

HAND SANITIZER- alcohol gel
Quimica Magna de 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

Drug Facts

Active Ingredient(s)

Alcohol 62% v/v. Purpose: Antiseptic

Purpose

Antiseptic

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, Carbomer, Triethanolamine

Package Label - Principal Display Panel

**Alcohol Antiseptic 62%
Topical Solution**

Hand Sanitizer

60 mL / 2 fl oz

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Product of Mexico | Made By Quimica Magna de México S.A de C.V. Saltillo, Coah. 25298

60 mL NDC: 74844-162-02

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74844-162
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL	
Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER 940 (UNII: 4Q93RCW27E)			
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0K00R)			
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74844-162-02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74844-162-08	220 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74844-162-17	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74844-162-34	1000 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	03/30/2020	

Labeler - Quimica Magna de Mexico, S.A. de C.V. (951576195)

Establishment

Name	Address	ID/FEI	Business Operations
Quimica Magna de Mexico, S.A. de C.V.		951576195	manufacture(74844-162)

Revised: 4/2020

Quimica Magna de Mexico, S.A. de C.V.