

HAND SANITIZER PORTCALL- 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) (70%) 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.

Active Ingredient(s)

Alcohol 70%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from fire and flame

Do not use

- Do not use in or near 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.

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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, citrus aurantium dulcis peel oil, tocopheryl acetate, maltodextrin, parfum

Package Label - Principal Display Panel



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

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, Polysorbate 20, Aloe Barbadensis Leaf Juice, Citrus Aurantium Dulcis (Orange) Peel Oil, Tocopheryl Acetate, Maltodextrin, Parfum (Fragrance)
Questions or Comments? 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76650-119
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
maltodextrin (UNII: 7CVR7L4A2D)	
ORANGE PEEL (UNII: T19T76XD44)	
ALOE (UNII: V5VD430YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76650-119-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - Genesis Salon Products LLC (079511065)

Registrant - Cospro Development Corp (785638821)

Establishment

Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(76650-119) , label(76650-119) , pack(76650-119)

Revised: 6/2020

Genesis Salon Products LLC