

ELECTROLYZED WATER- hypochlorous acid spray
ROOTS BEAUTY INNOVATIONS LLC

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.

Electrolyzed Water Hypochlorous Acid

Active Ingredient

Hypochlorous Acid 0.05%

Purpose

Antiseptic

Uses

- to prevent and treat infection of the skin

Warnings

For external use only

Stop use and ask a doctor if

- redness, irritation or swelling or pain persists or increases.

Do not use

- if sensitive to chlorine compounds.
- Do not mix with other chemicals.
- if swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children

Keep out of reach of children

Directions

- to use as liquid sterilization by immersing completely for about 3 to 5 minutes.
- For instruments that are difficult to immerse, spray and sterilize for about 3 minutes before wiping off.

Questions and Comments

Use this product only below 65°C

Do not immerse for more than 30 minutes to prevent corrosion and damage to equipment made of ferrous metal

Inactive Ingredient

Water

3785 mL NDC:80932-002-37



Electrolyzed Water

Hypochlorous Acid

Antiseptic Spray

Made in the USA

1 Gal - 3.8 L



Drug Facts

Active Ingredient

Hypochlorous Acid (0.05%).....

Purpose

Antiseptic

Uses

- to help reduce bacteria that potentially can cause disease.

Warnings

- For external use only
- Keep out of eyes. In case of contact with eyes, flush thoroughly with water
- Avoid contact with broken skin
- Do not ingest or inhale

Stop use and ask a doctor if

- redness, irritation or swelling or pain persists or increases.

Do not use

- if sensitive to chlorine compounds.
- Do not mix with other chemicals.

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 to avoid swallowing.
- if swallowed, get medical help or contact a Poison Control Center right away.

Other information or comments

- Use this product only below 65°C
- Do not immerse for more than 30 minutes to prevent corrosion and damage to equipment made of ferrous metal

Inactive ingredients Water

Manufactured by RBI LABS, LLC
Wagoner, Oklahoma 74467
www.rbi-labs.com
888-421-7668

ELECTROLYZED WATER

hypochlorous acid spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80932-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYPOCHLOROUS ACID (UNII: 712K4CDC10) (HYPOCHLOROUS ACID - UNII:712K4CDC10)	HYPOCHLOROUS ACID	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80932-002-37	3785 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/13/2021	

Labeler - ROOTS BEAUTY INNOVATIONS LLC (111051318)

Establishment

Name	Address	ID/FEI	Business Operations
ROOTS BEAUTY INNOVATIONS LLC		111051318	manufacture(80932-002)

Revised: 2/2022

ROOTS BEAUTY INNOVATIONS LLC