

HAND SANITIZER- 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.

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.
- c. 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

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.

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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

aqua, glycerin, polysorbate 20, aloe barbadensis leaf juice, citrus aurantium dulcis peel oil, tocopheryl acetate, maltodextrin

Package Label - Principal Display Panel



Managing communities people are proud to call home.



Hand Sanitizer

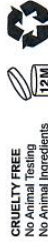
WITH ALOE & VITAMIN E

70% Ethyl Alcohol
Refreshing Citrus Scent

242 ml e 8.2 fl oz

Drug Facts	
Active Ingredient Ethyl Alcohol 70%	Purpose Antiseptic
Use • Hand sanitizer to help reduce bacteria on the skin	
Warnings Flammable. Keep away from fire and flame	
For external use only	
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 hands together briskly until dry. • Children under 6 years of age should be supervised when using this product	
Other Information • Store Below 110°F (43°C) • May discolor certain fabrics or surfaces	
Inactive Ingredients Aqua (Deionized Water), Glycerin, Poly sorbate 20, Aloe Barbadiansis Leaf Juice, Citrus Aurantium Dulcis (Orange) Peel Oil, Tocopheryl Acetate, Maltodextrin, Parfum (Fragrance)	
Questions or Comments? 855-592-6199	

Never be without protection!
Shield your hands from germs naturally with our plant-based hand sanitizers. Infused with Aloe Vera, Vitamin E and Glycerin to keep your hands feeling silky smooth. Now you can cleanse and protect your hands with our vegan formula that leaves your hands hydrated & healthy.



Made in USA
Distr. by
Genesis Salen Products LLC,
1200 Ridgeway Rd.,
Reading, PA 19611

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76650-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
ORANGE PEEL (UNII: T19T76XD44)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76650-112-01	242 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
2	NDC:76650-112-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

Labeler - Genesis Salon Products LLC (079511065)

Registrant - Cospro Development Corp (785638821)

Establishment

Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(76650-112) , pack(76650-112) , label(76650-112)