



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

May 21, 2025

Heather Bjornson-Lam
Regulatory Consultant to Veltek Associates, Inc.
Veltek Associates, Inc.
Electronic Transmittal: heather.bjornson@sterile.com

Subject: PRIA Label Amendment – To add new efficacy claims
Product Name: HYPO-CHLOR 0.25%
EPA Registration Number: 68959-7
Received Date: 5/8/2024
Action Case Number: 00611281

Dear Ms. Bjornson-Lam:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6), you must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the

website may not substantially differ from those claims approved through the registration process, FIFRA section 12(a)(1)(B). Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Oiguenblik.Emilia@epa.gov or Fuller.Demson@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'iD L', is positioned above the typed name of the sender.

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped label

{Main Panel Front Panel}

{NAFTA Statement Main Panel Front at Top}

IMPORTANT NOTICE

This product is registered in both the U.S. and Canada
It has BOTH U.S. and Canadian Labeling
WHEN USING THIS product in the U.S. follow the U.S. information, where indicated
WHEN USING THIS product in Canada, follow the Canadian information, where indicated

ACCEPTED

05/21/2025

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 68959-7

HYPO-CHLOR 0.25% [®] mc
For Use in Cleanrooms and Controlled Areas
Hard, Non-porous Surface Disinfectant
Germicidal
***Virucidal**
Fungicidal
Non-Food Contact Sanitizer
Aseptically Filtered at 0.2 µm

Active Ingredients:

Sodium Hypochlorite CAS# 7681-52-9.....0.25%

Other Ingredients:

*Water99.75%

Total**100.00%**

*USP Water for Injection

KEEP OUT OF REACH OF CHILDREN
WARNING

(Note to reviewer: The following reference statements available for various packaging scenarios.)

[See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary statements]
[directions for use] [additional precautions] [and] additional product information].]

[Refer to the primary case label for [additional] precautionary statements, directions for use, and additional
product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

Net Contents: (US XX fl. oz. or gallons) (Canada XX mL or litres)

US EPA Reg. No.: 68959-7

US EPA Est. No.: For EPA Est. No. see the final character of the lot #: L = 68959 –PA-01, C = 68959-PA-03,
T = 68959-PA-02

Canadian DIN: 02360225

Manufactured by:

Veltek Associates, Inc.

15 Lee Blvd., Malvern PA 19355–1234 USA

Tel: 610-644-8335

www.sterile.com

In Canada: Distributed by:

XXXXXXXXXXXXXXXXX
XXXXXXXXXXXX
XXXXXXXXXXXXXXXXX
Inquiries: (XXX) XXX-XXXX

Made in USA

VAI {corporate logo}

{side/back panel}

FIRST AID

If in Eyes

If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes, remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Swallowed

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or a doctor. Do not give anything to an unconscious person.

If Inhaled

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

EMERGENCIES: In the case of emergency call: 1-866-928-0789 (toll free, USA), 1-800-579-7421 (toll free, Canada), 1-215-207-0061 (Americas), or +52 55 5004 8763 (México)

{Precautionary Statements Section}

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

PHYSICAL AND CHEMICAL HAZARDS: Contact with acid releases toxic chlorine gas. Do not mix this product with other chemicals.

{DIRECTIONS FOR USE SECTION}

DIRECTIONS FOR USE

Read the label before using.

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In Canada: This product is to be used only in accordance with the directions on the label. It is an offence to use this product in a way that is inconsistent with the directions on the label.

This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

LOCATIONS OF USE: Disinfects and sanitizes clean rooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most non-porous hard surface materials.

HYPO-CHLOR 0.25% is ready to use. Do not dilute.

DISINFECTION: Pre-clean surfaces. Thoroughly wet hard, non-porous surface with HYPO-CHLOR 0.25% and allow to visibly remain wet for a minimum of 5 minutes. For trigger spray application, hold bottle 6-8 inches (15-20 cm) from treated surface. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth wiper.

***VIRUCIDAL:** Pre-clean surfaces. Thoroughly wet hard, non-porous surface with HYPO-CHLOR 0.25% and allow to remain visibly wet for a minimum of 3 minutes, Poliovirus requires a 10 minute contact time. Allow surface to air dry, or after 3 minutes or 10 minutes for Poliovirus. For trigger spray application, hold bottle 6-8 inches (15-20 cm) from treated surface. Allow surface to air dry, or after 3 minutes (10 minutes for Poliovirus) wipe dry with sterilized cloth wiper.

SANITIZATION: Pre-clean surfaces. Thoroughly wet hard, non-porous surface with HYPO-CHLOR 0.25% and allow to remain visibly wet for a minimum of 3 minutes. For trigger spray application, hold bottle 6-8 inches (15-20 cm) away treated surface. Allow surface to air dry, or after 3 minutes wipe dry with sterilized cloth wiper.

FUNGICIDAL: Pre-clean surfaces. Thoroughly wet hard, non-porous surface with HYPO-CHLOR 0.25% and allow to remain visibly wet for a minimum of 5 minutes. For trigger spray application, hold bottle 6-8 inches (15-20 cm) from treated surface. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth wiper.

Rinsing may be performed with sterile water, if needed.

{Storage and Disposal SECTION **[boxed]**}

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Disposal: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

Container Handling: *(Note to reviewer: This product is not dilutable.)*

Non-refillable container. Do not reuse or refill this container to hold materials other than this product. [(For containers equal to or less than 5 gallons) Offer container for recycling if available, or puncture and dispose of in a sanitary landfill, or by incineration.] or [(For containers greater than 5 gallons) Offer container for recycling if available, or reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by incineration.]

{Other notes and optional information to appear on containers}

Reorder #: vai xxabc,

{label} Rev mm/yy

LOT: xxxxxx {note: Date of manufacture is on Certificate of Analysis}

EXPIRY: day/MONTH/year. (18 months from date of manufacture). Once opened use within 90 days.

{Section for user to enter their own information.}

User Information
Date Opened/Operator:
<input type="text"/>
Expiration Date:
<input type="text"/>
Area:
<input type="text"/>

Optional Label Claims:

- HYPO-CHLOR 0.25% is a registered disinfectant, virucide and fungicide for use in areas where housekeeping and controlling cross-contamination is of prime importance.
- When used as directed, HYPO-CHLOR 0.25% is an effective disinfectant on inanimate, hard non-porous surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 4352), and *Trichophyton interdigitale* (ATCC 9533) in 5 minutes.
- When used as directed, HYPO-CHLOR 0.25% is an effective virucide on inanimate, hard non-porous (,non-food contact) surfaces, in the presence of organic load (5% Bovine Serum), demonstrated in testing against *Influenza A Virus H1N1 (strain A/PR/8/34), Human Adenovirus Type 5 (ATCC VR-5), and Rhinovirus Type 37 (ATCC VR-1607) in 3 minutes, and **Poliovirus Type 1 (ATCC VR-1562) in 10 minutes.
- When used as directed, HYPO-CHLOR 0.25% is an effective sanitizer on inanimate, hard non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in 3 minutes.
- Sterile {note for reviewer: when product is produced aseptically}