POLYSAN- alcohol solution US Polychemical Holding Corporation

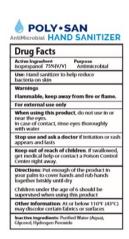
Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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.

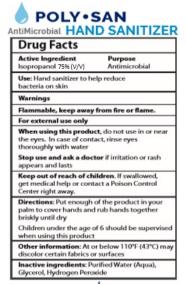
The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.













U.S. POLYCHEMICAL CORPORATION EXECUTIVE OFFICES - PLANT - LABORATORY 840-Chesthut Ridge Road Chesthut Ridge, NY 10977 (800) 431-2072 (845) 336-5530 www.uspoly.com

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

1 Quart (0.946L)

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

3.785 L (3785 mL) NDC: 76644-0002-1

Poly San Hand Sanitizer Gallon Size 1.jpg







0.946L (946mL) NDC:76644-0002-2

Poly San Hand Sanitizer Qt size 1.jpg

U.S. POLYCHEMICAL CORPORATION



1 Quart (0.946L)



Drug Facts

Active Ingredient Isopropanol 75% (V/V) Purpose Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin

Flammable, keep away from fire or flame.

For external use only

When using this product, do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation or rash appears and lasts

appears and lasts

Keep out of reach of children. If swallowed,
get medical help or contact a Poison Control
Center right away.

Directions: Put enough of the product in your
palm to cover hands and rub hands together
briskly until dry

Children under the age of 6 should be supervised
when using this product

Other information. At or below 110°E (42°C) page

Other information: At or below 110°F (43°C) may discolor certain fabrics or surfaces

Inactive ingredients: Purified Water (Aqua), Glycerol, Hydrogen Peroxide



(800) 431-2072 (845) 356-5530 www.uspoly.com



POLYSAN

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76644-0002
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	ISOPROPYL ALCOHOL	2.839 L in 3.785 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.0549 L in 3.785 L
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.00473 L in 3.785 L
WATER (UNII: 059QF0KO0R)	0.886 L in 3.785 L

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:76644- 0002-1	3.785 L in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	08/12/2020	
	, NDC:76644-	0.946 L in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-	N 8 /12 /2 N 2 N	

	nckage	00/12/2020	
Marketing Information			
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not fin	al part333A	08/12/2020	

Labeler - US Polychemical Holding Corporation (078395539)

Registrant - US Polychemical Holding Corporation (078395539)

Establishment			
Name	Address	ID/FEI	Business Operations
US Polychemical Holding Corporation		078395539	manufacture(76644-0002), pack(76644-0002), label(76644-0002), repack(76644-0002), relabel(76644-0002)

Revised: 8/2020 US Polychemical Holding Corporation