

PURENIQUE HYGIENE SOLUTIONS HAND SANITIZER- alcohol liquid
JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.

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.

Drug Fact

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Uses

- Hand sanitizer to help decrease virus on the skin when water, soap and towel are not available.
- recommended for repeated use.

Warnings

For external use only. Avoid contact with the wound. Do not allow this product to come into contact with eyes or nearby.

If you accidentally touch a wound or eye, rinse immediately with water.

If skin irritation or sensitivity occurs, discontinue use and consult your doctor immediately.

Not recommended for infants.

Other information:

Store at 20°-68° to 77° in a cool place. May discolor fabrics.

Keep out of reach of children.

Do not allow children under 6 years of age to handle or apply this product. If swallowed, contact your doctor immediately.

Directions

No water needed. Apply a small amount of product to dry skin.

Inactive Ingredients

Pure Water, Glycerine, Carbomer, Triethanolamine, Disodium EDTA

Product Labeling

Hand Sanitizer



0.17 fl.oz. (5 ML)

Drug Facts:

Active Ingredients.....Purpose
Ethyl Alcohol 62%.....Antiseptic

Warnings:

For external use only. Avoid contact with the wound. Do not allow this product to come into contact with eyes or nearby. If you accidentally touch a wound or eye, rinse immediately with water. If skin irritation or sensitivity occurs, discontinue use and consult your doctor immediately. Not recommended for infants. Keep out of reach of children. Do not allow children under 6 years of age to handle or apply this product. If swallowed, contact your doctor immediately.

Uses:

Hand sanitizer to help decrease virus on the skin when water, soap, and towel are not available. Recommended for repeated use.

Directions:

No water needed. Apply a small amount of product to dry skin.

Other Information:

Store at 20°C (68 to 77°F) in a cool place. May discolor fabrics.

Inactive Ingredients

Pure water, Glycerine, Carbomer, Triethanolamine, Disodium EDTA

**Manufactured for Purenique
Hygiene Solutions by Fits Inc.
Made in China**

PURENIQUE HYGIENE SOLUTIONS HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71734-329
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71734-329-01	5 mL in 1 DOSE PACK; Type 0: Not a Combination Product	09/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/25/2020	

Labeler - JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD. (544530534)**Establishment**

Name	Address	ID/FEI	Business Operations
JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.		544530534	manufacture(71734-329)

Revised: 9/2020

JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.