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

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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

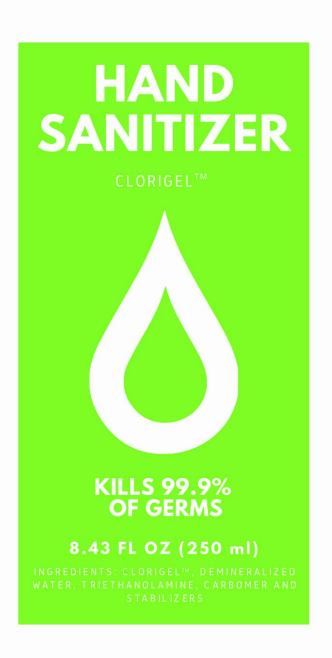
Store below 83F (30C). Avoid freezing.

Inactive ingredients

demineralized water, triethanolamine, carbomer and stabilizers.

Package Label - Principal Display Panel

250 mL NDC: 78391-002-01



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

Inactive Ingredients: demineralized water, triethanolamine carbomer and stabilizers

MADE IN MEXICO FOR: Kepter México SA de CV Av. Valencia 115, Col. America, Obras GPE NII. México 57120 Distributed by: Medek, LLC 315 E. Business Hwy 83 Alamo, TX 78516

NDC Code: 75432-002-01



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: 9 O 3 K 9 3 S 3 T K)	1.2 mL in 100 mL		
CARBOMER 940 (UNII: 4Q93RCW27E)	1 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			

ı	Pa	ckaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 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