

U S ENVIKONMENTAL PROTECTION AGENCY

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

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x Registration Reregistration

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Number

68959 7

Date of Issuance

JUL 19 2012

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Term of Issuance

Unconditional

Name of Pesticide Product

HYPO CHLOR 0 25%®

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 ℓ

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 461645) 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 7

Signature of Appraving Official

Monisha Harris

Product Manager 32

Regulatory Management Branch II Antimicrobials Division (7510P) Date

JUL 19 2012

FPA Form 8570-6

b Submit a 1 year Store Stability and Corrosion Characteristic idies (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

Product Manager 32

Regulatory Branch II

Antimicrobials Division (7510P)

Enclosure (Stamped Labeling)

307

mark 1007.7

HYPO-CHLOR 0.25% ® MC

For Use in Clean Rooms and Controlled Areas Hard Surface Sanitizer Disinfectant

Aseptically Filtered at 0 2 µm

Active Ingredients

Sodium Hypochlorite CAS# 7681 52 9

0 25%

Other Ingredients

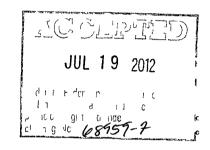
*Water

99 75%

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

In Canada distributed by Canada Clean Room (CCR) www ccrkanata com 280 Terance Mathews Kanata On K2M 2C6

Made in USA VAI (corporate logo)

	FIRST AID
lf 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
f swallowed	Call a poison control center or doctor immediately for treatment advice
	Have person sip a glass of water if able to swallow
	Move person to fresh air
	Do not induce vomiting unless told to by a poison control center or
	doctor
	 Do not give anything to an unconscious person
	Have product container or label with you when calling poison control or
	doctor or going for treatment
f inhaled	Move person to fresh air
	 If person is not breathing call 911 or an ambulance them give artificial respiration preferably mouth to mouth if possible
	Call poison control center or doctor for treatment advice
f on skin or	
clothing	• Rinse skin immediately with plenty of water for 15 – 20 minutes
"	Call a poison control center or doctor for treatment advice
EMERGENCIES	For Spill/Exposure/Poison Control Emergency Response Service from the
USA and Canada	a in English French and Spanish (and 23 other languages) call
	oll free at 866-928-0789]

FIRST AID

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 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 pene rate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preciean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

LOCATIONS OF USE <u>Disinfects and sSanitizes</u> 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 porcelaien and stainless steel. It is compatible with most hard surface materials

DISINFECTION HYPO-CHLOR 0.25% ® MC 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 0.25% ® MC and allow to remain wet for a minimum of 20 minutes. Allow surface to air dry. or after 20 minutes wipe dry with sterilized cloth wiper. Rinsing may be done with clean water. If needed

SANITIZATION HYPO CHLOR 0 25% ® MC is ready to use Do not dilute 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 25% ® MC 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. Rinsing may be done with sterile water, if

needed Follow all disinfection directions and allow surface to remain wet for a minimum of 5 minutes

FUNGICIDAL Follow all disinfection directions and allow surface to remain wet for a minimum of 10 minutes

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 in 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 Product 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 indeed or outdoor drain.

Container Handling Disposal Non refillable container. Do not reuse or refill use. I is container to hold materials other than this product. Fill the container ¼ 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 or diluted product (rinsate). Triple rinse container promptly after emptying. Triple rinse as follows: (Exer containers less than 5 gallons). Fill container ¼ 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 ¼ 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.

Reorder # vai xxabc Rev mm/yy

cc

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User information
Date Opened/Operator
Expiration Date
AME.

{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

Optional Label Claims

HYPO-CHLOR 0 25% ® MC is bactericidal. The results of AOAC Efficacy Tests show that HYPO-CHLOR 0 25% ® MC is an effective hard surface disinfectant on inanifitate non-porous non-food contact surfaces demonstrated in testing against Pseudomonas aeruginosa (ATCC# 15442) Staphylococcus aureus (ATCC#6538) and Salmonollac centerica (ATCC#10708) in 20 minutes

HYPO CHLOR 0 25% ® ^{MC} 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 25% ® MC is an effective fungicide on inanimate non-porous non-food contact surfaces demonstrated by the results of AOAC Efficacy Tests against Tricophyton mentagrophytes (ATCC# 9533) in 10 minutes