CANYON DIABLO SPIRITS HAND SANITIZER- alcohol liquid Canyon Diablo Spirits, LLC

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

SPL Unclassified

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.



HAND SANITIZER Alcohol Antiseptic 80% Topical Solution Non-sterile Solution NET 3785 ML (128 FL OZ)

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Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antisepc

| Drug Facts | |
|---|---|
| Active ingredient Alcohol 80% v/v | Purpose Antiseptic |
| Use(s) Hand sanitizer to help reduce bacteria that potentially For use when soap and water are not available. | can cause disease. |
| Warnings For external use only. Flammable. Keep away from he 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 me | |
| thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. T Keep out of reach of children. If swallowed, get medic | hese may be signs of a serious condition. al help or contact a Poison Control Center right away. |
| Directions Place enough product on hands to cover all surfaces. Supervise children under 6 years of age when using to | Rub hands together until dry. his 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 | |
| Questions? Adverse event? Tel: 1-928-853-9265 | email: diablo@canyondiablospirits.com |
| Produced By | Batch no.: |
| Canyon Diablo Spirits, LLC 506 N. Grant St, Ste C Flagstaff, AZ 86004 | Manf date: |

Purpose

Antiseptic, Hand Sanitizer

| Drug Facts Active ingredient Alcohol 80% v/v | Purpose Antiseptic |
|--|--|
| Use (s) Hand sanitizer to help reduce bacteria that potentially of For use when soap and water are not available. | an cause disease. |
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Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

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Warnings

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Do not use

- in children less than 2 months of age
 on open skin wounds

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When using

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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Stop use

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Package Label - Principal Display Panel and Front Label

(Canyon Diablo Spirits logo)

HAND SANITIZER

Alcohol Antiseptic 80%

Topical Solution

Non-sterile Solution

NET 3785 ML (128 FL OZ)



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CANYON DIABLO SPIRITS HAND SANITIZER

alcohol liquid

| Product T ype | HUMAN OTC DRUG | Item Code | (Source) | ND | C:74396-001 |
|--|--|-----------|---------------------------|----------------------|-----------------------------|
| Route of Administration | TOPICAL | | | | |
| | | | | | |
| Active Ingredient/Activ | e Moiety | | | | |
| | | | | | |
| | Ingredient Name | | Basis of Stren | gth | Strength |
| | Ingredient Name M) (ALCOHOL - UNII:3K9958V90M) | | Basis of Stren ALCOHOL | - | Strength 80 mL in 100 mL |
| | • | | | - | _ |
| ALCOHOL (UNII: 3K9958V90 | • | | | | _ |
| ALCOHOL (UNII: 3K9958V90 | M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name | | | Str | 80 mL in 100 mL ength |
| ALCOHOL (UNII: 3K9958V90 Inactive Ingredients | M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name | | ALCOHOL | Str 100 mL | 80 mL in 100 mL ength |

| # | Item Code | | Package Description | | Marketing Start Date | Marketing End Date | | | |
|-----------------------|----------------------|---|--|------|-------------------------|-----------------------|--|--|--|
| 1 | NDC:74396-001- 01 | 3785 | 3785 mL in 1 JUG; Type 0: Not a Combination Product | | 04/01/2020 | | | | |
| 2 | NDC:74396-001- 02 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | | 04/01/2020 | | | | |
| 3 | NDC:74396-001- 04 | | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | 04/01/2020 | | | | |
| 4 | NDC:74396-001- 05 | | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | 04/01/2020 | | | | |
| 5 | NDC:74396-001- 06 | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | | 04/17/2020 | | | | |
| 6 | NDC:74396-001- 07 | 001- 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | | 04/17/2020 | | | | |
| 7 | NDC:74396-001- 08 | | 1893 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | 04/17/2020 | | | | |
| 8 | NDC:74396-001- 09 | ⁰¹⁻ 18297 mL in 1 CONTAINER; Type 0: Not a Combination Product | | luct | 04/25/2020 | | | | |
| 9 | NDC:74396-001- 10 | 60 ml Produ | L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct | | 05/21/2020 | | | | |
| | | | | | | | | | |
| Marketing Information | | | | | | | | | |
| Marketing Catego | | ory | Application Number or Monograph Citation | Ma | rketing Start Date | Marketing End Date | | | |
| 0 | OTC monograph not | | inal part333A | |) 1/20 20 | | | | |
| | | | | | | | | | |

Labeler - Canyon Diablo Spirits, LLC (025915991)

| Establishment | | | | | | | | | |
|----------------------------|---------|-----------|----------------------------|--|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | | |
| Canyon Diablo Spirits, LLC | | 025915991 | manufacture(74396-001) | | | | | | |

Revised: 5/2020

Canyon Diablo Spirits, LLC