

68959-6

8/22/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Megan E. Pletka
C/o Veltek Associates
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington D.C. 20036

AUG 22 2014

HYPO-CHLOR 5.25%
EPA Registration Number 68959-5
HYPO-CHLOR 0.52%
EPA Registration Number 68959-6
HYPO-CHLOR 0.25%
EPA Registration number 68959-7
Your Submission Dated July 17, 2013
EPA Received Date July 19, 2013

The amendments referred to above, submitted in connection with the registration under the Federal Insecticide, Fungicide and Rodenticide Act, FIFRA, as amended, to review the product labeling under the NAFTA labeling process, is acceptable.

A stamped copy for each of the product labeling is enclosed.

If you have any questions concerning this letter, please contact Ben Chambliss at (703) 308-8174.

Sincerely,

Demson Fuller
Product Manager 32
Regulatory Branch II
Antimicrobials Division (7510C)

(NAFTA Statement Main Panel Front at Top)
IMPORTANT NOTICE
This product is registered in both the U.S. and Canada
It has **DIFFERENT** U.S. and Canadian labeling
WHEN USING THIS product in U.S. jurisdictions, where indicated
WHEN USING THIS product in Canada, follow the Canadian information, where indicated

HYPO-CHLOR 0.52%[®] m/d
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%
Total..... 100.00%
*USP Water for Injection

KEEP OUT OF REACH OF CHILDREN
WARNING

(See [other|side|back|panel|package insert] for [first aid] [directions for use] [and additional precautions].)

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)

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.

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(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.

HYP-O-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 HYP-O-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 HYP-O-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 HYP-O-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: Non-refillable container. Do not reuse or refill this container to hold materials other than this product. Fill the container $\frac{1}{2}$ full with water and recap. Shake for 10 seconds and dispose of rinsate in sanitary sewer. Offer container for recycling if available, or place in trash.

{other notes and optional information on containers}

Reorder #: val 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:	
Expiration Date:	
AME:	

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Proposed NAFTA Label CLEAN COPY
EPA and Health Canada
Reg # 68959-6 and DIN # 02350217

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.

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