

**HAND SANITIZER- isopropyl alcohol gel**  
**SANITIZER PPE PRODUCTS GROUP INC.**

*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.*

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**Hand Sanitizer 70% IP 125 ml**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

**Active Ingredient(s)**

Isopropyl 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

glycerin, hydrogen peroxide, purified water USP, Trolamine, Polyacrylic Acid

### Package Label - Principal Display Panel

<b>Drug Facts</b>	
<b>Active Ingredient(s)</b> ..... Purpose Isopropyl Alcohol 70% <i>v/v</i> ..... Antiseptic	
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> 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	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep Out of reach of children</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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	
<b>Other Information</b> • Store between 15-30°C (59-89°F) • Avoid freezing and excessive heat above 43°C (110°F)	
<b>Inactive Ingredients:</b> Carbomer, Glycerin, Hydrogen Peroxide, Purified Water USP, Triethanolamine	

**Essential 70  
HAND SANITIZER GEL**

**Kills 99.99% of germs**  
Fragrance Free / Dye Free

Made In Canada by  
**Sanitizer PPE Products Group Inc**  
Vaughan, Ontario L4K 4L8

NPN#80102100LOT#105EXP:08/2023

4.23 fl oz - 125 mL

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125 ml NDC: 79597-005-01

## HAND SANITIZER

isopropyl alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79597-005
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	87.5 mL in 125 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.8125 mL in 125 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.156 mL in 125 mL
WATER (UNII: 059QF0KO0R)	34.3 mL in 125 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.625 mL in 125 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.625 mL in 125 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79597-005-01	125 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/14/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/14/2020	

**Labeler** - SANITIZER PPE PRODUCTS GROUP INC. (204147896)

**Registrant** - SANITIZER PPE PRODUCTS GROUP INC. (204147896)

### Establishment

Name	Address	ID/FEI	Business Operations
SANITIZER PPE PRODUCTS GROUP INC.		204147896	manufacture(79597-005)

Revised: 12/2020

SANITIZER PPE PRODUCTS GROUP INC.