

ATALA BIO LIQUID HAND SANITIZER- didecyldimonium chloride and benzalkonium chloride liquid liquid

Kemix Química, 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.

Active Ingredient(s)

DIDECYLDIMONIUM CHLORIDE 0.25% v/v. Purpose: Antiseptic

BENZALKONIUM CHLORIDE 0.01% 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 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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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, water, MAGNESIUM DISODIUM EDTA, ISOPROPYL ALCOHOL, METHYL ALCOHOL

Package Label - Principal Display Panel

4 L NDC: 77396-060-01

ECO FRIENDLY • BIODEGRADABLE • BIO

ATALA™
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

USES: Direct undiluted with atomizer or foam dispenser for hands.
Ideal for Restaurants - Hospitals - Schools - Offices - Homes

DIRECTIONS: Liquid sanitizer with a wide spectrum of body application. SVA has sanitizing properties that act upon contact with the hands 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.

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
- Presentation: Liquid

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:**

ATALA BIO LIQUID HAND SANITIZER

didecyldimonium chloride and benzalkonium chloride liquid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77396-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
METHYL ALCOHOL (UNII: Y4S76JWH15)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77396-060-01	4 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	03/30/2020	

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(77396-060) , label(77396-060)

Revised: 9/2020

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