

**POLY SAN HAND SANITIZER- isopropyl alcohol liquid
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.

**Poly San Liquid Hand Sanitizer
(Isopropyl Alcohol based Hand Sanitizer)**

Poly San Hand Sanitizer; Purpose

Purpose: Antimicrobial

Poly San Hand Sanitizer; Active Ingredient Section

Active Ingredient: Isopropyl Alcohol.....75%(v/v)

Poly San Hand Sanitizer; Indications & Usage Section

Use: □Hand sanitizer tTo help reduce the amount of bacteria on the skin.

Poly San Hand Sanitizer; Do Not Use Section

For external use only, do not use

- on children less than 2 months of age
- on an open skin wound
- in or near the eyes, ears or mouth

In case of contact, rinse eyes thoroughly with water

Poly San Hand Sanitizer; Warnings Section

Warnings: Flammable, keep away from fire or flame.

Poly San Hand Sanitizer Gel; Stop use and ask Doctor if section

Stop use and ask Doctor if □ irritation appears and lasts

Poly San Hand Sanitizer; Keep out of reach of children section

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

Poly San Hand Sanitizer; Dosage & Administration Section

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

Poly San Hand Sanitizer; Inactive Ingredient Section

Inactive ingredients: Water(Aqua), glycerol, Fragrance (Parfum)

Poly San Hand Sanitizer Gel; Other Safety Information

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

Avoid freezing and excessive heat.

Store between 59-86°F (15-30°C).

Poly San Hand Sanitizer Drug Facts Label

The following Hand sanitizer is manufactured according to the 1994 TFM for OTC antiseptic drug products that published in the Federal Register of June 17, 1994 (59 FR 31402).

Drug Facts

Active Ingredient: Isopropanol 75% (v/v) Purpose: Antimicrobial

Use: Hand sanitizer to help reduce bacteria on skin

Warnings: Flammable, keep away from fire or flame.

For external use only, do not use

- on children less than 2 months of age
- on an open skin wound
- in or near the eyes, ears or mouth

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

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

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Store between 59-86°F (15-30°C).

Inactive ingredients: Water(Aqua),glycerol, fragrance (Parfum)

Poly San Hand Sanitizer Gallon Size 1.jpg

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: Water(Aqua), glycerol, fragrance (Parfum)	

U.S. POLYCHEMICAL CORPORATION



1 Gallon

POLY•SAN
AntiMicrobial **HAND SANITIZER**

POLY•CHEM

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

Poly San Hand Sanitizer Qt size 1.jpg

U.S. POLYCHEMICAL CORPORATION

AntiMicrobial
**HAND
SANITIZER**

1 Quart

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

isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76644-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	2.846 L in 3.785 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.86 L in 3.785 L
GLYCERIN (UNII: PDC6A3C0OX)	0.076 L in 3.785 L
COUMARIN (UNII: A4VZ22K1WT)	0.000001445 L in 3.785 L
HEXAMETHYLINDANOPYRAN (UNII: 14170060AT)	0.00001445 L in 3.785 L
TERPINEOL (UNII: R53Q4ZWC99)	0.00001445 L in 3.785 L
BENZYL ACETATE (UNII: 0ECG3V79ZJ)	0.000007225 L in 3.785 L
TERPINYL ACETATE (UNII: NIT9SZT3D7)	0.000007225 L in 3.785 L
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	0.00001445 L in 3.785 L
CINNAMYL ALCOHOL (UNII: SS8YOP444F)	0.000001445 L in 3.785 L
DECANAL (UNII: 31Z90Q7KQJ)	0.000001445 L in 3.785 L
PHENYLACETALDEHYDE (UNII: U8J5PLW9MR)	0.000001445 L in 3.785 L
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	0.000001445 L in 3.785 L
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	0.00001445 L in 3.785 L
GERANIOL (UNII: L837108USY)	0.00001445 L in 3.785 L
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	0.00001445 L in 3.785 L
LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.00000289 L in 3.785 L
4-TERT-BUTYLCYCLOHEXANYL ACETATE, TRANS- (UNII: ATR4EHD017)	0.0000289 L in 3.785 L
EUGENOL (UNII: 3T8H1794QW)	0.000001445 L in 3.785 L
DIHYDROMYRCENOL (UNII: 46L1B02ND9)	0.000001445 L in 3.785 L
LINALYL ACETATE, (+)- (UNII: 3ID3M89AV9)	0.000001445 L in 3.785 L
LIMONENE, (+/-)- (UNII: 9MC3I34447)	0.00000578 L in 3.785 L
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	0.000001445 L in 3.785 L
3,3'-DIHYDROXYDIPROPYL ETHER (UNII: S1OQ81LMNA)	0.00007225 L in 3.785 L

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76644-0001-1	3.785 L in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	06/12/2020	
2	NDC:76644-0001-2	0.946 L in 1 BOTTLE, SPRAY; Type 1: Convenience Kit of Co-Package	06/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/08/2020	

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(76644-0001) , label(76644-0001) , pack(76644-0001) , repack(76644-0001)

Revised: 4/2020

US Polychemical Holding Corporation