

## **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.*

-----

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.

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

  
**Constellation  
Brands**  
**Hand Sanitizer**  
Non-Sterile Solution  
Alcohol Antiseptic 80%  
Topical Solution  
240mL  
Not for Resale  
Not for Consumption  
For Mission Bell Facility Use Only

<b>Drug Facts</b>
<b>Active ingredient(s)</b> Ethanol 80% v/v..... Antiseptic
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
<b>Warnings</b> For external use only. <b>Flammable. Keep away from heat or flame.</b>
<b>Do not use</b> - in children less than 2 months of age
<b>Stop use and ask a doctor</b> - if irritation or rash occurs. If you have ever had a reaction to any of the ingredients of this product, stop use and ask a doctor. These may be signs of a serious condition.
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b> - Place enough product on hands to cover all surfaces. Rub hands together until dry.
<b>Other information</b> - Store between 15-30°C (59-86°F)
<b>Inactive ingredients</b> glycerol, hydrogen peroxide, purified water

MANUFACTURED BY CONSTELLATION BRANDS INC. • MADERA, CA

## 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

## Non-Sterile Solution

Alcohol Antiseptic 80%  
Topical Solution

240mL

Not for Resale  
Not for Consumption  
For Mission Bell Facility Use Only

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient(s)</b> Ethanol 80% v/v	Antiseptic
<b>Uses(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b> <b>Do not use</b> - in children less than 2 months of age - on open wounds <b>Keep this product</b> keep out of eyes, ears, and mouth in case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. There may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> - 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.	
<b>Other information</b> - Store between 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerol, hydrogen peroxide, purified water	

MANUFACTURED BY CONSTELLATION BRANDS INC. • MADERA, CA



Constellation  
Brands

# Hand Sanitizer

## Non-Sterile Solution

Alcohol Antiseptic 80%  
Topical Solution

130mL

Not for Resale  
Not for Consumption  
For Mission Bell Facility Use Only

<b>Drug Facts</b>	<b>Purpose</b> Antiseptic
<b>Active ingredient(s)</b> Ethanol 80% v/v	
<b>Use(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> <b>For external use only. Flammable. Keep away from heat or flame.</b> - In children less than 2 months of age - on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water. <b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> - 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.	
<b>Other information</b> - Store at 20°C (68°F-82°F) - Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerol, hydrogen peroxide, purified water	

MANUFACTURED BY CONSTELLATION BRANDS INC. • MADERA, CA



Constellation  
Brands

# Hand Sanitizer

## Non-Sterile Solution

Alcohol Antiseptic 80%  
Topical Solution

500mL

Not for Resale  
Not for Consumption  
For Mission Bell Facility Use Only

<b>Drug Facts</b>
<b>Active Ingredient(s)</b> Ethanol 80% v/v
<b>Purpose</b> Antiseptic
<b>Uses(s)</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame. Do not use - in children less than 2 months of age
<b>Directions</b> 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.
<b>Other information</b> - Store between 15-30°C (59-86°F) - Avoid freezing and excessive heat above 40°C (104°F) <b>Inactive ingredients</b> Glycerol, hydrogen peroxide, purified water

MANUFACTURED BY CONSTELLATION BRANDS INC. • MADERA, CA

## CONSTELLATION BRANDS HAND SANITIZER

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69347-004
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	192 mL in 240 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	3.5 mL in 240 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.3 mL in 240 mL
WATER (UNII: 059QF0KO0R)	44.2 mL in 240 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69347-004-01	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:69347-004-02	130 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:69347-004-03	500 mL in 1 BOTTLE, PLASTIC; 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** - Mission Bell Winery (619115137)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Mission Bell Winery		619115137	manufacture(69347-004)

Revised: 5/2020

Mission Bell Winery