

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.

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

- 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

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

DO NOT USE IF SAFETY SEAL IS BROKEN

SANI CLEAN

PREMIUM
HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution

Lemon Scented Gel
58039-105-02

2 fl. oz./ 59 mL



Drug Facts	Purpose
Active ingredient(s) Alcohol 80% 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, lemon fragrance, methylcellulose, purified water USP	



6906 Dixie St.,
Columbus, GA 31907

0.118 L NDC: 58039-105-03

DO NOT USE IF SAFETY SEAL IS BROKEN

SANI CLEAN

PREMIUM
HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution

Lemon Scented Gel
58039-105-03

4 fl. oz. / 118 mL



Drug Facts	Purpose
Active ingredient(s) Alcohol 80% w/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, lemon fragrance, methylcellulose, purified water USP	



6906 Dixie St.,
Columbus, GA 31907

0.236 L NDC: 58039-105-04

DO NOT USE IF SAFETY SEAL IS BROKEN

SANI CLEAN

PREMIUM
HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution

Lemon Scented Gel
58039-105-04

8 fl. oz. / 236 mL



Drug Facts	Purpose
Active ingredient(s) Alcohol 80% 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, lemon fragrance, methylcellulose, purified water USP	



6906 Dixie St.,
Columbus, GA 31907

0.473 L NDC: 58039-105-05

DO NOT USE IF SAFETY SEAL IS BROKEN

SANI CLEAN

PREMIUM
HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution

Lemon Scented Gel
58039-105-05

16 fl. oz. / 473 mL



Drug Facts	Purpose
Active ingredient(s) Alcohol 80% w/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 • 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. There 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 • 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	



6906 Dixie St.,
Columbus, GA 31907

3.78 L NDC: 58039-105-06

DO NOT USE IF SAFETY SEAL IS BROKEN

SANI CLEAN

PREMIUM
HAND SANITIZER

Alcohol Antiseptic 80% Topical Solution

Lemon Scented Gel
58039-105-06

1 gal. / 3780 mL



Drug Facts	Purpose
Active ingredient(s) Alcohol 80% w/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, lemon fragrance, methylcellulose, purified water USP	

HPPE
HIGH PERFORMANCE
PRODUCT ENGINEERING

6906 Dixie St.,
Columbus, GA 31907

HAND SANITIZER

alcohol gel

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 Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	800 L in 1000 L

Inactive Ingredients

Ingredient Name	Strength
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	11 L in 1000 L
GLYCERIN (UNII: PDC6A3C0OX)	14.5 L in 1000 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	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
1	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	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC 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