

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.

ACTIVE INGREDIENT

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.

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

hydroxyethylcellulose, isopropyl myristate, propylene glycol, water

PACKAGE LABEL - PRINCIPAL DISPLAY PANEL

237 mL NDC: 58039-119-03



PTI Group, Inc.
Chesterfield, MD 63005
www.ptigroupinc.com
Phone: 636-240-4741





HAND SANITIZER GEL

Soothing Gel With Aloe

MADE IN USA

8.0 fl. oz. (237 mL)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antiseptic

Use • Hand Sanitizer to help reduce bacteria on hands.

Warnings
Flammable. Keep away from fire or flame.
For external use only.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask a doctor if irritation or redness develops and lasts.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions
■ place enough product in your palm to thoroughly cover hands and rub hands together until dry.
■ children under 6 years should be supervised when using this product

Inactive ingredients hydroxyethyl cellulose, Isopropyl myristate, Propylene glycol, Water.

Other information
■ store at temperature below 105°
■ may discolor certain fabrics

Questions or comments? 1-636-240-4741



8 49207 00545 2

355 mL NDC: 58039-119-04



HAND SANITIZER GEL

Soothing Gel With Aloe

MADE IN USA

12.0 fl. oz. (355 mL)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antiseptic

Use • Hand Sanitizer to help reduce bacteria on hands.

Warnings
Flammable. Keep away from fire or flame.
For external use only.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask a doctor if irritation or redness develops and lasts.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions
■ place enough product in your palm to thoroughly cover hands and rub hands together until dry.
■ children under 6 years should be supervised when using this product

Inactive ingredients Hydroxyethyl cellulose, Isopropyl myristate, Propylene glycol, Water.

Other information
■ store at temperature below 105°
■ may discolor certain fabrics

Questions or comments? 1-636-240-4741




PTI Group, Inc.
Chesterfield, MD 63005
www.ptigroupinc.com
Phone: 636-240-4741



8 49207 00547 6

473 mL NDC: 58039-119-05



HAND SANITIZER GEL

Soothing Gel With Aloe

MADE IN USA

16.0 fl. oz. (473 mL)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70%.....	Antiseptic

Use • Hand Sanitizer to help reduce bacteria on hands.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or redness develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

■ place enough product in your palm to thoroughly cover hands and rub hands together until dry.

■ children under 6 years should be supervised when using this product

Inactive ingredients Hydroxyethyl cellulose, Isopropyl myristate, Propylene glycol, Water.

Other information

■ store at temperature below 105°

■ may discolor certain fabrics

Questions or comments? 1-636-240-4741



pti group, inc.
product through innovation

PTI Group, Inc.
Chesterfield, MO 63005
www.ptigroupinc.com
Phone: 636-240-4741



3.8 L NDC: 58039-119-06



HAND SANITIZER GEL

Soothing Gel With Aloe

MADE IN USA

1 gallon (3.8 L)

Drug Facts

Active Ingredient

Ethyl Alcohol 70%..... Antiseptic

Purpose

Use • Hand Sanitizer to help reduce bacteria on hands.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if irritation or redness develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

■ place enough product in your palm to thoroughly cover hands and rub hands together until dry.

■ children under 6 years should be supervised when using this product

Inactive ingredients Hydroxyethyl cellulose, Isopropyl myristate, Propylene glycol, Water.

Other information

■ store at temperature below 105°

■ may discolor certain fabrics

Questions or comments? 1-844-788-6621



PTI Group, Inc.
Chesterfield, MO 63005
www.ptigroupinc.com
Phone: 636-240-4741



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58039-119
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58039-119-03	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
2	NDC:58039-119-04	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
3	NDC:58039-119-05	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
4	NDC:58039-119-06	3800 mL in 1 JUG; Type 0: Not a Combination Product	06/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/16/2020	

Labeler - HPPE, LLC (078769356)

Establishment

Name	Address	ID/FEI	Business Operations
HPPE, LLC		078769356	manufacture(58039-119)

Revised: 6/2020

HPPE, LLC