

COMIX ALCOHOL HAND SANITIZER- alcohol gel
Shantou Shengmei Biotechnology 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.

Comix Alcohol Hand Sanitizer

Active Ingredient

Ethyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Uses

Helps reduce bacteria on the skin

Warnings

For external use only. Flammable. Keep away from heat or flame.

Do not use

on children less than 6 months of age

When using this product

do not use in or near the eyes. In case of contact with eyes, rinse eyes thoroughly with water. Avoid contact with broken skin.

Stop use and ask 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

Apply product onto hands and rub until dry. Children under 6 years old under adult supervision.

Other information

Store below 105F (40F). * This product can effectively kill 99.99% Escherichia coli, Staphylococcus aureus, Candida albicans, Pseudomonas aeruginosa under experimental conditions. These results are for reference only.

Inactive ingredients

Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Parfum, Aminomethyl Propanol, Hydrolyzed Jojoba Esters, Aloe Barbadensis Leaf Juice Powder, Citric Acid

55450-010-01 500mL

Comix

75% Alcohol

HAND

SANITIZER

Kills 99.99% of Germs*

Non-sterile Solution

L914

16.9FL OZ (500mL)

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 75%w/v	Antiseptic

Uses : Helps reduce bacteria on the skin.

Warnings : For external use only. Flammable. Keep away from fire or flame.

Do not use: on children less than 6 months of age.

When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Avoid contact with broken skin.

Stop use and ask 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 : Apply product onto hands and rub until dry. Children under 6 years old under adult supervision.

Other information : Store below 104 °F(40°C). * This product can effectively kill 99.99% Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa under experimental conditions. The results are for reference only.

Inactive ingredients : Water, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Hydrolyzed Jojoba Esters, Aloe Barbadensis Leaf Juice Powder, Citric Acid, Aminomethyl Propanol, Parfum

[Company] Shenzhen COMIX Group Co., Ltd.
[Company Address] 05-06,17/F,Block A,World Trade Plaza, Fuhong Road,Shenzhen,Guangdong Province, P.R.China
[Manufacturer] Shantou Shengmei Biotechnology Co., Ltd.
[Manufacturer Address] 2nd floor, North side,Jiudouyang, taowaijinglianshe, Taoxi neighborhood committee, Xiashan street, Chaonan District, Shantou City, Guangdong Province
[Valid Period] 2-Year (see bottle bottom)




COMIX ALCOHOL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55450-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55450-010-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/20/2020	

Labeler - Shantou Shengmei Biotechnology Co., Ltd. (554528509)

Establishment

Name	Address	ID/FEI	Business Operations
Shantou Shengmei Biotechnology Co., Ltd.		554528509	manufacture(55450-010) , label(55450-010)

Revised: 8/2020

Shantou Shengmei Biotechnology Co., Ltd.