

LIMPIEL- ethyl alcohol gel
Ecodeli Comercial SA de CV

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.

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.

Warnings

For external use only. Flammable. Keep away from heat of flame.

Inactive Ingredients

Water, propylene glycol, glycerin, polyacrylic acid, triethanolamine.

Use

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

If swallowed, get medical help or contact a Poison Control Center right away.

Purpose

Antiseptic, hand sanitizer

Active Ingredient(s)

Ethyl alcohol 75 % v/v

Do not use

In children less than 2 months of age

On open skin wounds

Keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

If irritation or rash occurs. These may be signs of a serious condition.

Store between 15-30 °C (59-86 °F)

Avoid freezing and excessive heat above 40 °C (104 °F)

Package label Principal Display Panel



Limpiel

Hand Sanitizer

Ethyl Alcohol 75%

Topical

1.33 gal (166.6 fl oz) (5L)

Drug Facts	
Active ingredient[s]	Purpose
Ethyl alcohol 75% v/v	Antiseptic
Use[s]	
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	
<ul style="list-style-type: none"> 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.	
Directions	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> Store between 15 30C (59 86F) Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients water, propylene glycol, glycerin, polyacrylic acid, triethanolamine	

Manufactured by: Ecodeli Comercial, S.A. de C.V. Av. Restauradores Ote. #1001 Bodega 2 Fracc. Los Arcos Z.C. 37490 León , Gto, México



5000 ml NDC 76880-001-01

LIMPIEL			
ethyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76880-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	0.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	20.2 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76880-001-01	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - Ecodeli Comercial SA de CV (588530951)

Registrant - Ecodeli Comercial SA de CV (588530951)

Establishment

Name	Address	ID/FEI	Business Operations
Ecodeli Comercial SA de CV		588530951	manufacture(76880-001)

Revised: 4/2020

Ecodeli Comercial SA de CV