STE-MEDI- hypochlorous acid liquid ELLAMUSE KOREA

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.

77599-202

Active Ingredient

Hypochlorous acid water (HOCL) 90%

Ethyl Alcohol 5%

Tea tree oil 0.2%, Chamaecyparis obtusa oil 0.15%, Lavender oil 0.15%

Purpose

Antiseptic

Uses

Hand Sanitizer to reduce skin bacteria and viruses on the skin

Warnings

External use only: hand

When disinfecting the object, spray it and wipe it with a dry cotton cloth.

When using this product

Avoid the eyes. If it gets into your eyes, rinse them thoroughly with water.

Do not inhale or ingest.

Stop use and ask a doctor if

Irritation or redness develops

Keep out of reach of children.

If swallowed, seek medical attention.

Directions

Wet hands thoroughly with product and allow to dry without wiping

For children under 6, use only adult supervision

Not recommended for infants

Other information

Do not store above 105F

Inactive ingredients

Hyaluronic acid, chitosan, allantoin, witch hazel extract

Package Label







STE-MEDI: HAND SANITIZER

99% Full Natural Ingredients



Moisturizing

- Liquid type -

3.38 fl.oz / 100ml

Drug Facts

Active Ingredient Purpose
Hypochlorous acid water (HOCL) 90% Antiseptic
Ethyl Alcohol 5% Antiseptic
Tea tree oil, Chamaecyparis obtusa oil, Lavender oil 0.5% Antiseptic

Uses * Hand Sanitizer to reduce skin bacteria and viruses on the skin

Warnings

External use only: hands

When disinfecting the object, spray it and wipe it with a dry cotton cloth.

When using this product * Avoid the eyes. If it gets into your eyes, rinse them thoroughly with water. * Do not inhale or ingest

Stop use and ask a doctor if * Irritation or redness develops

Keep out of reach of children. If swallowed, seek medical attention.

Directions * Wet hands thoroughly with product and allow to dry without wiping * For children under 6, use only under adult supervision * Not recommended for infants

Other information * Do not store above 105°F * May discolor certain fabrics

Inactive ingredients Hyaluronic acid, chitosan, allantoin, witch hazel extract

Manufacturer: Ellamuse Korea 127-28, Pureundeulpan-ro 1010beon-gil, Bibong- myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea MADE IN KOREA







STE-MEDI®

HAND SANITIZER

99% Full Natural Ingredients



Moisturizing

- Liquid type -

6.76 fl.oz / 200ml

Drug Facts

Active Ingredient

Hypochlorous acid water (HOCL) 90%

Antiseptic

Ethyl Alcohol 5%

Tea tree oil, Chamaecyparis obtusa oil, Lavender oil 0.5% Antiseptic

Uses * Hand Sanitizer to reduce skin bacteria and viruses on the skin

Warnings

External use only: hands

When disinfecting the object, spray it and wipe it with a dry cotton cloth.

When using this product * Avoid the eyes, If it gets into your eyes, rinse them thoroughly with water, * Do not inhale or ingest

Stop use and ask a doctor if * Irritation or redness develops

Keep out of reach of children. If swallowed, seek medical

Directions * Wet hands thoroughly with product and allow to dry without wiping * For children under 6, use only under adult supervision * Not recommended for infants

Other information * Do not store above 105 F * May discolor certain fabrics

Inactive ingredients Hyaluronic acid, chitosan, allantoin, witch hazel extract

Manufacturer: Ellamuse Korea 127-28, Pureundeulpan-ro 1010beon-gil, Bibong-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea

MADE IN KOREA





STE-MEDI.

HAND SANMZER

99% Full Natural Ingredients



Moisturizing

- Liquid type -

10.14 fl.oz / 300ml

Drug Facts

Active Ingredient

Hypochlorous acid water (HOCL) 90% Ethyl Alcohol 0,5% Tea tree oil, Chamaecyparis obtusa oil, Lavender oil 0,5%

Purpose Antiseptic Antiseptic Antiseptic

Uses * Hand Sanitizer to reduce skin bacteria and viruses on the skin

External use only: hands

When disinfecting the object, spray it and wipe it with a dry cotton cloth.

When using this product * Avoid the eyes. If it gets into your eyes, rinse them thoroughly with water. * Do not inhale or ingest

Stop use and ask a doctor if * Irritation or redness develops

Keep out of reach of children. If swallowed, seek medical attention.

 $\label{lem:product} \textbf{Directions} * \text{ Wet hands thoroughly with product and allow to dry without wiping } * \text{For children under 6, use only under adult supervision } * \text{Not recommended for infants}$

Other information * Do not store above 105 F * May discolor certain fabrics

Inactive ingredients Hyaluronic acid, chitosan, allantoin, witch hazel extract

Manufacturer: Ellamuse Korea 127-28, Pureundeulpan-ro 1010beon-gil, Bibong-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea

MADE IN KOREA





Drug Facts

Active Ingredient

Purpose

Uses * Hand Sanitizer to reduce skin bacteria and viruses on the skin

Warnings External use only: hand When disinfecting the object, spray it and wipe it with a dry cotton cloth.

When using this product * Avoid the eyes, If it gets into your eyes, rinse them thoroughly with water, * Do not inhale or ingest

Stop use and ask a doctor if * Irritation or redness develops

 $\textbf{Keep out of reach of children.} \ \textbf{If swallowed, seek medical attention},$

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Manufacturer: Ellamuse Korea 127-28, Pureundeulpan ro 1010beon-gil, Bibong myeon, Hwaseong si, Gyeonggi-do, Republic of Korea

MADE IN KOREA



STE-MEDI

hypochlorous acid liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77599-202

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYPO CHLO ROUS ACID (UNII: 712K4CDC10) (HYPO CHLO ROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	90 g in 100 mL		
TEA TREE OIL (UNII: VIF565UC2G) (TEA TREE OIL - UNII:VIF565UC2G)	TEA TREE OIL	0.2 g in 100 mL		
CHAMAECYPARIS OBTUSA WOOD OIL (UNII: P2OMP71Y62) (CHAMAECYPARIS OBTUSA WOOD OIL - UNII:P2OMP71Y62)	CHAMAECYPARIS OBTUSA WOOD OIL	0.15 g in 100 mL		
LAVENDER O IL (UNII: ZBP1YXW0H8) (LAVENDER O IL - UNII: ZBP1YXW0H8)	LAVENDER OIL	0.15 g in 100 mL		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	5 mL in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
HYALURO NIC ACID (UNII: S270 N0 TRQY)		
POLIGLUSAM HYDRO CHLO RIDE (UNII: F351U03I47)		
ALLANTO IN (UNII: 344S277G0 Z)		
WITCH HAZEL (UNII: 10 114J0 U34)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77599-202- 01	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/04/2020	
2	NDC:77599-202- 02	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/04/2020	
3	NDC:77599-202- 03	200 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/04/2020	
4	NDC:77599-202- 04	300 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/04/2020	
5	NDC:77599-202- 05	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/04/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		06/04/2020		

Labeler - ELLAMUSE KOREA (695538826)

Registrant - ELLAMUSE KOREA (695538826)

Establishment			
Name	Address	ID/FEI	Business Operations
ELLAMUSE KOREA		695538826	manufacture(77599-202)

Revised: 6/2020 ELLAMUSE KOREA