

NURINSE- hand sanitizer hocl gel with vitamin e and aloe gel NuGenTec

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.

NuRinse Hand Sanitizer HOCL Gel with Aloe and Vitamin E

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. HOCL 385ppm
- b. 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.

HOCl solutions are already included in the WHO list of coronavirus-effective biocides, and in the US EPA 'N' list of disinfecting agents able to control emerging pathogens like SARS-CoV-2. 37,126 More than ten branded aqueous HOCl formulations have been cleared by the US FDA for topical use in wound management over the last decade. A Class III medical product approval for HOCl has been granted in the EU, and the Japanese Ministry of Health has approved use of HOCl for topical medical applications. The US FDA has approved HOCl for high level disinfection and sterilization of medical instruments, including those for use at critical (i.e., sterile) sites

Active Ingredient(s)

HOCL 385ppm 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

None

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.

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.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- Avoid Direct Sunlight, store in an opaque bottle.
- Keep sealed when not in use.

Inactive ingredients

Purified water USP

Hydroxymethyl Cellulose

Aloe

Vitamin E

Package Label - Principal Display Panel

3785 mL NDC: 77368-389-01

PRODUCT IDENTIFIER:

Code: NuR-HOCL

Product Name: NuRinse HOCL**Product Description:** Disinfection of Hand and skin. Effective sanitizer of gram negative and gram positive bacteria.**DIRECTIONS FOR USE:**

Spray on any skin. Allow surface to air dry.

HAZARD STATEMENTS:

None.

Made in USA*Before using, read Safety Data Sheet (SDS) for this material.***PRECAUTIONARY STATEMENTS:**Store in original sealed container.
Avoid sunlight & heat.
Do not reuse container.**NuRinse**[®]**NuRinse**[®] HOCL Gel**ALL-NATURAL ELECTROLYZED SALT
ANTIBACTERIAL SANITIZER**

Active Ingredient: Hypochlorous Acid 385 ppm

Other Ingredients: Purified RO Water
Hydroxymethyl Cellulose
Aloe & Vitamin E**CAUTION: Keep out of reach of children.**1155 Park Avenue, Emeryville, CA 94608
Phone (800) 409-3142 || Fax (877) 997-8436
www.nugentec.com || info@nugentec.com**Signal Word: None**

D.O.T.: Non-regulated material.

Net Volume: 1 Gal**NURINSE**

hand sanitizer hocl gel with vitamin e and aloe gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77368-389
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	0.000385 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
VITAMIN E POLYETHYLENE GLYCOL SUCCINATE (UNII: O03S90U1F2)	0.00005 g in 100 mL
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	7 g in 100 mL
WATER (UNII: 059QF0KO0R)	

ALOE (UNII: V5VD430YW9)

0.00005 g in 100 mL

Product Characteristics

Color	white (Clear Color)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77368-389-05	18927 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
2	NDC:77368-389-55	208198 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
3	NDC:77368-389-75	10409875 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
4	NDC:77368-389-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
5	NDC:77368-389-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
6	NDC:77368-389-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

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

Labeler - NuGenTec (090331927)**Registrant** - NuGenTec (090331927)**Establishment**

Name	Address	ID/FEI	Business Operations
NuGenTec		090331927	manufacture(77368-389)

Revised: 12/2022

NuGenTec