# 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.

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.

### **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

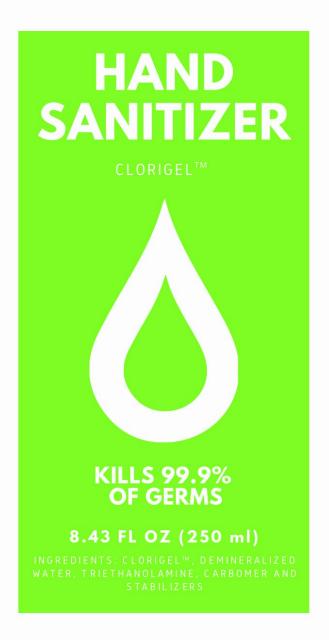
Store below 83F (30C) Avoid freezing.

## **Inactive ingredients**

demineralized water, triethanolamine, carbomer and stabilizers

## **Package Label - Principal Display Panel**

250 mL NDC: 75432-002-01



## **Drug Facts**

Active ingredients: Clorigel, free chlorine (Cl-)

Purpose: Antiseptic

When using this product: Keep out of eyes,

Stop use and ask doctor: If irritation, rash or

Keep out of reach of children: If swallowed,

Inactive Ingredients: demineralized water



#### HAND SANITIZER

hypochlorous acid gel

#### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:75432-002

Route of Administration TOPICAL.

#### Active Ingredient/Active Mojety

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Ingredient Name	Basis of Strength	Strength	
<b>HYPO CHLOROUS ACID</b> (UNII: 712K4CDC10) (HYPO CHLOROUS 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: 059QF0KO0R)			
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 100 mL		

l	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	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