PROOF BREWING CO. HAND SANITIZER- alcohol liquid Proof Brewing Company

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.

Hand sanitizer

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

Alcohol 80% 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.

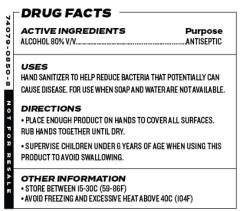
Other information

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

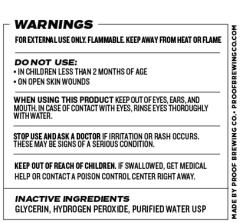
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

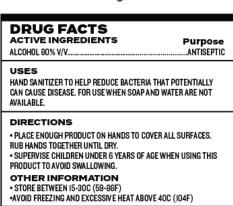
Package Label - Principal Display Panel











INACTIVE INGREDIENTS

GLYCERIN, HYDROGEN PEROXIDE, PURIFIED WATER USP

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.

WARNINGS

RIGHT AWAY.

NOT FOR RESALE

KEEP OUT OF REACH OF CHILDREN, IF SWALLOWED, GET

MEDICAL HELP OR CONTACT A POISON CONTROL CENTER

OFBREWINGCO.COM LLAHASSE



.COHOLANTISEPTIC 80% TOPICAL SOLUTION

NON-STERILE SOLUTION

■ 12oz. /355ml ■ 4079-0850-4

COHOL ANTISEPTIC 80% TOPICAL SOLUTION

NON-STERILE SOLUTION

∎ 16oz. /473mi ı 74079-0850-5



COHOL ANTISEPTIC 80% TOPICAL SOLUTION

NON-STERILE SOLUTION -

∎32oz. /946mi∎ 74079-0850-6



.COHOL ANTISEPTIC 80% TOPICAL SOLUTION

NON-STERILE SOLUTION

6oz. / 177ml ı 74079-0850-2-

DRUG FACTS

ACTIVE INGREDIENTS

ALCOHOL 80% V/V.

Purpose ..ANTISEPTIC

HAND SANITIZER TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT

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)

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ALCOHOL 80% V/V..

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BREWINGCO



ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION

TOPICAL SOLUTION

HAND SANITIZER

- NON-STERILE SOLUTION -

128oz. /3.79L



ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION

TOPICAL SOLUTION

HAND SANITIZER

-NON-STERILE SOLUTION

3oz. / 89ml I

74079-0850-1-



ALCOHOL ANTISEPTIC 80%

TOPICAL SOLUTION

HAND SANITIZER

-NON-STERILE SOLUTION -

DRUG FACTS

ACTIVE INGREDIENTS

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Purpose
.....ANTISEPTIC

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DRUG FACTS

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PRODUCT TO AVOID SWALLOWING

OTHER INFORMATION

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NOT FOR RESALE

PROOF BREWING CO. HAND SANITIZER

alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74079-0850

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M)

ALCOHOL

80 mL in 100 mL

| Inactive Ingredients | | | | |
|--|--------------------|--|--|--|
| Ingredient Name | Strength | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL | | | |
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL | | | |
| WATER (UNII: 059QF0KO0R) | | | | |

| Packaging | | | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:74079- 0850-1 | 89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 2 | NDC:74079- 0850-3 | 237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 3 | NDC:74079- 0850-2 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 4 | NDC:74079- 0850-4 | 355 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 5 | NDC:74079- 0850-5 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 6 | NDC:74079- 0850-6 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 7 | NDC:74079- 0850-7 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/30/2020 | | | |
| 8 | NDC:74079- 0850-8 | 500 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 - Proof Brewing Company (032188654)

| Establishment | | | | | | |
|-----------------------|---------|-----------|-------------------------|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | |
| Proof Brewing Company | | 032188654 | manufacture(74079-0850) | | | |

Revised: 5/2020 Proof Brewing Company