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

Hand Sanitizer 70% IP 250 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.

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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, purified water USP, Trolamine, Polyacrylic Acid

Package Label - Principal Display Panel

250 ml NDC: 79597-001-01

HAND SANITIZER
isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79597-001

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	175 mL in 250 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3.625 mL in 250 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.3125 mL in 250 mL
WATER (UNII: 059QF0KO0R)	68.6 mL in 250 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	1.25 mL in 250 mL
TROLAMINE (UNII: 9O3K93S3TK)	1.25 mL in 250 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79597-001-01	250 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(79597-001)

Revised: 12/2020

SANITIZER PPE PRODUCTS GROUP INC.