PURLEAN HAND SANITIZER- isopropyl alcohol gel
Triden Systems, Inc.

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 institute of personal care science.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients.

a. Isopropyl Alcohol (70% w/w) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. 1,3 Propanediol (5.0% w/w).
c. Sepimax Zen (1.2% w/w).
d. Sterile distilled water

The firm does not add other active or inactive ingredients.

Active Ingredient(s)

Isopropyl Alcohol 70% w/w. 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

1,3 Propanediol, Sepimax Zen, purified water USP

Package Label - Principal Display Panel

30 ml NDC: 79046-001-01


MADE IN THE USA
PURLEAN
HAND SANITIZER
ADVANCED FORMULA
ANTISEPTIC
TOPICAL
SOLUTION
KILLS 99.99% OF GERMS
30ml (1oz)


Drug Facts
Active ingredient[s]
Isopropyl alcohol 75% w/v
Purpose
Antiseptic
Use[s]
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
Warnings
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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, Triethanolamine, Sepimax Zen, Aloe Vera Fillet Juice, Carrageenan, Citric Acid, Potassium Sorbate, Purified Water
Dist. by Trident Systems Inc San Diego, CA 92123
Questions? Call 1-844-5Trident

PURLEAN HAND SANITIZER

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79046-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	70 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
Propanediol (UNII: 5965N8W85T)	5 g in 100 g
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	1.2 g in 100 g
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79046-001-01	1 g in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/29/2020	

Labeler - Triden Systems, Inc. (081302292)

Establishment

Name	Address	ID/FEI	Business Operations
Triden Systems, Inc.		081302292	manufacture(79046-001)

Revised: 6/2020 Triden Systems, Inc.