

**GEL HAND SANITIZER, NO SCENT- alcohol gel**  
**Custom Agronomics, Inc.**

*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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**Gel Hand Sanitizer No Scent**

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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### 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, modified guar gum

### Package Label - Principal Display Panel

3785 mL NDC: 78637-102-01

NDC 78637-102-01

# Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Gel Solution

Contents: 3,785 mL

946.25 mL NDC: 78637-102-02

NDC 78637-102-01

<b>Drug Facts</b>	<b>Purpose</b>
<b>Active ingredient[s]</b> Alcohol 80% v/v	Antiseptic
<b>Use[s]</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</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 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 between 15° - 30°C (59° - 86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
<b>Inactive ingredients</b> glycerin, hydrogen peroxide, purified water USP, and modified guar gum	

NDC 78637-102-02

# Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub  
Non-sterile Gel Solution

Contents: 946.25 mL

473.13 mL NDC: 78637-102-03

NDC 78637-102-03

# Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub  
Non-sterile Gel Solution

Contents: 473.13 mL

NDC 78637-102-02

**Drug Facts**

Active ingredient[s]	Purpose
Alcohol 80% v/v	Antiseptic

**Use[s]**

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

**Warnings**

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**Do not use**

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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP, and modified guar gum

NDC 78637-102-03

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## GEL HAND SANITIZER, NO SCENT

alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78637-102
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	63.12 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.81 g in 100 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.14 g in 100 g
WATER (UNII: 059QF0K00R)	

<b>GUARAPROLOSE (1300 MPAS AT 1%) (UNII: 1530WMS90S)</b>	0.5 g in 100 g
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<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78637-102-01	3368.65 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78637-102-02	842.16 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78637-102-03	421.09 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

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

**Labeler** - Custom Agronomics, Inc. (008383600)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Custom Agronomics, Inc.		008383600	manufacture(78637-102) , label(78637-102) , pack(78637-102)

Revised: 7/2020

Custom Agronomics, Inc.