# CONSTELLATION BRANDS HAND SANITIZER- alcohol liquid Mission Bell Winery

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

[Logo]

Constellation Brands

Hand Sanitizer

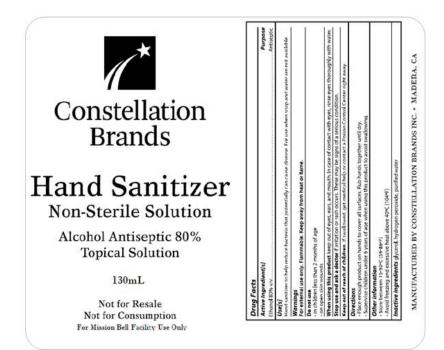
Non-Sterile Solution

Alcohol Antiseptic 80%

**Topical Solution** 

130mL (variable) Not for Resale Not for Consumption For Mission Bell Facility Use Only







# **CONSTELLATION BRANDS HAND SANITIZER**

alcohol liquid

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:69347-004	
Route of Administration	TOPICAL				
Active Ingredient/Active Mo	iety				
Ingredient Name				ength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)					
<b>ALCOHOL</b> (UNII: 3K9958V90M) (AL	COHOL - UNII:3K9958V90M)		ALCOHOL		192 mL in 240 mL
ALCOHOL (UNII: 3K9958V90M) (ALG Inactive Ingredients	COHOL - UNII:3K9958V90M)		ALCOHOL		192 mL in 240 mL
Inactive Ingredients	COHOL - UNII:3K9958V90M) ngredient Name		ALCOHOL		192 mL in 240 mL
Inactive Ingredients					trength
Inactive Ingredients	ngredient Name		3.5 m	S	t <b>rength</b> mL
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX)	ngredient Name		3.5 m	<b>S</b> L in 240 1	t <b>rength</b> mL
Inactive Ingredients In GLYCERIN (UNII: PDC6A3C0OX)	ngredient Name		3.5 m 0.3 m	<b>S</b> L in 240 1	t <b>rength</b> mL mL

1 IDC:69347-004- 2 IDC:69347-004-	, , , , , , , , , , , , , , , , , , , ,	03/30/2020 03/30/2020 03/30/2020					
2 IDC:69347-004-	Product 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination						
DC:69347-004-	, , , , , , , , , , , , , , , , , , , ,	02/20/2020					
	NDC:69347-004- 03 500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product						
Marketing Information							
larketing Catego	ry Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
C monograph not fi	nal part333A	03/30/2020					
la	arketing Catego	arketing Category Application Number or Monograph Citation	arketing Category Application Number or Monograph Citation Marketing Start Date				

Labeler - Mission Bell Winery (619115137)

**Registrant** - Mission Bell Winery (619115137)

# Establishment

Name	Address	ID/FEI	Business Operations
Mission Bell Winery		6 19 115 137	manufacture(69347-004)

Revised: 5/2020

Mission Bell Winery