

**ATALA BIO HAND SANITIZER- didecyldimonium chloride and benzalkonium chloride liquid gel**

**Kemix Quimica, 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)**

DIDECYLDIMONIUM CHLORIDE 0.25 % v/v. Purpose: Antiseptic

BENZALKONIUM CHLORIDE 0.1 % 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. Avoid Eye Contact. Flammable. Keep away from heat or flame. Do not ingest

**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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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, purified water USP, MAGNESIUM DISODIUM EDTA, ISOPROPYL ALCOHOL, METHYL ALCOHOL

## Package Label - Principal Display Panel

4 L NDC: 77396-050-01

**GEL**

**ECO FRIENDLY BIODEGRADABLE BIO**

**ATALA<sup>TM</sup> BIO**

**HANDS SANITIZER**

BROAD-SPECTRUM SANITIZER WITH QUATERNARY AMMONIUM COMPOUNDS

**KILLS 99.9% OF VIRUS & BACTERIA**

**ATALABIO.COM**

**NET CONTENT**  
1.05 GALLON / 4 LT

**KILLS 99.9% OF VIRUS & BACTERIA**

**USES:** Hand sanitizer helps to eliminate bacteria and viruses on the skin when water, soap and towel are not available. Recommended for repeated use.  
Ideal for Restaurants - Hospitals - Schools - Offices - Homes

**DIRECTIONS:** Sanitizer with a wide spectrum of body application. SVA has sanitizing properties that act upon contact with the surface to be treated instantly. Eliminates 99.9% of germs present. Broad spectrum and effective against **Coronavirus, HIV, Hepatitis, among others**. Its balanced active formula achieves a neutral product (balances pH) that does not attack the skin. The product dries quickly into the air in a natural way without leaving traces of liquid or sticky residue and continues to actively fight germs thanks to its residual.

**WARNINGS:** Avoid contact with eyes. In case of contact, immediately wash under running water for at least 15 minutes keeping eyelids open. Remove contact lenses if any.  
In case of ingestion: induce vomiting. Flammable. Keep away from heat and flame.

**STORAGE & TRANSPORTATION:** Keep in a dry and cool place, in its well covered container.

**ACTIVE INGREDIENTS:** Didecyl, Dimethyl Ammonium Chloride and Benzalkonium Chloride.

**OTHER INGREDIENTS:** Water, alcohols, Glycerin, Magnesium Disodium EDTA.

**POLLUTION RATE | INDICE DE CONTAMINACION**

1	2	3	4	5	6	7	8	9	10
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- Color: Transparent Blue
- Odor: Odorless
- Specific Weight: 1.01 kg / lt
- Solubility: 100%
- Presentation: Gel

May cause eye irritation

Manufactured in Mexico  
Imported and distributed by:  
ATALA CARIBE INC. USA  
TEL: 786.542.8510  
**WWW.ATALACARIBE.COM**

**FDA Labeler Code:**

8 1600041589301 3

250 mL (0.25 L) NDC: 77396-050-03

GEL



ATALA<sup>TM</sup>  
BIO

HANDS SANITIZER

BROAD-SPECTRUM SANITIZER WITH  
QUATERNARY AMMONIUM COMPOUNDS

KILLS 99.9% OF VIRUS & BACTERIA

ATALABIO.COM

NET CONTENT  
8.4 FL OZ / 250 ML



KILLS 99.9% OF VIRUS & BACTERIA

**DRUG FACTS**

Active Ingredients	Purpose
• Didecyl Dimethyl Ammonium Chloride 0.25%.....	Antiseptic
• Benzalkonium Chloride 0.1%.....	Antiseptic

- Uses**
- Hand sanitizer helps to eliminate bacteria and viruses on the skin when water, soap and towel are not available.
  - Recommended for repeated use.

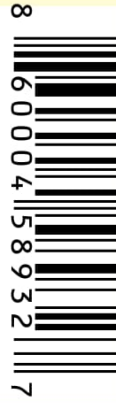
- Warnings**  
**For external use only.**
- Avoid eye contact.
  - Do not ingest.
  - Avoid contact with skin wounds.
  - Flammable. Keep away from heat and flame.

