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

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

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: Y4S76JWI15)	

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.