

## **HAND SANITIZER- alcohol gel**

**Diquisa, 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 Gel**

The hand sanitizer gel is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product.

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (0.2% v/v).
- c. Trolamine (0.15% v/v).
- d. Carbomer (0.3 % )
- e. Sterile distilled water or boiled cold water.

### **Active Ingredient(s)**

Alcohol 70% 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.

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### **Inactive ingredients**

glycerin, trolamine, carbomer, steriled or distilled water

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## 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.

## Package Label - Principal Display Panel

70% Ethyl Alcohol

**HAND  
INSTANT  
SANITIZER**

TOPICAL SOLUTION  
ANTISEPTIC HAND RUB  
NON-STERILE SOLUTION

1 GALLON (128 FL OZ.)

### DRUG FACTS

**Active Ingredients:** Ethyl Alcohol 70%

**Purpose:** Antiseptic

**Uses:** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water not available.

**Warning:** 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, mouth. In case of contact with eyes, rinse thoroughly with water.

**Stop use and ask doctor:** If irritation or rash occurs. These might 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°C-30°C (59°F-86°F). Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients:** Glycerin, Trolamine, Carbomer, Purified Water

Manufactured by:  
DIQUISA, S.A. DE C.V.  
Monterrey, NL, 64630

Contact:  
+52(81)8333-0570

MADE IN MEXICO



1 gallon NDC: 78361-002-04

70% Ethyl Alcohol

# HAND INSTANT SANITIZER

TOPICAL SOLUTION  
ANTISEPTIC HAND RUB  
NON-STERILE SOLUTION

1,000 ML (33.8 FL OZ.)

## DRUG FACTS

**Active Ingredients:** Ethyl Alcohol 70%

**Purpose:** Antiseptic

**Uses:** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water not available.

**Warning:** 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, mouth. In case of contact with eyes, rinse thoroughly with water.

**Stop use and ask doctor:** If irritation or rash occurs. These might 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°C-30°C (59°F-86°F). Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients:** Glycerin, Trolamine, Carbomer, Purified Water

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MADE IN MEXICO



1000 ml NDC 78361-002-06

70% Ethyl Alcohol

# HAND INSTANT SANITIZER

TOPICAL SOLUTION  
ANTISEPTIC HAND RUB  
NON-STERILE SOLUTION

500 ML (16.9 FL OZ.)

## DRUG FACTS

**Active Ingredients:** Ethyl Alcohol 70%

**Purpose:** Antiseptic

**Uses:** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water not available.

**Warning:** 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, mouth. In case of contact with eyes, rinse thoroughly with water.

**Stop use and ask doctor:** If irritation or rash occurs. These might 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°C-30°C (59°F-86°F). Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients:** Glycerin, Trolamine, Carbomer, Purified Water

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MADE IN MEXICO



500 ml NDC 78361-002-07

70% Ethyl Alcohol

# HAND INSTANT SANITIZER

TOPICAL SOLUTION  
ANTISEPTIC HAND RUB  
NON-STERILE SOLUTION

250 ML (8.5 FL OZ.)

## DRUG FACTS

**Active Ingredients:** Ethyl Alcohol 70%

**Purpose:** Antiseptic

**Uses:** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water not available.

**Warning:** 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, mouth. In case of contact with eyes, rinse thoroughly with water.

**Stop use and ask doctor:** If irritation or rash occurs. These might 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°C-30°C (59°F-86°F). Avoid freezing and excessive heat above 40°C (104°F).

**Inactive Ingredients:** Glycerin, Trolamine, Carbomer, Purified Water

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MADE IN MEXICO



250 ml NDC 78361-002-08

70% Ethyl Alcohol

# HAND INSTANT SANITIZER

TOPICAL SOLUTION  
ANTISEPTIC HAND RUB  
NON-STERILE SOLUTION

60 ML (2 FL OZ.)

## DRUG FACTS

**Active Ingredients:** Ethyl Alcohol 70%

**Purpose:** Antiseptic

**Uses:** Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water not available.

**Warning:** 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, mouth. In case of contact with eyes, rinse thoroughly with water.

**Stop use and ask doctor:** If irritation or rash occurs. These might 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 15C°-30C° (59F°-86F°) Avoid freezing and excessive heat above 40C° (104F°).

**Inactive Ingredients:** Glycerin, Trolamine, Carbomer, Purified Water

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MADE IN MEXICO



60 ml NDC 78361-002-09

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78361-002
<b>Route of Administration</b>	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)	0.3 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.1 mL in 100 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.4 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78361-002-05	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78361-002-06	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78361-002-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78361-002-08	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:78361-002-09	60 mL in 1 BOTTLE; 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** - Diquisa, S.A. de C.V (815736509)**Establishment**

Name	Address	ID/FEI	Business Operations
Diquisa, S.A. de C.V.		815736509	manufacture(78361-002)

Revised: 6/2020

Diquisa, S.A. de C.V