

CEE-BEE HAND SANITIZER- isopropyl alcohol gel McGean-Rohco, Inc.

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. 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.

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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 - Principal Display Panel

Hand Sanitizer

Isopropyl Alcohol Antiseptic 75%
Topical Solution
Non-Sterile Solution

3785.41mL

McGean-Rohco Inc. | 2910 Harvard Avenue, Cleveland, Ohio 44105-3010 | www.mcgean.com | Made in USA | 216-441-4900

Drug Facts	
Active ingredient[s] Isopropyl alcohol 75% v/v	Purpose 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 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 <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. 	
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3785 ml NDC: 74552-2700-1

CEE-BEE HAND SANITIZER				
isopropyl alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74552-3785	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL		
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		
	WATER (UNII: 059QF0KO0R)			
Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:74552-3785-2	1 in 1 BOTTLE	03/30/2020	
1	NDC:74552-3785-1	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:74552-3785-3	208175 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74552-3785-4	946 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/01/2020	

Marketing Information

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

Labeler - McGean-Rohco, Inc. (071112593)

Establishment

Name	Address	ID/FEI	Business Operations
McGean-Rohco, Inc		069820181	label(74552-3785)

Establishment

Name	Address	ID/FEI	Business Operations
McGean-Rohco, Inc.		071112593	manufacture(74552-3785)

Revised: 11/2020

McGean-Rohco, Inc.