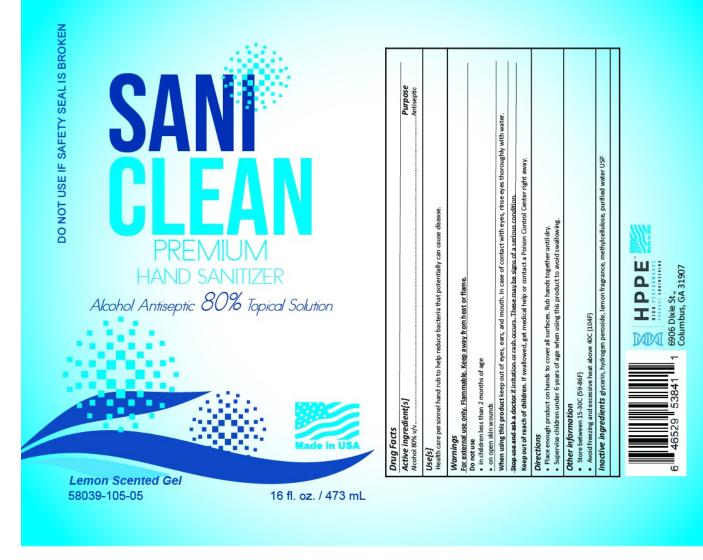
0.118 L NDC: 58039-105-03



0.236 L NDC: 58039-105-04



0.473 L NDC: 58039-105-05



3.78 L NDC: 58039-105-06





| HAND SANITIZER | | | | | |
|--|-----------------|-----------|------------------|------------------|--|
| alcohol gel | | | | | |
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| Product Information | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code | (Source) | NDC:58039-105 | |
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| | | | | | |
| Active Ingredient/Active | Moiety | | | | |
| Ingredient Name | | | Basis of Strengt | th Strength | |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | | | ALCOHOL | 800 L in 1000 I | |
| | | | | | |
| | | | | | |
| Inactive Ingredients | | | | | |
| | Ingredient Name | | | Strength | |
| METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H) | | | 11 L in 1000 L | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | 14.5 | 14.5 L in 1000 L | |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | | | 1.25 | 1.25 L in 1000 L | |

| WATER (UNII: 059QF0KO0R) | 179.3 L in 1000 L |
|--------------------------|-------------------|
| LEMON (UNII: 24RS0A988O) | 5 L in 1000 L |
| | |

| Packaging | | | | | |
|-----------------------|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | NDC:58039-105- 01 | 1000 L in 1 NOT APPLICABLE; Type 0: Not a Combination Product | 06/17/2020 | | |
| 2 | NDC:58039-105- 02 | 0.059 L in 1 BOTTLE; Type 0: Not a Combination Product | 06/17/2020 | | |
| 3 | NDC:58039-105- 03 | 0.118 L in 1 BOTTLE; Type 0: Not a Combination Product | 06/17/2020 | | |
| 4 | NDC:58039-105- 04 | 0.236 L in 1 BOTTLE; Type 0: Not a Combination Product | 06/17/2020 | | |
| 5 | NDC:58039-105- 05 | 0.473 L in 1 BOTTLE; Type 0: Not a Combination Product | 06/17/2020 | | |
| 6 | NDC:58039-105- 06 | 3.78 L in 1 BOTTLE; Type 0: Not a Combination Product | 06/17/2020 | | |
| | | | | | |
| Marketing Information | | | | | |
| Marketing Category | | ory Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| 0' | ГС monograph not : | final part333A | 06/17/2020 | | |

Labeler - HPPE, LLC (078769356)

Establishment

| Name | Address | ID/FEI | Business Operations | |
|----------|---------|-----------|----------------------------|--|
| HPPE LLC | | 078769356 | manufacture(58039-105) | |

Revised: 7/2020

HPPE, LLC