

ANTIBACTERIAL 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 Facts

Active ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Use

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

Warnings

For external use only.

Flammable, keep away from fire or flame

Do not use in ears and mouth

When using this product, avoid contact with eyes. In case of contact flush eyes with water.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

Keep out of reach of children.

Children must be supervised in use of this product.

Directions

- Pump as needed into your palms and thoroughly spread on both hands.
- Rub into skin until dry.

Inactive ingredients

Purified Water, Glycerin, Carbomer, Triethanolamine, Disodium EDTA

Other Information

- Store at 20 ° (68 to 77 °)
- May discolor fabrics.

Packaging

Columbia Sussex

Antibacterial Hand Sanitizer

1.7 fl. oz. (50 ml)

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Ethyl Alcohol 62% Antiseptic

Use • hand sanitizer to help decrease bacteria on the skin • when water, soap & towel are not available • recommended for repeated use

Warnings For external use only
Flammable. Keep away from fire or flame
Do not apply around eyes.
Do not use in ears & mouth
When using this product, avoid contact with eyes. In case of contact flush eyes with water.
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours
Keep out of reach of children. Children must be supervised in use of this product.

Directions • pump as needed into your palms and thoroughly spread on both hands
• rub into skin until dry

Other information • store at 20 °C (68 °F to 77 °F). • may discolor fabrics

Inactive Ingredients
Purified water, triethanolamine, glycerine, Disodium EDTA, carbomer

Made in China

ANTIBACTERIAL HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71734-319
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
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71734-319-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/04/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.		544530534	manufacture(71734-319)

Revised: 7/2020

JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.