HAND SANITIZER- alcohol spray Cerabella Group Corp

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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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 80% 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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

away.

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, hydrogen peroxide, purified water USP

Package Label

1000 ml NDC:76671-123-02

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

Drug Facts

Active ingredient[s] Purpose Alcohol 80% v/v...... Antiseptic

Use[s]

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.



Topical Solution

Hand Sanitizer Non-sterile Solution

Drug Facts

Active ingredient[s] Purpose Alcohol 80% v/v...... Antiseptic

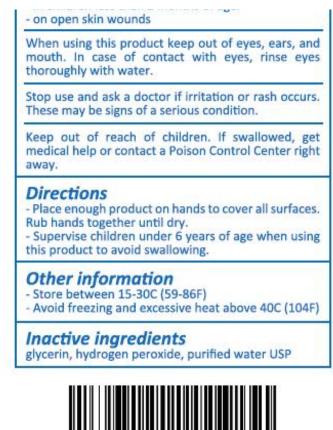
Use[s]

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.



76671-123-02



Cerabella Group Corp 2100 NW 129th Avenue Ste 110 Miami FL 33182

HAND S	SANITIZER
--------	-----------

alcohol spray

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:76671-123	
Route of Administration	TOPICAL				
· · · · · · · · · · · ·					
Active Ingredient/Activ	e Moiety				
Ingredient Name			Basis of Strength		
	8		0	Strength	
	M) (ALCOHOL - UNII:3K9958V90M)	ALCO	•	80 mL in 100 mI	
	•		•		
	•		•		
ALCOHOL (UNII: 3K9958V90	•		HOL		
ALCOHOL (UNII: 3K9958V90 Inactive Ingredients	M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name		HOL	80 mL in 100 mI	
ALCOHOL (UNII: 3K9958V90	M) (ALCOHOL - UNII:3K9958V90M) Ingredient Name		HOL	80 mL in 100 mI Strength mL	

Packaging						
# Item Code		Package Description	Marketing Start Date	Marketing End Date		
1 01	1000 i Produc	mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination ct	04/21/2020			
2 NDC:76671-123- 02	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		04/21/2020			
Marketing Information						
Marketing Category			Maultating Staut Data	Markating End Date		
marketing Categ	gory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not	final	part333A	04/21/2020			

Labeler - Cerabella Group Corp (048234187)

Establishment							
Name	Address	ID/FEI	Business Operations				
Cerabella Group Corp		048234187	manufacture(76671-123)				

Revised: 4/2020

Cerabella Group Corp