HAND SANITIZER- alcohol gel Guangzhou Xujohn Bio-Technique 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.

Active Ingredient(s)

Alcohol 70% v/v. 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

Aqua,glycerin,lactose,microcrystalline cellulose,sucrose,zea mays starch,hydroxypropyl methylcellulose,

Package Label - Principal Display Panel

500 mL NDC: 75351-010-01





70% ALCOHOL ADVANCED HAND SANITIZER

Features: 100% brand new and high quality maintaining clean hands is very important to prevent the spread of germs. Quickly kill microorganisms on your hands without irritating or drying out your skin. The hand sanitizer will leave your hands clean while smelling great. The hand sanitizer will leave your hands feeling smooth and refreshed. Use it at your office, home, in your car, school or anywhere else you need to quickly clean your hands.

Main ingredients: Alcohol/70%), aqua, glycerin, lactose, microcrystalline cellulose, sucrose, zea mays starch, hydroxypropyl methylcellulose, mica, acrylatesic 10-30 alkyl acrylate crosspolymer, triethanolamine, ci 77491 ci 77891.

Vses:To decrease bacteria on the skin that could cause disease Recommended for repeated use.

Recommended for repeated use.

Directions: Squeeze proper amount of hand washing into the pain rub your hands together until your hands dry, and do not need to rins with water. For children under 6, use only under adult supervision.

Warning-Flammable, Keep away from fire or flame. For external use only keep out of eyes. In case of contact with eyes, flush thoroughly with water avoid contact with broken skin; do not inhale or ringest.

Stop use and ask a doctor if-irritation and redness develop; condition persists for more than 72 hours. Keep out of reach of children! It swallowed, get medical help or contact a poison control center right away.











HAND SANITIZER

alcohol gel

Product Information

HUMAN OTC DRUG NDC:75351-010 Product Type Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
SUCROSE (UNII: C151H8 M554)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
TROLAMINE (UNII: 9O3K93S3TK)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
MICA (UNII: V8A1AW0880)				
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)				

GLYCERIN (UNII: PDC6A3C0OX)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
WATER (UNII: 059QF0KO0R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NE 01	OC:75351-010-	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	03/30/2020			

Labeler - Guangzhou Xujohn Bio-Technique Co., Ltd. (403308789)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guangzhou Xujohn Bio-Technique Co., Ltd.		403308789	manufacture(75351-010)	

Revised: 4/2020 Guangzhou Xujohn Bio-Technique Co., Ltd.