



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 1, 2015

Mr. Micah T. Reynolds
Regulatory Consultant To: Veltek Associates, Inc.
Technology Sciences Group
1150 18th Street, NW; Suite 1000
Washington, DC 20036

Subject: Label Amendment – Minor Label Changes
Product Name: **Hypo Chlor® 0.52%**
EPA Registration Number: **68959-6**
Application Date: September 30, 2015
Decision Number: 510824

Dear Mr. Reynolds:

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. 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 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.

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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 Killian Swift by phone at 703-308-6346, or via email at Swift.Killian@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Demson Fuller, for".

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

Enclosure

Proposed NAFTA Label CLEAN COPY

EPA and Health Canada

Reg # 68959-6 and DIN #02350217

{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

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

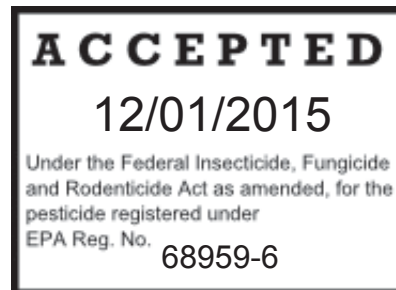
In Canada: Distributed by:

Canada Clean Room (CCR) www.ccrkanata.com

200 Terence Matthews

Kanata, ONT K2M 2C6

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 puncture or incinerate container. 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.