

ZEPOL- ethyl alcohol gel
DILE ENTERPRISES LLC

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.

Ethyl Alcohol 65% v/v. Purpose: Antiseptic

Antisptic, Hand Sanitizer

Flammable. Keep away from fire or flame. For external use.

In children less than 2 months of age

On open skin wounds

Do not use in eyes. In case of contact with eyes, rinse with water.

Stop use and ask a doctor if irritation or rash occurs.

If swallowed, get medical help promptly.

Place enough product on hands to cover all surface. Rub hands together until dry.

Supervise children under 6 years of age when using this product to avoid swallowing

Store between 15-30C (59-89F)

For handwashing to decrease bacteria for the skin.

Water, carbomer, isopropyl alcohol, triethanolamine

Drug Facts

NDC 79198-656-01

Active Ingredients**Purpose**

Ethyl Alcohol 65% v/v.....Antiseptic

Use

Hand Sanitizer to Help reduce bacteria that potentially can cause disease.
For use when soap and water are not available.

Warnings

Flammable. Keep away from fire or flame. For external use.

Do not use

- *In children less than 2 month of age.
- *On open skin wounds.

When using this product

Do not use in eyes. In case of contact with eyes, rinse with water

Stop use and ask a doctor if

Stop use and ask a doctor if irritation or rash occurs.

Keep out of reach of children.

If swallowed, get medical help promptly

Directions

Place enough product on hand 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)

Inactive ingredients

Water, carbomer, isopropyl alcohol, triethanolamine

3.785L NDC 79198-656-01

ZEPOL

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79 198-656
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
FENOPROP TRIETHANOLAMINE (UNII: 2F3CU8K84U)	
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79198-656-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	06/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/22/2020	

Labeler - DILE ENTERPRISES LLC (117555202)

Establishment

Name	Address	ID/FEI	Business Operations
DILE ENTERPRISE LLC		117555202	manufacture(79198-656)

Revised: 6/2020

DILE ENTERPRISES LLC