

**HAND SANITIZER- alcohol gel**  
**Química Blantex, 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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**Active Ingredient(s)**

Product: 78342-001 Alcohol 70% v/v. Purpose: Antiseptic

Product: 78342-002 Alcohol 80% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**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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**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**

Product 78342-001: glycerin, carbomer, triethanolamine, purified water USP

Product 78342-002: glycerin, carbomer, triethanolamine, purified water USP

**Package Label - Principal Display Panel**

500 mL NDC: 78342-001-01

**Alcohol Antiseptic 70%  
Gel**

**Antiseptic Hand Rub  
Non-sterile Solution**

**500 ml**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v.....	Antiseptic
<b>Use[s]</b>	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
For external use only. Flammable. Keep away from heat or flame	
Do not use	
<ul style="list-style-type: none"><li>• in children less than 2 months of age</li><li>• on open skin wounds</li></ul>	
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<ul style="list-style-type: none"><li>• Store between 15-30C (59-86F)</li><li>• Avoid freezing and excessive heat above 40C (104F)</li></ul>	
<b>Inactive ingredients</b> glycerin, carbomer, triethanolamine, purified water.	

MADE IN MEXICO  
PRODUCED BY:  
Quimica Blantex S.A. de C.V.  
Circuito de la industria Norte  
123, parque Industrial Lerma,  
Zip Code 52000, Estado de  
Mexico, Mexico.

BLANCARE™

**Alcohol Antiseptic 70%  
Gel**

**Antiseptic Hand Rub  
Non-sterile Solution**

**1,000 lts**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v.....	Antiseptic
<b>Use[s]</b>	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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<b>Inactive ingredients</b> glycerin, carbomer, triethanolamine, deionized water.	

**MADE IN MEXICO**

MANUFACTURED BY:  
Quimica Blantex S.A. de C.V.  
Circuito de la Industria Norte 123,  
Parque Industrial Lerma, Zip  
Code 52000, Estado de Mexico,  
Mexico.

20000 mL NDC: 78342-001-03

**Alcohol Antiseptic 70%  
Gel**

**Antiseptic Hand Rub  
Non-sterile Solution**

**20 lts**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 70% v/v.....	Antiseptic
<b>Use[s]</b>	
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
<b>Warnings</b>	
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Mexico, Mexico.

**Alcohol Antiseptic 80%  
Gel**

**Hand Sanitizer  
Non-sterile Solution**

**500 ml**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	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>	
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Do not use	
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**Alcohol Antiseptic 80%  
Gel**

**Hand Sanitizer  
Non-sterile Solution**

**1,000 lts**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
Alcohol 80% v/v.....	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.	
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**Alcohol Antiseptic 80%  
Gel**

**Hand Sanitizer  
Non-sterile Solution**

**20 lts**

<b>Drug Facts</b>	
<b>Active ingredient[s]</b>	<b>Purpose</b>
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alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78342-001
<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)	1 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	3.5 mL in 100 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	1.5 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78342-001-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78342-001-03	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78342-001-04	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78342-001-02	1000 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	

## HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78342-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		1.5 mL in 100 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)		6.6 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
TROLAMINE (UNII: 9O3K93S3TK)		0.4 mL in 100 mL		
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78342-002-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78342-002-03	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78342-002-04	1000000 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78342-002-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

**Labeler** - Química Blantex, S.A. de C.V. (810400366)

**Registrant** - Química Blantex, S.A. de C.V. (810400366)

### Establishment

Name	Address	ID/FEI	Business Operations
Química Blantex, S.A. de C.V.		810400366	manufacture(78342-001, 78342-002) , label(78342-001, 78342-002)

Revised: 7/2020

Química Blantex, S.A. de C.V.