

**HAND SANITIZER- hypochlorous acid gel**  
**Medek, LLC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Hand Sanitizer - Hypochlorous Acid**

This is a hand sanitizer manufactured using only the following United States Pharmacopoeia (USP) grade ingredients:

Hypochlorous Acid (0.0005% volume/volume (v/v)).

Triethanolamine (1.2% v/v).

Edetic Acid (0.05% v/v).

Carbopol (1.0% v/v).

Demineralized water.

**Active Ingredient(s)**

Hypochlorous Acid 0.0005% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

Antiseptic hand sanitizer to reduce germs on skin. For use when soap and water are not available.

**Warnings**

For external use only. Keep out of reach of children.

**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, rash or redness 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**

Apply a small amount of product into hands and rub between both sides of hands until dry. Supervise children under 6 years of age when using this product to avoid swallowing.

**Other information**

Store below 83F (30C)

Avoid freezing.

**Inactive ingredients**

demineralized water, triethanolamine, carbomer and stabilizers

**Package Label - Principal Display Panel**

250 mL NDC: 75432-002-01

# HAND SANITIZER

CLORIGEL™



**KILLS 99.9%  
OF GERMS**

**8.43 FL OZ (250 ml)**

INGREDIENTS: CLORIGEL™, DEMINERALIZED  
WATER, TRIETHANOLAMINE, CARBOMER AND  
STABILIZERS

## Drug Facts

**Active ingredients:** Clorigel, free chlorine (Cl-)

**Purpose:** Antiseptic

**Uses:** Antiseptic hand sanitizer to reduce germs on the skin. For use when soap and water not available.

**Warning:** For external use only. Keep out of reach of children.

**Do not Use:** In children less than 2 months of age. On open skin wounds.

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**Other Information:** Store below 83°F (30°C). Avoid freezing.

**Inactive Ingredients:** demineralized water, triethanolamine, carbomer and stabilizers.

MADE IN MEXICO FOR:  
Kepter Mexico SA de CV  
Av. Valencia 115, Col. America,  
Obrera GPE, NL, México, 67120

Distributed by:  
Medek, LLC  
315 E. Business Hwy 83  
Alamo, TX 78016

NDC Code: 75432-002-01  
contacto@kepter.com.mx



## HAND SANITIZER

hypochlorous acid gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75432-002
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYPOCHLOROUS ACID</b> (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	0.0005 mg in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	1.2 mL in 100 mL
EDETIC ACID (UNII: 9G34HU7RV0)	0.05 mL in 100 mL
WATER (UNII: 059QF0K00R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75432-002-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/30/2020	

**Labeler** - Medek, LLC (055524072)

## Establishment

Name	Address	ID/FEI	Business Operations
Medek, LLC		055524072	manufacture(75432-002)

Revised: 6/2020

Medek, LLC