

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.

Hand Sanitizer (HP2513) Proforma

Active Ingredient(s)

Alcohol 70% 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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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, PEG-6 AMP-acrylates/vinyl isodecanoate

crosspolymer, purified water USP

Package Label - Principal Display Panel

3785.4 mL NDC: 58039-325-06

NOT FOR RETAIL SALE



Hand Sanitizer

Hand Sanitizer Gel

Alcohol Antiseptic 70% Topical Solution

1 GAL / 128 FL OZ / 3785.4 ML

NOT FOR RETAIL SALE

Drug Facts	
Active Ingredient Alcohol 70% 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">on children less than 2 months of ageon 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 at 1-800-222-1222.	
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 15-30°C (59-86°F)Avoid freezing and excessive heat above 40°C (104°F)	
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Manufactured By: HPPE LLC
6906 Dixie St.
Columbus, GA31907
Questions or Comments?
706-563-9290

Expiration Date:
09/2022
Lot #:
HP2513-002.20
NDC #:
58039-325-06

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58039-325
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACRYLATES/VINYL ISODECANOATE CROSSPOLYMER (10000 MPAS NEUTRALIZED AT 0.5%) (UNII: 2N8MDB79NA)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
LEMON (UNII: 24RS0A988O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-325-06	3785.4 mL in 1 JUG; Type 0: Not a Combination Product	09/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/30/2020	

Labeler - HPPE LLC (078769356)

Establishment

Name	Address	ID/FEI	Business Operations
HPPE LLC		078769356	manufacture(58039-325)

Revised: 9/2020

HPPE LLC