

DISINFECTING WIPES- alcohol cloth
Fuan HnH Bio Tech 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.

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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away.

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

79681-006-06

Kills 99.99% of most common germs that may make you sick

- Helps reduce the risk of infections
- Leaves no stickiness or residue
- Removes light soil and dirt
- Recommended for frequent use
- Does not contain bleach or ammonia

Inactive ingredients
Phenoxyethanol, Ethylhexylglycerin,
Benzalkonium Chloride, D,DAC,
Propylene Glycol, Glycerin,
Purified Water, Spunlace Nonwoven

TMD
INDUSTRIAL
Disinfecting Wipes

160 Wipes

MFG: 15062020

8 43944 15431 2

Drug Facts
Active ingredient
Isopropanol 15%
Ethanol 7.5%
Ethylene Glycol Monobutyl Ether (2-Butoxyethanol) ... 1-5%
Didecyl Dimethyl Ammonium Chloride 0.76%

Use
• For hand washing to decrease bacteria on the skin
• Recommended for frequent use


Warnings
Flammable. Keep away from fire or flame.
For external use only.
When using 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 right away.

Directions
• It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
• Wipe hand with wipe. Let air dry. Discard used wipe in trash. Do not flush in toilet.

Other information
• Store below 110°F (43°C)
• May discolor certain fabrics

To Open Package:
• Flip open dispensing cap and remove entire lid from canister by lifting upward.
• Locate wipe at center of roll, twist corner to a point and thread through small opening in lid.
DO NOT PUSH FINGER THROUGH OPENING.
• Replace lid and pull sheet up at an angle. Remaining wipes feed automatically.
• When finished, snap lid cap shut to retain moisture.

MADE IN CHINA
Manufacturer
Fuan Hei Bio Tech co., Ltd.
No. 8, Shanzhen
Sudi Village, Moyang Town,
Fuan, Fujian, China



DISINFECTING WIPES

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79681-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	15 mg in 100 mg
2-BUTOXYETHANOL (UNII: I0P9XEZ9WV) (2-BUTOXYETHANOL - UNII:I0P9XEZ9WV)	2-BUTOXYETHANOL	1 mg in 100 mg
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.76 mg in 100 mg
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	7.5 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79681-006-01	30 mg in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:79681-006-02	50 mg in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:79681-006-03	70 mg in 1 BAG; Type 0: Not a Combination Product	03/30/2020	
4	NDC:79681-006-05	100 mg in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
5	NDC:79681-006-04	70 mg in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	
6	NDC:79681-006-06	160 mg in 1 CANISTER; 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 - Fuan HnH Bio Tech Co., Ltd. (415711361)

Establishment

Name	Address	ID/FEI	Business Operations
Fuan HnH Bio Tech Co., Ltd.		415711361	manufacture(79681-006)

Revised: 7/2020

Fuan HnH Bio Tech Co., Ltd.