#### HAND SANITIZER- alcohol liquid Arizona Craft Beverage Inc - AZCB

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.

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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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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.

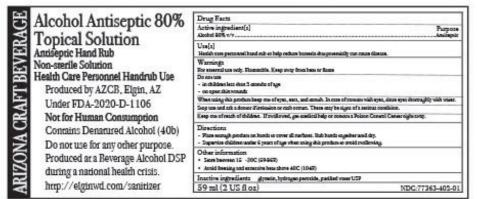
#### Other information

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

#### **Inactive ingredients**

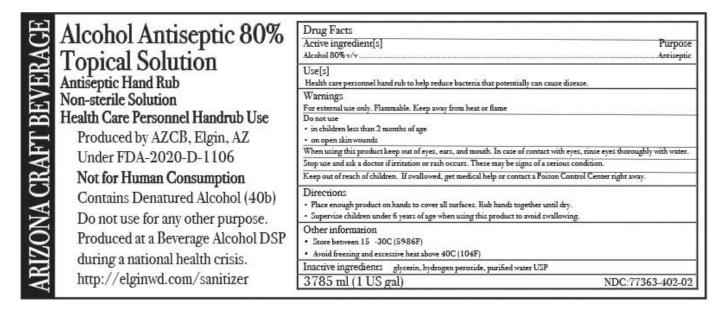
glycerin, hydrogen peroxide, purified water USP

#### Package Label - Principal Display Panel



59 mL NDC: 77363-402-01

3785 mL NDC: 77363-402-02



AGE	Alcohol Antiseptic 80%	Drug Facts Active ingredient[s] Alcohol 80% v/v
ERA	Topical Solution Antiseptic Hand Rub	Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease.
BEV	Non-sterile Solution Health Care Personnel Handrub Use	Warnings For external use only. Flammable. Keep away from heat or flame Do not use
F.	Produced by AZCB, Elgin, AZ	<ul> <li>in children less than 2 months of age</li> <li>on open skin wounds</li> <li>When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</li> </ul>
A	Under FDA-2020-D-1106	Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
<b>H</b>	Not for Human Consumption	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
VA (	Contains Denatured Alcohol (40b) Do not use for any other purpose.	Directions <ul> <li>Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul>
ARIZONA CRAFT	Produced at a Beverage Alcohol DSP	Other information • Store between 15 -30C (5986F) • Avoid freezing and excessive heat above 40C (104F)
during a national health crisis. http://elginwd.com/sanitizer		Inactive ingredients glycerin, hydrogen peroxide, purified water USP 18927 ml (5 US gal) NDC:77363-402-03

## HAND SANITIZER

alcohol liquid

Product Inform	nation					
Product Type	liativii	HUMAN OTC DRUG	Item Code	(Source	ז (י	NDC:77363-402
Route of Adminis	twotion	TOPICAL	Item Code (Source)		.)	
Route of Adminis	tration	TOPICAL				
Active Ingredi	ent/Active Moi	ety				
Ingredient Name Basis of Stro					of Strength	Strength
ALCOHOL (UNII: 3	K9958V90M) (ALC	OHOL - UNII:3K9958V90M)		ALCOHC	)L	80 mL in 100 mL
Inactive Ingred	lients					
mactive ingret		gredient Name			S	Strength
				1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)						
Packaging						
# Item Code		Package Description		Mar	keting Start Date	Marketing End Date
NDC:77363-402- 01	59 mL in 1 BOTTI Product	.E, PLASTIC; Type 0: Not a Con	nbinatio n	03/30/2	2020	
2 NDC:77363-402- 02	3785 mL in 1 BOT Product	TLE, PLASTIC; Type 0: Not a C	o mbinatio n	03/30/2	2020	
<b>B</b> NDC:77363-402- 03	18927 mL in 1 PAI	L; Type 0: Not a Combination Pr	roduct	03/30/2	2020	
NDC:77363-402-		LE, PLASTIC; Type 0: Not a Co	_			

5	NDC:77363-402- 05	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

# Marketing Information

Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
part333A	03/30/2020	
	11 51	

Labeler - Arizona Craft Beverage Inc - AZCB (121090481)

Registrant - Arizona Craft Beverage Inc (121090481)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Arizona Craft Beverage Inc - AZCB		121090481	manufacture(77363-402)

Revised: 5/2020

Arizona Craft Beverage Inc - AZCB