

## **ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION- isopropyl alcohol liquid Axalta Coating Systems**

*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.*

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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.

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

3785.41 mL NDC: 79276-001-01



Drug Facts	Purpose
<b>Active ingredient(s)</b> Isopropyl alcohol 75% v/v	Antiseptic
<b>Use(s)</b> Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame.	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop using and ask doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Glycerin, hydrogen peroxide, purified water USP	

# Isopropyl Alcohol Antiseptic 75% Topical Solution

**Antiseptic Hand Rub  
Non-sterile Solution**

**3785.41 mL**

2AX-A01758536-COVID-19-GAL-200417



0 12500 08352 0

**AN AXALTA COATING SYSTEMS BRAND**  
50 Applied Bank Boulevard, Suite 300, Glen Mills, PA 19342  
PRODUCT INFORMATION TEL.: 855-629-2582 axalta.us

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Country of Origin: U.S.A.

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 issued by the FDA March 2020.

Batch Code:

Fill Date:

## ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

isopropyl alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79276-001
<b>Route of Administration</b>	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	
<b>Inactive Ingredients</b>				
		<b>Ingredient Name</b>	<b>Strength</b>	
		GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL	
		HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL	
		WATER (UNII: 059QF0K00R)		
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:79276-001-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	03/30/2020	

**Labeler** - Axalta Coating Systems (079524986)

**Registrant** - Axalta Coating Systems (079524986)

**Establishment**

Name	Address	ID/FEI	Business Operations
Axalta Coatings Systems LLC		021466339	manufacture(79276-001)

**Establishment**

Name	Address	ID/FEI	Business Operations
Axalta Coating Systems LLC		606875391	manufacture(79276-001)

Revised: 6/2020

Axalta Coating Systems