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.

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

Package Label - Principal Display Panel

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

HAND SANITIZER

alcohol liquid

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75808-080-27	1022060 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75808-080-55	208198 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75808-080-05	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75808-080-26	999349 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Bullwheel Spirits Company LLC (117505068)

Registrant - Bullwheel Spirits Company LLC (117482826)

Establishment

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

Revised: 4/2020 Bullwheel Spirits Company LLC