

HAND SANITIZER- isopropyl alcohol liquid

Saint-Gobain Performance Plastics 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.

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 - Principal Display Panel

<p>Isopropyl Alcohol Antiseptic 75% Topical Solution Antiseptic Hand Rub Non-sterile Solution</p> <p>3.78L</p> <p>NDC 74629-001-01 Lot No</p> <p><small>Saint-Gobain Performance Plastics Corporation 717 Plantation St., Worcester, MA 01605</small></p>	<table border="1"> <tr> <td colspan="2">Drug Facts</td> </tr> <tr> <td>Active Ingredient(s)</td> <td>Purpose</td> </tr> <tr> <td>Isopropyl Alcohol 75% v/v</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Use(s)</td> </tr> <tr> <td colspan="2">Health care personnel hand rub to help reduce bacteria that potentially can cause disease.</td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • In children less than 2 months of age • On open skin wounds </td> </tr> <tr> <td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <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 </td> </tr> <tr> <td colspan="2">Other Information</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Store between 15 – 30C (59 - 86F) • Avoid freezing and excessive heat above 40C (104F) </td> </tr> <tr> <td colspan="2">Inactive Ingredients glycerin, hydrogen peroxide, purified water USP</td> </tr> </table>	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		<ul style="list-style-type: none"> • Store between 15 – 30C (59 - 86F) • Avoid freezing and excessive heat above 40C (104F) 		Inactive Ingredients glycerin, hydrogen peroxide, purified water USP	
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																																			
<ul style="list-style-type: none"> • Store between 15 – 30C (59 - 86F) • Avoid freezing and excessive heat above 40C (104F) 																																			
Inactive Ingredients glycerin, hydrogen peroxide, purified water USP																																			

(3780 ml) NDC: 74629-001-01

HAND SANITIZER			
isopropyl alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74629-001
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	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74629-001-01	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/07/2020	

Labeler - Saint-Gobain Performance Plastics Corporation (836223305)

Establishment

Name	Address	ID/FEI	Business Operations
Saint-Gobain Performance Plastics Corporation		836223305	manufacture(74629-001)

Revised: 4/2020

Saint-Gobain Performance Plastics Corporation