

**HAND SANITIZER- alcohol gel**  
**Margrey Industrial, 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.*

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**Hand Sanitizer**

Drug Facts

**Active Ingredient(s)**

Alcohol 65% 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**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

# Alcohol Antiseptic 65% Topical Solution

## Hand Sanitizer Non-sterile Solution

130 mL / 4.4 fl oz

<b>Drug Facts</b>	
<b>Active ingredient[s]</b> Alcohol 65% v/v.....	<b>Purpose</b> Antiseptic
<b>Use[s]</b> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b> For external use only. Flammable. Keep away from heat or flame	
<b>Do not use</b> • in children less than 2 months of age • on open skin wounds	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • 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.	
<b>Other information</b> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
<b>Inactive ingredients</b> Carbomer, Triethanolamine, Water	

Product of Mexico | Margrey Industrial, S.A. de C.V. Tlaquepaque, Jalisco 45601

130 mL NDC: 74543-165-04

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74543-165
<b>Route of Administration</b>	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
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74543-165-04	130 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74543-165-08	220 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74543-165-17	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74543-165-	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination	03/30/2020	

34	Product	03/30/2020	
5	NDC:74543-165-02 60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Margrey Industrial, S.A. de C.V. (814572392)

### Establishment

Name	Address	ID/FEI	Business Operations
Margrey Industrial, S.A. de C.V.		814572392	manufacture(74543-165)

Revised: 8/2020

Margrey Industrial, S.A. de C.V.