HAND SANITIZERBET- 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. Glycerin
- 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.

Warnings

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

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.

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

Keep 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)

Inactive ingredients

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

Package Label - Principal Display Panel



HAND SANITIZERBET

alcohol solution					
Product Information	n				
Product Type		HUMAN OTC DRUG	Item Code (S	ource)	NDC:76650-120
Route of Administratio	n	TOPICAL			
A .1 T . 11 .//					
Active Ingredient/A		v			
Ingredient NameBasis of StALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)ALCOHOL				Basis of Strength	
ALCONUL (UNII: 3K995	0 v 9 0 1vi) (ALCI	2110F - OIMT972329 A30 M)	AL	CORUL	70 mL in 100 mL
Inactive Ingredient	S				
		Ingredient Name			Strength
GLYCERIN (UNII: PDC6					
ALOE (UNII: V5VD430 YV	V9)				
WATER (UNII: 059QF0K	00R)				
POLYSORBATE 20 (UN	II: 7T1F30V5YF	f)			
ORANGE PEEL (UNII: TI	9T76XD44)				
maltodextrin (UNII: 7CV	R7L4A2D)				
Packaging					
# Item Code]	Package Description	Mar	keting Start Date	Marketing End Dat
1 NDC:76650-120-01 24	2 mL in 1 BOT	TLE; Type 0: Not a Combinati	on Product 07/09	9/2020	
Marketing Info	mation				
Marketing Category		on Number or Monograph	Citation Mar	keting Start Date	Marketing End Date
OTC monograph not final		0 1		9/2020	

Labeler - Genesis Salon Products LLC (079511065)

Registrant - Cospro Development Corp (785638821)

Establishment

Name	Address	ID/FEI	Business Operations
Cospro Development Corp		785638821	manufacture(76650-120), pack(76650-120), label(76650-120)

Revised: 7/2020

Genesis Salon Products LLC