HAND SANITIZER WIPES- ethyl alcohol solution 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

Sanitizer Wipes 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. (800)222-1222

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

- Wipe surface to be disinfected.
- 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, Water

Package Label - Principal Display Panel

500 ml NDC: 75778-002-60

DRUG FACTS

Active Ingredient

Ethyl Alcohol 75% v/v -

Purpose

- Antimicrobial

Use

 Sanitizer Wipes 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.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. (800) 222-1222

Do not use

- On 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.

Inactive Ingredients: Glycerin, Water

Directions

- · Wipe surface to be disinfected.
- 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)

Distrubuted by: Audy Global Enterprises Inc. 1457 VFW Pkwy, West Roxbury, MA 02132, United States



For Any Concerns Contact Us at: (617) 379-0023 customerservice@audyglobal.com

ethyl alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75778-002	
Route of Administration	TOPICAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 in 100		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)	24.8		
GLYCERIN (UNII: PDC6A3C0OX)	0.2		

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:75778-002-60	60 in 1 CARTON; 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	
Imperial Palace Commodity(Dongguan) CO LTD.		544367643	manufacture(75778-002)	

Revised: 4/2020 Audy Global Enterprises Inc.