

HAND SANITIZER- alcohol gel

AT Bio Pharm 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.

Hand Sanitizer

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.

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.

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

Water, Glycerin, Carbomer, Triethanolamine, Butylene Glycol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Paeonia Suffruticosa Bark Extract, Aloe Barbadensis Leaf Extract, Calendula Officinalis Flower Extract

Package Label - Principal Display Panel

500 mL in 1 Bottle ND

Active ingredient	Purpose
Ethyl Alcohol, 75% v/v	Antiseptic

Uses instant hand antiseptic to reduce bacteria that potentially can cause disease

- instant hand antiseptic to decrease bacteria on the skin
- recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or flames.

When using this product keep out of eyes. If contact with eyes occurs, rinse promptly and thoroughly with water.

Stop use and ask a doctor if significant irritation or sensitization develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.

- Supervise children in the use of this product.

Other information Store at 1-30°C (33.8-86°F)

Inactive ingredient

Water, Glycerin, Carbomer, Triethanolamine, Butylene Glycol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Paeonia Suffruticosa Bark Extract, Aloe Barbadensis Leaf Extract, Calendula Officinalis Flower Extract

Question? Call 1-82-70-4207-3533 (Mon to Fri 9am-6pm)

Made in Korea
Manufacturer: AT Bio Pharm Co., Ltd.
255, Sandan-ro, Pyeongsok-si, Gyeonggi-do, Republic of Korea
Seller: S.J. International Co., Ltd.
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73932-0018-1

C:

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73932-0018
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
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73932-0018-1	500 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 - AT Bio Pharm Co Ltd (695742996)

Establishment

Name	Address	ID/FEI	Business Operations
AT Bio Pharm Co Ltd		695742996	manufacture(73932-0018)

Revised: 3/2021

AT Bio Pharm Co Ltd