

2 IN 1 HAND SANITIZER/DISINFECTANT- isopropyl alcohol liquid

Rocky Research

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.

2 in1 Hand Sanitizer/Disinfectant

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

- a. Isopropyl Alcohol (70%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.5% v/v).
- c. Hydrogen peroxide (0.126% v/v).
- d. Distilled water.
- e. Aloe.
- f. Essential oil.

Active Ingredient(s)

Isopropyl Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer & Surface Disinfectant

Use

Hand Sanitize and surface disinfectant 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

- Hands: Spray product in your palm. Rub hands together until dry.
- Surface: Spray product 6-8 inches from surface until thoroughly wet. Wait about 10 seconds then wipe dry. Do not air 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)
- May cause surface paint or fabric discoloration

Inactive ingredients

glycerin, hydrogen peroxide, distilled water, aloe, essential oil

Package Label - Principal Display Panel

2 IN 1
TOPICAL & DISINFECTANT
SOLUTION



NON-STERILE
32 oz [946 mL]

NDC: 77509-070-02

77509-070-02

946 ml NDC:

2 IN 1 HAND SANITIZER/DISINFECTANT

isopropyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77509-070

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	1.5 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.126 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77509-070-02	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/25/2020	

Labeler - Rocky Research (152672127)

Registrant - Rocky Research (152672127)

Establishment

Name	Address	ID/FEI	Business Operations
Rocky Research		152672127	manufacture(77509-070)

Revised: 5/2020

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