

## **HAND SANITIZER- handwash gel**

### **Mexiquim SA de CV**

*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.*

-----

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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

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.

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.

## 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, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

Antibacterial Handwash ABS-CLEAN Natural Mint protects, softens and hydrates your skin every day leaving a refreshing cleansing sensation as it contains Aloe Vera. Its formula acts against germs, viruses and bacteria and helps prevent diseases by direct and indirect contact.

**Instructions for use**

1. Apply a small amount to the palm of the hand.
2. Gently rub into a rich lather.
3. Rinse hands with plenty of water.

**Warnings**

Keep the product out of the reach of children. Do not apply to cut or irritated skin. External use. Avoid contact with the eyes. In case of irritation, discontinue use and consult a doctor.

**abs CLEAN**

**ANTIBACTERIAL HANDWASH**

NATURAL MINT

NET WT.: 8 OZ

**Ingredients**

Water, Sodium laureth sulfate, Pentaerythrityl Tetrastearate, Betaine, Coconut Amide, Phenoxyethanol, Mint essence, Sodium Chloride, Aloe vera.

**Made in Mexico by:** Grupo Quimae SA de CV. Jose Marti 203 B, Col. Tlacopa Toluca Edo de Mex C.P. 50010

**Distributed and commercialized by:** Mexiquim, S.A. de C.V. Calle de la Barranca 3-A Col, Tlacopa Toluca, Edo. de México, C.P. 50010

For more information, contact: +52 772 207 3600  
Info@absclean.com

www.absclean.net

f absclean  
@ absclean

7 502294 090345

FREE OF PARABENS, TRICLOSAN AND PHTHALATES

EXTRA SOFT

FDA

ALOE VERA

240 mL NDC: 80137-420-01

## HAND SANITIZER

handwash gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80 137-420
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CHLORATE</b> (UNII: T95DR77GMR)	1.5 g in 100 g
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	12 g in 100 g
<b>PEG-150 PENTAERYTHRITYL TETRASTEARATE</b> (UNII: 8L4OOQ76AM)	0.25 g in 100 g
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>COCAMIDE</b> (UNII: 3YXD33R71G)	1 g in 100 g
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	0.2 g in 100 g

CO CAMIDO PROPYL BETAINE (UNII: 5OCF3011KX)

3 g in 100 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80137-420-01	240 g 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** - Mexiquim SA de CV (589907237)

### Establishment

Name	Address	ID/FEI	Business Operations
Mexiquim SA de CV		589907237	manufacture(80137-420)

Revised: 11/2020

Mexiquim SA de CV