RCD HAND SANITIZER- hand sanitizer liquid Rush Creek Distilling, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Drug Facts - Active Ingredients

Drug Facts

Active Ingredients

Purpose

Alcohol 80% v/vAntiseptic

Uses(s)

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.

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

Alcohol 80% v/v

Drug Facts - Purpose

Antiseptic

Drug Facts - Uses

Drug Facts - Warning

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Front/Main Label





Company logo - Rush Creek Distilling

Product Description - Hand Sanitizer

Active Ingredent - Denatured Ethanol 80%

Size in mL - this will vary depending on the package size per packagin NDC

Manufacturing location and contact information

RCD HAND SANITIZER

hand sanitizer liquid

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73977-001 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M) | ALCOHOL | 80 mL in 100 mL | |

Inactive Ingredients

| Ingredient Name | Strength |
|--|--------------------|
| HYDRO GEN PERO XIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| GLYCERIN (UNII: PDC6 A3C0 OX) | 1.45 mL in 100 mL |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:73977-001- 01 | 125 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |
| 2 | NDC:73977-001- 02 | 250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |
| 3 | NDC:73977-001- 03 | 375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |
| 4 | NDC:73977-001- 05 | 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |
| 5 | NDC:73977-001- 10 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |
| 6 | NDC:73977-001- 19 | 1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |
| 7 | NDC:73977-001- 38 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/25/2020 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 03/25/2020 | |
| | | | |

Labeler - Rush Creek Distilling, LLC (013420004)

Registrant - Rush Creek Distilling, LLC (013420004)

| Establishment | | | | | |
|----------------------------|---------|-----------|-------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Rush Creek Distilling, LLC | | 013420004 | manufacture (73977-001) | | |

Revised: 3/2020 Rush Creek Distilling, LLC