

**COVISIDE HAND SANITIZER- isopropyl alcohol solution
CREAGEN 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.

Product is made available to consumers in plastic bottles labelled as COVISIDE Hand Sanitizer

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.

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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

Package Label - Principal Display Panel

The image shows the principal display panel of a Coviside hand sanitizer package. The background is blue. On the left, there is a white cross graphic with a teal and white pattern. Text on the left includes: WHO Recommended Handrub Formulation, Use (Apply a palm full of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry.), Active Ingredient (Isopropyl Alcohol 75% (v/v)), Other Ingredients (Glycerol, Purified Water, Hydrogen Peroxide 0.125% (v/v)), Warning (Flammable: Keep away from flame and heat. For external use only. Do not swallow. Avoid contact with eyes. Keep out of reach of children.), Other Information (Store below 110F (43C)), Manufactured by (CreaGen Inc., Woburn, MA 01801, www.creageninc.com, www.coviside.com), Made in USA (with US flag icon, April 2020 4102020). In the center, the word 'Coviside' is written in large white font, with 'Hand Sanitizer & Advanced Disinfectant' below it. On the right, 'OUR MISSION' is written in white, followed by a paragraph: 'Coviside is manufactured by a group of Medicinal chemists who feel the responsibility to help fight the Covid-19 pandemic. Our chemists are currently developing antiviral & anti-bacterial drug products to combat this virus and others. Coviside is our way of making an immediate impact to consumers and federal agencies beyond our R&D efforts.'

189271 ml NDC: 76737-001-01

COVISIDE HAND SANITIZER

isopropyl alcohol solution

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76737-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	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:76737-001-01	189271 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 - CREAGEN INC. (791218881)

Registrant - Raj Rajur (791218881)

Establishment

Name	Address	ID/FEI	Business Operations
CREAGEN INC.		791218881	manufacture(76737-001)

Revised: 4/2020

CREAGEN INC.