

HAND SANITIZER- alcohol liquid

UMED PHARMA LAB PRIVATE LIMITED

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.

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 80% 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, hydrogen peroxide, purified water USP

Maximum 100000000 mL in 1 CONTAINER (82414-001-01)

UMED PHARMA LAB PRIVATE LIMITED		Drugs Facts
HAND SANITIZER 80 % Alcohol <hr/> Kills 99.99% of germs <hr/> 2.36 oz (70mL) Lot MFD date: Manufactured By: UMED PHARMA LAB PRIVATE LIMITED. Address: Plot No.G30/2, General Park, IP, Sultanpur Village 502319 Sangareddy India	Active Ingredient Ethyl Alcohol , 70%	Purpose Antimicrobial
	Uses Hand sanitizer to help reduce bacteria on the skin.	
	Warnings Flammable. Keep away from fire or flame. For external use only	
	When use this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask a 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.	
	Drug Facts (cont.) Directions Put enough product in your palm to cover hands and rub hands together briskly until dry. Kills more than 99.99% of most common germs that may make you sick. Children under 6 years of age should supervised when using product.	
Other information Store below 110° F(43°C). May discolor certain fabrics or surfaces		
Storage : Store in a Cool Place		
Shelf Life : 24 Months		
DUNS : 854220531		

80 mL NDC: 82414-001-01

HAND SANITIZER alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82414-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82414-001-01	80 mL in 1 BOTTLE; 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 - UMED PHARMA LAB PRIVATE LIMITED (565277252)

Registrant - UMED PHARMA LAB PRIVATE LIMITED (565277252)

Establishment

Name	Address	ID/FEI	Business Operations
UMED PHARMA LAB PRIVATE LIMITED		565277252	manufacture(82414-001)

Revised: 11/2021

UMED PHARMA LAB PRIVATE LIMITED