

HAND SANITIZER- hypochlorous acid gel
Kepter Mexico S.A de C.V

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.

Hand Sanitizer - Hypochlorous Acid

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

- a. Hypochlorous Acid (0.0005% volume/volume (v/v)).
- b. Triethanolamine (1.2% v/v).
- c. Edetic Acid (0.05% v/v).
- d. Carbopol (1.0% v/v).
- e. 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 the skin. For use when soap and water 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 doctor: If irritation, rash or redness occurs. These may be signs of 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: 78391-002-01



**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.

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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 83°F (30°C). Avoid freezing.

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

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

Distributed by:
Medek, LLC
316 E. Business Hwy 83
Alamo, TX 78516

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



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hypochlorous acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78391-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	0.05 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	1.2 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78391-002-01	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 - Kepter Mexico S.A de C.V (812889284)

Establishment

Name	Address	ID/FEI	Business Operations
Kepter Mexico S.A de C.V		812889284	manufacture(78391-002)

Revised: 5/2020

Kepter Mexico S.A de C.V