



U S ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington D C 20460

EPA Reg Number
68959 6

Date of Issuance
JUL 19 2012

Term of Issuance
Unconditional

Name of Pesticide Product
HYPO CHLOR 0 52%

NOTICE OF PESTICIDE

- x Registration
Reregistration

(under FIFRA as amended)

Name and Address of Registrant (include ZIP Code)

Veltek Associates Inc c/o Micah Reynolds TSG 1150 18th Street NW Suite 1000 Washington DC 20036

Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant the above named pesticide is hereby registered/reregistered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product (OPP Decision No 461644) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you

- 1 Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data and submit acceptable responses required for re registration of your product under FIFRA section 4
2 Make the labeling changes listed below before you release the product for shipment
a Add the phrase EPA Registration Number 68959 6

Signature of Approving Official

Monisha Harris
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date

JUL 19 2012

b Submit a 1 year Storage Stability and Corrosion Characteristics Data (OPPTS 830 6317 and OPPTS 830 6320)

c P 1 Should you wish to retain a reference to the company's websites on your label then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 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. Although EPA has not yet determined the extent to which it will routinely review company websites if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

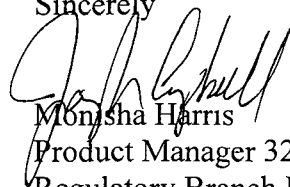
The original proposed submitted label dated 2/24/2012 and was updated on July 17 2012 (pin punch 7/18/12)

Submit promptly three (3) copies of the final printed label with the above noted comments prior to releasing this product for sale.

If these conditions are not complied with the registration will be subject to cancellation in accordance with FIFRA sec 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely



Monisha Harris  
Product Manager 32  
Regulatory Branch II  
Antimicrobials Division (7510P)

Enclosure (Stamped Labeling)

307

# HYPO-CHLOR 0.52% ® MC

For Use in Clean Rooms and Controlled Areas  
Hard Surface Disinfectant  
Aseptically Filtered at 0.2 µm

*marked copy*

**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

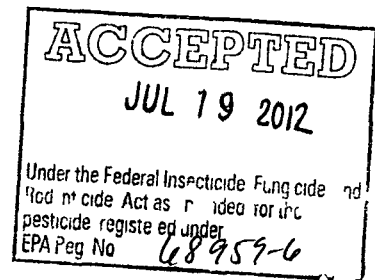
~~Store at room temperature~~

See other panel for first aid and additional precautions

Net Contents (US XXoz or gallons)

EPA Reg No 68959 XX  
EPA Est No 68959 PA 001

**Manufactured by**  
Veltek Associates Inc  
15 Lee Blvd  
Malvern PA 19355 – 1234 USA  
Tel 610 644 8335  
Fax 610 644 8336  
[www.sterile.com](http://www.sterile.com)



In Canada distributed by  
Canada Clean Room (CCR) [www.ccrkanata.com](http://www.ccrkanata.com)  
280 Terance Mathews  
Kanata On K2M 2C6

Made in USA VAI {corporate logo}

<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Move person to fresh air.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> <li>• Have product container or label with you when calling poison control or doctor, or going for treatment.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15—20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>EMERGENCIES:</b> 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.]</p>	

**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 five 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 glassful of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth 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**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**WARNING** ~~Causes substantial but temporary eye injury Harmful if swallowed or absorbed through skin This product may be irritating to the eyes skin gastrointestinal tract and respiratory system It may cause eye damage Harmful if swallowed or inhaled Do not get in eyes, on skin, or on clothing Avoid breathing vapor or spray mist Avoid contact with skin and clothing Wear protective eyewear (such as goggles or face shield or safety glasses) protective clothing and chemically resistant gloves Wash thoroughly with soap and water after handling and before eating drinking chewing gum or using tobacco or using the toilet Remove and wash contaminated clothing before reuse Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals~~

**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**

**Read the label before using**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

*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 cleanrooms 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 and stainless steel It is compatible with most hard surface materials

**DISINFECTION** HYPO CHLOR 0 52% ®<sup>MC</sup> is ready to use Do not dilute

Pre clean surface or item of heavy soil or gross filth before application

Hold container upright 15 30 cm (6 12 inches) from surface or apply with saturated cloth or immerse item in a basin Thoroughly wet surface with HYPO CHLOR 0 52% ®<sup>MC</sup> 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

**SANITIZATION** Follow all disinfection directions and allow to remain wet for a minimum of 5 minutes

**FUNGICIDAL** Follow all disinfection directions

**Storage and Disposal**

Do not contaminate water food or feed by storage and disposal

**Storage** Store 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 the original container in a dry cool place Absorb spills with inert material (e.g. dry absorbent sand or earth) then place in a chemical waste container

**Disposal** Products or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer and product wastes are toxic 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 Never place unused product down any indoor or outdoor drain

**Container Handling/Disposal** Non refillable container Do not reuse or refill this container to hold materials other than this product or diluted product (rinsate) Triple-rinse container promptly after emptying Triple-rinse as follows [ (For containers less than 5 gallons) Fill container 1/4 full with water and recap Shake 10 seconds Follow pesticide disposal instructions for rinsate disposal Drain 10 seconds after the flow begins to drip Repeat two more times ] or [ (For containers greater than 5 gallons) Fill container 1/4 full with water Tip container on its side and roll back and forth ensuring at least one complete revolution for 30 seconds Stand the container on its end and tip it back and forth several times Turn the container on its other end and tip it back and forth several times ] Follow pesticide Disposal Instructions for rinsate disposal Repeat procedure two more times Offer for recycling where available or puncture and dispose of in a sanitary landfill or by other procedures approved by state/provincial or other authorities Fill the container 1/4 full with water and recap Shake for 10 seconds and dispose of rinsate in sanitary sewer Offer container for recycling if available or reconditioning if appropriate or place in trash

Reorder # vai xxabc Rev mm/yy

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

{Lot label on container}  
LOT xxxx {Date of manufacture is on Certificate of Analysis}  
EXP Day/month/year {18 months} Once opened use within 90 days

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**Optional Label Claims**

HYPO CHLOR 0 52% ®<sup>MC</sup> is bactericidal. The results of AOAC Efficacy Tests show that HYPO CHLOR 0 52% ®<sup>MC</sup> is an effective hard surface disinfectant on inanimate non porous non food contact surfaces demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442) and *Staphylococcus aureus* (ATCC#6538) in 10 minutes

HYPO CHLOR 0 52% ®<sup>MC</sup> 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% ®<sup>MC</sup> 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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