S9 SOSEANG-SU- hypochlorous acid liquid Sejong Ecosys

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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.

Active Ingredient(s)

Hypochlorous Acid 0.01% v/v. 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

For external use only. Flammable. Keep away from heat or flame

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 or rash 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 or rash 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

- 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 to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water

Package Label - Principal Display Panel





(Salt disinfectant)

Patent-developed pure sea salt containing no color, no odor, no chemistry Ethanol-free, various harmful substances, strong sterilization/deodorization effect of bacteria

S9 SOSAENG-SU(Salt disinfectant)

strong sterilization/deodorization effect of bacteria

*Kills 99.9% of germs and bacteria

NON-TOXIC Sanitizer Refreshing Sprsy/100ml

Drug Facts

Active Ingredients

Hypochlorous Acid 0.01%

Purpose

Disinfecting Agent

▶ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease ▶ instant hand antiseptic to decrease bacteria on the skin

Warning

For external use only

When using this product

- 1)Hypersensitivity symptoms such as erythema, itching and dermatitis. 2)Skin Irritation
- 3)Following Instructions when using medication (1)For external use only (Do not use internally)

- (2)Avoid getting into the eyes (if contact occurs, wash well with clean water)

 Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur.
- ▶ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage.
- ▶ Do not use in combination with soap or antibacterial cleansing agents

▶ Pour a small amount into hands, spread evenly and rub into the skin

Other Information

▶ read the directions and warnings before use avoid freezing and excessive heat above 40 degree C (104 degree F)

Inactive ingredients

purified water

Manufacturer: Sejong Ecosys Phone, +82-82418571412 34 Gisanbangjukgol-gil, Gyeryong-myeon Gongju, Chungnam, 32613 Republic Of Korea Usage, Dose: Pump appropriate amount on hands and rub well to dry.













Ethanol free

100m

*Kills 99.9% of germs and bacteria

NON-TOXIC Sanitizer Refreshing Sprsy/500ml

Drug Facts

Purpose Disinfecting Agent

▶ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease ▶ instant hand antiseptic to decrease bacteria on the skin

Warning

- Vicil Im.;
 For external use only.

 When using this product.

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 Stop immediately and consult a doctor if you experience.

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- ▶ Stop minetalety's into consult a occur in you septem or Hyphypersentishing ymptoms such as eyrthema, itching and dematitis.
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Directions

Other Information

Inactive ingredients

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S9 SOSEANG-SU

hypochlorous acid liquid

Product Information

HUMAN OTC DRUG Item Code (Source) **Product Type** NDC:81612-002

Colorless/odorless Ethanol free

500ml

TOPICAL Route of Administration

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	1 mg in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)	99 mL in 100 mL	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81612- 002-01	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/25/2021	
2	NDC:81612- 002-02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/25/2021	
3	NDC:81612- 002-03	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/25/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/25/2021	

Labeler - Sejong Ecosys (695097532)

Registrant - Sejong Ecosys (695097532)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sejong Ecosys		695097532	manufacture(81612-002)	

Revised: 2/2021 Sejong Ecosys