

GEL HAND SANITIZER- 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.

Gel Hand Sanitizer

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, lemongrass fragrance

Package Label - Principal Display Panel

3785 mL NDC: 78637-101-01

NDC 78637-101-01

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub

Non-sterile Gel Solution

Contents: 3,785 mL

946.25 mL NDC: 78637-101-02

NDC 78637-101-01

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	
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.	
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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° - 30°C (59° - 86°F) • Avoid freezing and excessive heat above 40°C (104°F)	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP, modified guar gum, and lemongrass fragrance	

NDC 78637-101-02

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub
Non-sterile Gel Solution

Contents: 946.25 mL

473.13 mL NDC: 78637-101-03

NDC 78637-101-03

Alcohol Antiseptic 80%

Topical Solution

Antiseptic Hand Rub
Non-sterile Gel Solution

Contents: 473.13 mL

NDC 78637-101-02

Drug Facts	
Active ingredient[s] Alcohol 80% v/v	Purpose Antiseptic
Use[s] Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
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NDC 78637-101-03

Drug Facts	
Active ingredient[s] Alcohol 80% v/v	Purpose Antiseptic
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GEL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78637-101
Route of Administration	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
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.025 g in 100 g

.ALPHA.-METHYLBENZYL ACETATE (UNII: FYS3E9NBA3)	0.025 g in 100 g
2,6,10-TRIMETHYL-9-UNDECENAL (UNII: JNM5JFE28J)	0.005 g in 100 g
3-(3,4-METHYLENEDIOPHENYL)-2-METHYLPROPANAL (UNII: L65EG8H6PA)	0.005 g in 100 g
2-METHYLUNDECANAL (UNII: S94QNS2VY5)	0.005 g in 100 g
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	0.35 g in 100 g
ORANGE OIL (UNII: AKN3KSD11B)	0.15 g in 100 g
2-ACETONAPHTHONE (UNII: 21D49LOP2T)	0.025 g in 100 g
DECANAL (UNII: 31Z90Q7KQJ)	0.005 g in 100 g
2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE (UNII: 452GFV2AFS)	0.025 g in 100 g
CYCLAMEN ALDEHYDE (UNII: 4U37UX0E1E)	0.005 g in 100 g
1H,5H-CYCLOPENTA(3,4)(1)BENZOPYRANO(6,7,8-IJ)QUINOLIZIN-12(9H)-ONE, 2,3,6,7,10,11-HEXAHYDRO- (UNII: 9RGV583D48)	0.005 g in 100 g
10-UNDECENAL (UNII: DU1OTA08RY)	0.005 g in 100 g
CITRONELLA OIL (UNII: QYO8Q067D0)	0.005 g in 100 g
GUARAPROLOSE (1300 MPAS AT 1%) (UNII: 1530WMS90S)	0.5 g in 100 g
GRAPEFRUIT OIL (UNII: YR377U58W9)	0.075 g in 100 g
DIPROPYLENE GLYCOL (UNII: E107L85C40)	0.35 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	1.81 g in 100 g
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.14 g in 100 g
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78637-101-01	3368.65 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78637-101-02	842.16 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78637-101-03	421.09 g in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78637-101-04	52.64 g 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 - Custom Agronomics, Inc. (008383600)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Agronomics, Inc.		008383600	manufacture(78637-101) , pack(78637-101) , label(78637-101)

Revised: 9/2020

Custom Agronomics, Inc.