

HAND SANITIZER- isopropyl alcohol liquid

Apex Engineering Products Corporation

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.

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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

3785ml NDC: 74989-075-01

APEX ENGINEERING PRODUCTS CORPORATION
128 Fl. Oz. (3785ml) NDC: 74989-075-01

HAND SANITIZER
Non-Sterile Solution
ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

Drug Facts Active Ingredient(s) Isopropyl alcohol 75% v/v..... PurposeAntiseptic	Drug Facts.....Continued Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age while using this product to avoid swallowing.
Warnings For external use only. Flammable. Keep away from heat or flame.	Other information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)
Do not use • in children less than 2 months of age • on open skin wounds	Inactive ingredients glycerin, hydrogen peroxide, purified water USP
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.	

Apex Engineering Products Corporation 1241 Shoreline Drive Aurora, IL 60504 630-820-8884 www.ApexEngineeringProducts.com

CERTIFIED ISO COMPANY
MADE IN USA

18,925ml NDC: 74989-075-05



Non-Sterile Solution

HAND SANITIZER

ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

Drug Facts

Active Ingredient[s]	Purpose
Isopropyl alcohol 75% 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. These may be signs of a serious condition.

FDA Registered Facility

NDC: 74989-075-05

640 Fl. Oz. (18,925 mL)



Drug Facts.....Continued

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 while 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

Apex Engineering Products Corporation 1241 Shoreline Drive Aurora, IL 60504 630-820-8888 www.ApexEngineeringProducts.com

59mL NDC: 74989-075-02



Topical Liquid Solution

Hand Sanitizer

Fragrance Free

NDC: 74989-75-02

2 FL OZ (59 mL)

Drug Facts	
Active Ingredient[s]	Purpose
Isopropyl alcohol 75% 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.	
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 while using this product to avoid swallowing. 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

For SDS: www.ApexEngineeringProducts.com



HAND SANITIZER			
isopropyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74989-075
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL -	ISOPROPYL	75 mL

UNII:ND2M416302)		ALCOHOL	in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74989-075-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/09/2020	
2	NDC:74989-075-05	18925 mL in 1 JUG; Type 0: Not a Combination Product	04/09/2020	
3	NDC:74989-075-02	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/09/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/09/2020		

Labeler - Apex Engineering Products Corporation (005182373)

Establishment			
Name	Address	ID/FEI	Business Operations
Apex Engineering Products Corporation		005182373	manufacture(74989-075)

Revised: 8/2020

Apex Engineering Products Corporation