

HAND SANITIZER- ethyl alcohol gel
Laboratorios Descaa Mexico, S.A. de C.V

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

Active Ingredient

Ethyl Alcohol 70%

Pupose

Antimicrobial

Warnings

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

Do not ingest, if swallowed seek medical help. Avoid contact with eyes.

Keep out of reach of children.

Children under 6 years old to use under adult supervision. In case of irritation, discontinue use and consult your doctor.

May discolor certain fabrics or surfaces. Store below 106°F

Directions

Apply the gel on the hands and rub gently for 20 seconds until the product evaporates

Inactive Ingredients

Distilled Water, Glycerin, Carbomer, Aminomethyl propanol, Fragrance

Product Label

Hand Sanitizer

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% v/v.....	Antimicrobial

Use: Hand sanitizer to help reduce bacteria on the skin.

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MANUFACTURED IN MÉXICO BY
Fuego Envasado S.A. de C.V.,
Aluminio 7 Fraccionamiento Esfuerzo
Nacional, Xalostoc, Estado de México,
C.P. 55320

L: MM0520-1 • ASI # 56420 • 33.8 fl oz (1 L)

Hand Sanitizer

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L: MM0520-1 • ASI # 56420 • 2.03 fl oz (60 ml)

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78325-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78325-001-01	60 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/15/2020	
2	NDC:78325-001-02	1000 mL in 1 PACKAGE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/2020	

Labeler - Laboratorios Descaa Mexico, S.A. de C.V (951577674)**Establishment**

Name	Address	ID/FEI	Business Operations
Laboratorios Descaa Mexico, S.A. de C.V		951577674	manufacture(78325-001)

Revised: 7/2020

Laboratorios Descaa Mexico, S.A. de C.V