

4 UKLEAN HAND SANITIZER- isopropyl alcohol gel Creek Pine Group Miami 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.

Hand Sanitizer

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% 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

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Product made in the Dominican Republic for:
CreekPine Group, SRL
Distribution by:
Tucana Enterprises
Miami, Florida
USA

NDC CODE: 79038-070-01

Producto hecho en la República Dominicana por:
CreekPineGroup, SRL
Distribuido por:
Tucana Enterprises
Miami, Florida
USA

70% Alcohol content
Ready to use

70% contenido de Alcohol
Listo para su uso

Contains emollients and humectants
Contiene humectantes y emolientes

Net Weight: 1 Gallon

ALCOHOL ANTISEPTIC 70% NON STERILE HAND GEL	
Drug Facts	
Active Ingredient(s)	Purpose
Ethyl Alcohol 70% 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	
<ul style="list-style-type: none"> • 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 sign of a serious condition.	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control.	
Directions	
<ul style="list-style-type: none"> • 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, propylene glycol, triethanolamine, polyacrylate polymer, purified water and fragrance	

000 ml NDC: 79038-070-01

4 UKLEAN HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79038-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.0125 mL in 1 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.0145 mL in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79038-070-01	3785.41 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79038-070-02	59.1471 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79038-070-16	473.176 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79038-070-32	946.353 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79038-070-05	18927.1 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Creek Pine Group Miami Corp. (117552479)

Establishment

Name	Address	ID/FEI	Business Operations
Creek Pine Group Miami Corp.		117552479	manufacture(79038-070)

Revised: 6/2020

Creek Pine Group Miami Corp.