2 IN 1 HAND SANITIZER/DISINFECTANT- is opropyl 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 in 1 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 disinfectantr 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.

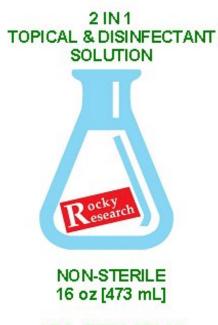
Other information

- 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



NDC: 77509-070-01

473 ml NDC:

77509-070-01

| 2 IN 1 HAND SANITIZER/DISINFECTANT | | | | | |
|------------------------------------|----------------|--------------------|---------------|--|--|
| isopropyl alcohol liquid | | | | | |
| | | | | | |
| Product Information | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77509-070 | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|----------------------|--------------------|
| | 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 | | |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.126 mL in 100 mL | | |
| WATER (UNII: 059QF0KO0R) | | | |

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|---|---|----------------------|--|-------------------------|-----------------------|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| | 1 | NDC:77509-070- 01 | 473 mL in 1 BOTTLE, SPRAY; 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 Rocky Research