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

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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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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.

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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