

## **ADVANCED HAND SANITIZER GEL- alcohol gel**

### **Sanare Bioscience**

*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 70% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

For hand washing to decrease bacteria on the skin –recommended for repeated use

### **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

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 occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help immediately or contact a Poison Control Center immediately

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

- Wet hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision

## Other information

Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics

## Inactive ingredients

Purified water, hydrogen peroxide, and glycerin , Carbomer

## Package Label - Principal Display Panel

**Drug Facts**

<b>Active Ingredients</b>	<b>Warnings</b>
Ethyl Alcohol 70% _____ Antiseptic, Broad Spectrum	<b>Use</b> - For hand wash to good contact on the skin - the amount of or repeated use
<b>Directions</b> - For external use only. If possible, keep away from heat and flame	<b>Warnings</b> - For external use only. If possible, keep away from heat and flame
<b>Directions</b> - Children less than 2 months of age - Do open skin wounds	<b>Directions</b> - Wash hands thoroughly with product, and allow to dry without wiping. For children under six, use only under adult supervision
<b>When using this product</b> - Keep out of eyes, ears, and mouth. In case of contact with eyes, do as eye thoroughly with water. Stop use and see doctor if irritation occurs. There may be signs of eye irritation. Keep out of reach of children. If irritation, get medical help immediately or contact Poison Control Center immediately	<b>Other Ingredients</b> - Purified water, hydrogen peroxide, and glycerin, carbomer
<b>Other Information</b> - Store between 15-30C. Avoid freezing and excessive heat above 40C (104F). May discolor some fabrics. Harmful to wood finishes and plastics	

Manufactured at: 3301 Eastern Avenue Baltimore, MD 21224 - 410.735.6290

\* Based on total content of leading national brands and other top-selling alcohol-based hand sanitizers. Kills 99.99% of most illness causing germs and bacteria. FDA approved.  
NDC: 78515-002-38

NDC: 78515-002-08

or

3785 mL NDC - 78515-002-28

ADVANCED HAND SANITIZER GEL			
alcohol gel			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78515-002
Route of Administration	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	0.125 mL in 100 mL
<b>WATER</b> (UNII: 059QF0K00R)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S)</b> (UNII: T967IEU43C)	4 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78515-002-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78515-002-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78515-002-32	946 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** - Sanare Bioscience (117382399)

**Registrant** - Sanare Bioscience (117382399)

### Establishment

Name	Address	ID/FEI	Business Operations
Sanare Bioscience		117382399	manufacture(78515-002)

Revised: 12/2020

Sanare Bioscience