

HAND SANITIZER- isopropyl alcohol liquid
INEOS COMPOSITES US, 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. 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

3785 ml NDC: 75284-4276-1

The logo for INEOS, featuring the word "INEOS" in a bold, sans-serif font. The letter "O" is stylized as a circle with a horizontal line through its center.

Isopropyl Alcohol Antiseptic 75% Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

[3785 mL]

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 75% v/v.....	Antiseptic
Use[s]	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease	
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. 	
Other information	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	
INEOS Composites US, LLC +1 614 790 9299	

HAND SANITIZER

isopropyl alcohol liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75284-4276	
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)		0.73 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75284-	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	04/17/2020	

4276-1	Product	04/17/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/17/2020	

Labeler - INEOS COMPOSITES US, LLC (117196678)

Registrant - INEOS COMPOSITES US, LLC (116877629)

Establishment

Name	Address	ID/FEI	Business Operations
INEOS COMPOSITES US LLC		034144605	label(75284-4276) , pack(75284-4276)

Establishment

Name	Address	ID/FEI	Business Operations
INEOS COMPOSITES US, LLC		117196678	manufacture(75284-4276)

Revised: 5/2020

INEOS COMPOSITES US, LLC