#### HAND SANITIZER- alcohol liquid Bullwheel Spirits Company 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.

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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) (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% (denatured) v/v. Purpose: Antiseptic

#### Purpose

Hand Sanitizer Topical Solution, Alcohol Antiseptic, Non-sterile solution

#### 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

#### Do Not Use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

#### Package Label - Principal Display Panel

5 Gallon (18,927 mL) NDC: 75808-080-05



### Package Label - Principal Display Panel

55 Gallon (208,198 mL) NDC: 75808-080-55

-8	HAND SANITIZER 0 % L SOLUTION	MAMMOTH
DRUG FACTS Active Ingredient[5] PURPOSE Alcahol 80% (denotered)Antiseptic	When using this product have out of eyes, ours, and mouth. In case of contract with eyes, rinese eyes thereughly with water. Stop use and ask a dactor if intriation or rash eccurs. These may be signs of a serious condition. Keep out of reach of children. If swellowed,	DISTILLING
USE[S] Hand sanifizer to help reduce bacteria that potentially can cause disease. For use when soop and water are not available. WARNINGS	get unedical help or contact a Poison Control Center right away. DIRECTIONS Place enough product on hands to cover all surfaces. Rub hands together until day. Supervise children under 6 years of age when using this product to avoid swallowing.	ALCOHOL ANTISEPTIC   NON-STERILE SOLUTION
For external use only. Flaanmable. Keep away from heat or flame DO NOT USE • In children less than 2 months of age • on open skin wounds	OTHER INFORMATION • Store botween 15:30C (59:86F) • Avoid freezing and excessive heat above 40C (104F) INACTIVE INGREDIENTS: glycerin, bydrogen perexide, purified water USP	JJ UALLUNJ

# Package Label - Principal Display Panel

264 Gallon (999,349 mL) NDC: 75808-080-26

-8	HAND SANITIZER 0% - L SOLUTION	MAMMOTH
DRUG FACITS ACTIVE INGREDIENT[S] Alcohol 80% (denotived) USE[S] USE[S]	When using this product keep out of syss, ears, and mouth. In case of context with eyes, rises syss thereughly with water. Stop use and ask a dactor if instantion or rash occurs. These may be signs of a sorious condition. Keep out of reach of children. If swellowed, get modical help or context a Poison Centrel Center right away.	ALCOHOL ANTISEPTIC   NON-STERILE SOLUTION
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soop 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	DIRECTIONS Place aeaogh 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 swallewing. OTHER INFORMATION Store bottneen 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) IRACTIVE INGREDIENTS: glycorin, bydrogen perectide, purified water USP	264 GALLONS

HAND SANITIZER alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75808-080
Route of Administration	TOPICAL		

	cuve ingreule	nt/Active Moiety			
		Ingredient Name	Basis	of Strength	Strength
A	LCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL			DL	80 mL in 100 mL
Iı	nactive Ingredi	ents			
	Ingredient Name Strength				
G	LYCERIN (UNII: PD	C6A3C0OX)		1.45 mL in 100	mL
н	YDRO GEN PERO X	IDE (UNII: BBX060AN9V)		0.125 mL in 100	) mL
W	ATER (UNII: 059QI	F0KO0R)			
P	ackaging				
ш	Item Cade	De cherre De covintie a	Mar	keting Start	Marketing End
#	Item Code	Package Description	Mar	keting Start Date	Marketing End Date
	<b>Item Code</b> NDC:75808-080- 27	Package Description 1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product	Mar 03/30/2	Date	U
1	NDC:75808-080-	1022060 mL in 1 CONTAINER; Type 0: Not a Combination		<b>Date</b>	U
1 2	NDC:75808-080- 27 NDC:75808-080-	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product 208198 mL in 1 CONTAINER; Type 0: Not a Combination	03/30/2	<b>Date</b> 2020 2020	U
1 2 3	NDC:75808-080- 27 NDC:75808-080- 55 NDC:75808-080-	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product 208 198 mL in 1 CONTAINER; Type 0: Not a Combination Product 18927 mL in 1 CONTAINER; Type 0: Not a Combination	03/30/2	Date           2020           2020           2020           2020	U
# 1 2 3 4	NDC:75808-080- 27 NDC:75808-080- 55 NDC:75808-080- 05 NDC:75808-080-	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product 208198 mL in 1 CONTAINER; Type 0: Not a Combination Product 18927 mL in 1 CONTAINER; Type 0: Not a Combination Product 999349 mL in 1 CONTAINER; Type 0: Not a Combination	0 3/30 /2 0 3/30 /2 0 3/30 /2	Date           2020           2020           2020           2020	0
1 2 3	NDC:75808-080- 27 NDC:75808-080- 55 NDC:75808-080- 05 NDC:75808-080- 26	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product 208 198 mL in 1 CONTAINER; Type 0: Not a Combination Product 18927 mL in 1 CONTAINER; Type 0: Not a Combination Product 999349 mL in 1 CONTAINER; Type 0: Not a Combination Product	0 3/30 /2 0 3/30 /2 0 3/30 /2	Date           2020           2020           2020           2020	U
1 2 3 4	NDC:75808-080- 27 NDC:75808-080- 55 NDC:75808-080- 05 NDC:75808-080-	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product 208 198 mL in 1 CONTAINER; Type 0: Not a Combination Product 18927 mL in 1 CONTAINER; Type 0: Not a Combination Product 999349 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2 03/30/2 03/30/2 03/30/2	Date 2020 2020 2020 2020	0

Labeler - Bullwheel Spirits Company LLC (117505068)

## Registrant - Bullwheel Spirits Company LLC (117482826)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Bullwheel Spirits Company		117505068	manufacture(75808-080)		

Revised: 4/2020

Bullwheel Spirits Company LLC