

HAND SANITIZER- isopropyl alcohol liquid
Rapid Cure Technologies, 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.

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 75% 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

Package Label - Principal Display Panel

WHO-recommended formulation

HAND SANITIZER

Kills Harmful Bacteria and Germs

Non-sterile Solution

Isopropyl Alcohol Antiseptic 75%

Topical Solution



Made in
the USA

MANUFACTURED & DISTRIBUTED BY:

RAPID CURE TECHNOLOGIES, INC.

7030 FLY RD, EAST SYRACUSE, NY 13057

(888) 847-3610 / WWW.RAPIDCURETECHNOLOGIES.COM

RCT 01 1272 HS



Drug Facts

Active Ingredient: Alcohol 75% by volume

Purpose: Antiseptic

Use(s): Hand sanitizer to help reduce bacteria that potentially can cause disease.

Warnings:

- For external use only.
- Do not use on children less than 2 months of age.
- Do not use on open skin wounds.
- Flammable. Keep away from source of heat, fire, or flame.
- When using this product keep out of eyes, ears, and mouth. If contact occurs, rinse thoroughly with water.
- Stop use and ask a doctor if irritation or redness develops and lasts. These may be signs of a serious condition.
- If swallowed, get medical help or contact a Poison Control Center immediately.

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.
- Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)

Inactive Ingredients: glycerin, hydrogen peroxide, purified water

1.0 gallons (3.785 liters)

3785 ml NDC: 75722-002-01

HAND SANITIZER

isopropyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75722-002

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75722-002-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Rapid Cure Technologies, Inc. (017489374)

Establishment

Name	Address	ID/FEI	Business Operations
Rapid Cure Technologies, Inc.		017489374	manufacture(75722-002)

Revised: 4/2020

Rapid Cure Technologies, Inc.