

HAND SANITIZER- ethyl alcohol gel
Audy Global Enterprises 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.

Active Ingredient(s)

Ethyl Alcohol 75% v/v. Purpose: Antimicrobial

Purpose: Antimicrobial

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

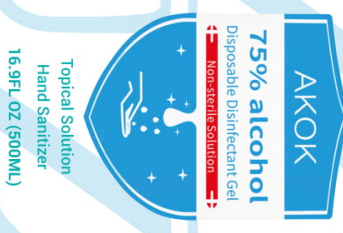
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water (Aqua) , Glycerin, Carbomer, Phenoxyethanol, Aminomethyl propanol

Package Label - Principal Display Panel

500 ml NDC: 75778-001-50



AKOK

DRUG FACTS	
Active ingredient	Ethyl Alcohol 75% v/v Antimicrobial
Purpose	Antimicrobial
Use	• Hand Sanitizer to help reduce bacteria on the skin
Warnings	Flammable, keep away from fire or flame. For external use only
Do not use	• Children less than 2 months of age • On Open Skin Wounds
When using this products 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.	
Stop use and ask a doctor if irritation or rash appears and lasts	
Directions	• Put enough product in your palm to cover hands and rub hands together briskly until dry • Children under 6 years of age should be supervised when using AKOK.
Other information	• Store between 69-89° F (15-30°C) • May discolor certain fabrics or surfaces • Avoid freezing and excessive heat above 104° F (40°C)
Inactive ingredients:	Water (Aqua), Glycerin, Carbomer, Phenoxyethanol, Ammoniumly propand

Distributed by: Kaid Global Enterprises Inc.
1866 Commonwealth Ave, Boston, MA 02135-5013 United States
Address: No. 81 Fenyong Road, Building 71, Shuangping Dongjiao Economic Development Zone,
Cangshan District, Guangzhou.

Made in China
If any complaint, call
6 972251 656948
LOT: 20200328
MFG: 28/03/2020
EXP: 27/03/2022

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75778-001
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
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.5 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	20.9 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75778-001-50	500 mL in 1 BOTTLE, DISPENSING; 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	03/28/2020	

Labeler - Audy Global Enterprises Inc. (079171473)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Pinshang Biotechnology Development Co.,Ltd.		554530020	manufacture(75778-001)

Revised: 4/2020

Audy Global Enterprises Inc.