

## **HANDSANITIZERAMERICANMALE- alcohol solution**

### **Genesis Salon Products LLC**

*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 rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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)
- b. Glycerol.
- c. Hydrogen peroxide.
- d. Sterile distilled water.

### **Active Ingredient(s)**

Ethyl Alcohol 70%. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria on the skin

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in or around eyes

When using this product do not use in or near eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- Put enough product in your palm to cover hands and rub together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

### **Other information**

- Store below 110F (43C)
- May discolor certain fabrics or surfaces

**Inactive ingredients**

deionized water, glycerin, polysorbate 20, aloe barbadensis leaf juice, orange peel oil, tocopheryl acetate, maltodextrin, parfum

**Package Label - Principal Display Panel**



**HAPPY HOLIDAYS**

# Hand Sanitizer

**WITH ALOE & VITAMIN E**

**70% Ethyl Alcohol**

**Refreshing Citrus Scent**

Shield your hands from germs naturally with our vegan plant-based hand sanitizer. Infused with Aloe Vera, Vitamin E, and Glycerin.

Now you can cleanse and protect your hands while leaving skin hydrated, healthy, and silky smooth.

**59 ml e 2 fl oz**

<b>Drug Facts</b>	
<b>Active ingredient</b> Ethyl Alcohol 70% .....	<b>Purpose</b> Antiseptic
<b>Use</b> • Hand sanitizer to help reduce bacteria on the skin	
<b>Warnings</b>	
<b>Flammable. Keep away from fire and flame</b>	
<b>For external use only</b>	
<b>When using this product</b> do not use in or near eyes. If contact occurs, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor if</b> irritation or rash appears and lasts	
<b>Keep this and all drugs out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • Put enough product in your palm to cover hands and rub hands together briskly until dry. • Children under 6 years of age should be supervised when using this product	
<b>Other Information</b> • Store Below 110°F (43°C) • May discolor certain fabrics or surfaces	
<b>Inactive Ingredients</b> Aqua (Deionized Water), Glycerin, Polysorbate 20, Aloe Barbadensis Leaf Juice, Citrus Aurantium Dulcis (Orange) Peel Oil, Tocopheryl Acetate, Maltodextrin, Parfum (Fragrance)	
<b>Questions or Comments?</b> 855-592-6199	



**CRUELTY FREE**  
No Animal Testing  
No Animal Ingredients

Made in USA  
Distr. by  
Genesis Salon Products LLC.  
345 Morgantown Rd.  
Reading, PA 19611

alcohol solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76650-121
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0K00R)	
ALOE (UNII: V5VD430YW9)	
ORANGE PEEL (UNII: T19T76XD44)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76650-121-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2020	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	10/09/2020	

**Labeler** - Genesis Salon Products LLC (079511065)

**Registrant** - Cospro Development Corp (785638821)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Cospro Development Corp		785638821	manufacture(76650-121) , pack(76650-121) , label(76650-121)

Revised: 10/2020

Genesis Salon Products LLC