



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 30, 2020

Heather Bjornson-Lam
Authorized Representative
Veltek Associates, Inc.
15 Lee Boulevard
Malvern, PA 19355

Subject: Notification per PRN 98-10 – Addition of the Canadian distributor on NAFTA label
Product Name: HYPO-CHLOR 0.52%
EPA Registration Number: 68959-6
Application Date: February 27, 2020
Decision Number: 562393

Dear Ms. Bjornson-Lam:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. 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) list 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. 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 Compliance.

If you have any questions, you may contact Melanie Bolden at (703) 347-0165 or via email at Bolden.Melanie@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Melanie Bolden for".

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

{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

HYPO-CHLOR 0.52%^{® mc}
For Use in Clean Rooms and Controlled Areas
Hard Surface Disinfectant
Aseptically Filtered at 0.2 µm

NOTIFICATION

68959-6

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

06/30/2020

Active Ingredients:

Sodium Hypochlorite CAS# 7681-52-9.....0.52%

Other Ingredients:

*Water.....99.48%

Total100.00%

*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: (In the US XXoz or gallons) (In Canada XX mL or litres)

US EPA Reg. No.: 68959-6

US EPA Est. No.: 68959-PA-1

Canadian DIN: 02350217

Manufactured by:

Veltek Associates, Inc.
15 Lee Blvd., Malvern PA 19355 – 1234 USA
Tel: 610-644-8335
Fax: 610-644-8336
www.sterile.com

In Canada: Distributed by:

Canada Clean Room (CCR) www.ccrkanata.com
~~200 Terence Matthews~~ 20 Cope Drive
Kanata, ONT K2M ~~2G62V8~~
Inquiries: (888) 595-8070

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 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: For Spill/Exposure/Poison Control Emergency Response Service from the USA and Canada in English, French and Spanish (and 23 other languages) call CARECHEM24 toll free at 866-928-0789.

{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 0.52% is ready to use. Do not dilute. Hold container upright 15-20 cm (6-8 inches) from surface when applying or apply with saturated cloth or immerse item in a basin.

DISINFECTION: Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with HYPO-CHLOR 0.52% and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

SANITIZATION: Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with HYPO-CHLOR 0.52% and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes wipe dry with sterilized cloth wiper.

FUNGICIDAL: Pre-clean surface or item of heavy soil or gross filth before application. Thoroughly wet surface with HYPO-CHLOR 0.52% and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth wiper.

Rinsing may be done 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 on containers}

Reorder #: vai xxabc, {label}Rev mm/yy

{Lot number/ Batch Code: XXXXX}

LOT: xxxx {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 on containers 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 0.52% is bactericidal. The results of AOAC Efficacy Tests show that HYPO-CHLOR 0.52% is an effective hard surface disinfectant on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538), and *Salmonella enterica* (ATCC# 10708) in 10 minutes.

HYPO-CHLOR 0.52% is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC# 4352) in 5 minutes.

HYPO-CHLOR 0.52% is an effective fungicide on inanimate, non-porous non-food contact surfaces demonstrated by the results of AOAC Efficacy Tests against *Trichophyton mentagrophytes* (ATCC# 9533) in 10 minutes.