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) (70%, 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.

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.

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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, polysorbate 20, aloe barbadensis leaf juice, citrus aurantium dulcis (orange) peel oil, tocopheryl acetate, maltodextrin, purified water

Package Label - Principal Display Panel



COMMUNITY REALTY MANAGEMENT

Hand Sanitizing Spray Infused with Aloe Vera & Vitamin E

242 ml e 8.2 fl oz









alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76650-111
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		
GLYCERIN (UNII: PDC6A3C0OX)			
ORANGE PEEL (UNII: TI9 T76 XD44)			
WATER (UNII: 059QF0KO0R)			
ALOE (UNII: V5VD430 YW9)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			

l	Pa	ckaging			
# Item Code Package Description		Package Description	Marketing Start Date	Marketing End Date	
l	1 1	NDC:76650-111-01	242 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/17/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/17/2020		

Labeler - Genesis Salon Products LLC (079511065)

Registrant - Cospro Development Corp (785638821)

Establishment			
Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(76650-111), pack(76650-111), label(76650-111)

Revised: 4/2020 Genesis Salon Products LLC