- When using this product**
- In case of eye contact, remove contact lenses and immediately flush with running water for at least 15 minutes, holding eyelids open.
  - If swallowed: Do not induce vomiting, get medical help or contact a Poison Control Center immediately.
  - Keep out of reach of children. Children must be supervised when using this product.

**Stop use and ask doctor if redness or irritation develops and persists for more than 72 hours.**

- Directions**
- Hands: Apply a generous amount and rub until is fully absorbed.

- Inactive Ingredients**
- Water, Alcohols, Glycerin, Triethanolamine



Manufactured in Mexico  
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ATALA CARIBE INC USA  
TEL: 786.542.8510  
WWW.ATALACARIBE.COM  
FDA Labeler Code:

Specially designed for high levels of disinfection, suitable for cleaning hands and body. Ideal for areas where safety is required, eliminating up to 99.9% of germs within 30 seconds of application. Highly effective against viruses such as CORONAVIRUS, HIV, INFLUENZA, (H1N1), HERPES, and others. Solution dries quickly, naturally without leaving traces of liquid or sticky residue, no rinsing required; with moisturizing, emollient and pH-balanced properties.

75 mL (0.075 L) NDC: 77396-050-02



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 ATALA CARIBE INC. USA  
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 WWW.ATALACARIBE.COM  
 FDA Labeler Code:

Specially designed for high levels of disinfection, suitable for cleaning hands and body. Ideal for areas where safety is required, eliminating up to 99.9% of germs within 30 seconds of application.

Highly effective against viruses such as CORONAVIRUS, HIV, INFLUENZA, (H1N1), HEPATITIS and others. Solution dries quickly, naturally without leaving traces of liquid or sticky residue, no rinsing required; with moisturizing, emollient and pH-balanced properties.



GEL



ATALA<sup>TM</sup>  
 BIO

HANDS SANITIZER  
 BROAD-SPECTRUM SANITIZER WITH  
 QUATERNARY AMMONIUM COMPOUNDS

KILLS 99.9% OF VIRUS & BACTERIA

ATALABIO.COM

2.5 FL OZ / 75 ML



KILLS 99.9% OF VIRUS & BACTERIA

**DRUG FACTS**

Active Ingredients	Purpose
• Didecyl Dimethyl Ammonium Chloride 0.25%.....	Antiseptic
• Benzalkonium Chloride 0.1%.....	Antiseptic

Uses
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• Avoid eye contact.
• Do not ingest.
• Avoid contact with skin wounds.
• Flammable. Keep away from heat and flame.

When using this product
• In case of eye contact, remove contact lenses and immediately flush with running water for at least 15 minutes, holding eyelids open.
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• Keep out of reach of children. Children must be supervised when using this product.

Stop use and ask doctor if redness or irritation develops and persists for more than 72 hours.
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Inactive Ingredients
• Water, Alcohols, Glycerin, Triethanolamine

**ATALA BIO HAND SANITIZER**

didecyldimonium chloride and benzalkonium chloride liquid gel

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77396-050
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIDECYLDIMONIUM CHLORIDE</b> (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	2.5 mg in 0.001 L
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 0.001 L

**Inactive Ingredients**

Ingredient Name	Strength
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM DISODIUM EDTA</b> (UNII: NDT563S5VZ)	
<b>WATER</b> (UNII: 059QF0K00R)	

GLYCERIN (UNII: PDC6A3C00X)

METHYL ALCOHOL (UNII: Y4S76JWI15)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77396-050-01	4 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
2	NDC:77396-050-02	0.075 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	
3	NDC:77396-050-03	0.25 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/01/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

**Labeler** - Kemix Quimica, S.A. de C.V. (813182128)

**Registrant** - Kemix Quimica, S.A. de C.V. (813182128)

### Establishment

Name	Address	ID/FEI	Business Operations
Kemix Quimica, S.A. de C.V.		813182128	manufacture(77396-050) , label(77396-050)

Revised: 9/2020

Kemix Quimica, S.A. de C.V.