

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.

POLY•SAN AntiMicrobial HAND SANITIZER	
Drug Facts	
Active Ingredient	Purpose
Isopropanol 75%(v/v)	Antimicrobial
Use: Hand sanitizer to help reduce bacteria on skin	
Warnings	
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	
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°F (43°C) may discolor certain fabrics or surfaces	
Inactive Ingredients: Purified Water (Aqua), Glycerol, Hydrogen Peroxide	



U.S. POLYCHEMICAL CORPORATION



1 Quart (0.946L)

POLY•SAN
AntiMicrobial **HAND SANITIZER**

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POLYCHEM

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EXECUTIVE OFFICES • PLANT • LABORATORY
584 Chestnut Ridge Road Chestnut Ridge, NY 10977
(800) 431-2072 (845) 356-5530 www.uspoly.com

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

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

Poly San Hand Sanitizer Gallon Size 1.jpg

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Other information: At or below 110°F (43°C) may discolor certain fabrics or surfaces.	
Inactive ingredients: Purified Water (deion), Glycerol, Hydrogen Peroxide.	



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

Poly San Hand Sanitizer Qt size 1.jpg

U.S. POLYCHEMICAL CORPORATION



1 Quart (0.946L)

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POLYSAN

alcohol solution

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	2.839 L in 3.785 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.0549 L in 3.785 L
HYDROGEN PEROXIDE (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
1	NDC:76644-0002-1	3.785 L in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	08/12/2020	
2	NDC:76644-	0.946 L in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-	08/12/2020	

0002-2

Package

08/12/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	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