

HAND SANITIZER- ethyl alcohol gel

Enter Labeler Name

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. Isopropyl Alcohol (75%, 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)

Isopropyl 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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

500 ml NDC: 76888-001-06

ydby
NON-WATER WASHING
ANTIBACTERIAL HAND WASHING GEL
PREVENTION
OF CROSS INFECTION

Non-irritating
Antibacterial,
Non-toxic
And Harmless
Available for
pregnant
women and children

Net: 500ml/16.91 fl.oz

Use without water
 Suitable for both children and adults
 Clean and non-greasy (formula)
 Mild and moisturizing

ydby

RANGE OF USAGE: for hand skin disinfection

USAGE:
Apply proper amount to palms. Evenly apply to hands and knead until hands are dry. Don't need to rinse.

INGREDIENT:
ALCOHOL75%, WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, ALOE YOHJYU MATSU EKISU

WARNING
1. Non-edible; Oral administration is not allowed; Rinse with water if splash into eyes accidentally.
2. Flammable; Keep away from fire and store in cool place.
3. Keep out of the reach of infants and babies.
4. In case of anaphylaxis, please stop using immediately. In serious cases, please seek medical advice.

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Made in China

EXECUTIVE STANDARD: GB 15979
EXPIRATION DATE: 24MONTHS

BATCH NO: F0080/0001
EXP: 2022/03/20

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HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76888-001
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
CARBOMER 934 (UNII: Z135WT9208)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76888-001-06	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/20/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/20/2020	

Labeler - Enter Labeler Name (403362142)

Establishment			
Name	Address	ID/FEI	Business Operations
Guangdong Meishanlian Cosmetics Co.,Ltd		403362142	manufacture(76888-001)

Revised: 6/2020

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