

HAND SANITIZER- alcohol liquid
Jadpro, 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.

Hand Sanitizer 75% 100 mL

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 75% 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

Glycerin, Carbomer, purified water USP, Aloe Vera Leaf, Triethanolamine

Package Label - Principal Display Panel

115X75mm

Aladeno®

**SOOTHE
RINSE FREE
HAND SANITIZER**

**75%
Alcohol
Denat.**

**KILLS MORE THAN 99.99%
KINDS OF GERMS**

Net: 100ml

⊙ Bacteriostatic
⊙ Skin Care Formula

Kills more than 99.99% of kinds of germs
Simple, fast and effective, with no need for soap or water. The rinse free, non-sticky formula makes it a great hygiene solution for mums and families needing on-the-go protection, no matter where you are in your busy day.

INGREDIENTS: aqua, glycerin, carbomer, ethyl alcohol, aloe vera extract

STORAGE INSTRUCTIONS: Store below 30°C

USAGE INFORMATION: Apply appropriate amount of instant hand sanitizer to the palm, the back of the hand, thoroughly knead

CAUTION: HIGHLY FLAMMABLE Keep away from fire or flames. For external use only. Avoid eyes.

KEEP OUT OF REACH OF CHILDREN

FIRST AID: In case of eye contact, flush with water. Discontinue use if skin irritation occurs. If condition persists consult a doctor. If swallowed, contact the Poisons Information Centre or visit your doctor.

JIAOZI CHEMICAL(GUANGZHOU)Pty.Ltd.
Address: 1-3 floor, NO19, Yinbian west street, Helong street, Baiyun district, Guangzhou
Model: Q/JZRH 11-2019

CE FARA

100 mL NDC: 78365-000-01

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78365-000
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
TROLAMINE (UNII: 9O3K93S3TK)	0.5 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	18.5 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78365-000-01	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - Jadpro, Inc. (117533274)

Registrant - Jadpro, Inc. (117533274)

Establishment

Name	Address	ID/FEI	Business Operations
JIAOZI CHEMICAL (GUANGZHOU) PTY LTD		679755413	manufacture(78365-000)

Revised: 5/2020

Jadpro, Inc.