

68959-5

2/5/2013

1/8



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

February 5, 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Micah Reynolds
Agent for Veltek Associates, Inc.
Technology Sciences Group, Inc.
1150 18th Street, Suite 1000
Washington, DC 20036

Subject: Hypo-chlor® 5.25%
EPA Registration No.: 68959-5
Notification Date: 1/17/2013
EPA Receipt Date: 01/23/2013

Dear Mr. Reynolds,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

- Minor corrections and modifications

General Comments

Based on a review of the submitted materials, your notification for the minor corrections and modifications is **acceptable** and has been made a part of your file.

Should you have any questions or comments concerning this letter, you may contact Jaclyn Pyne by telephone at (703) 347-0213 or by e-mail at pyne.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

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

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
--	---	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number <p style="text-align: center;">68959-5</p>	2. EPA Product Manager <p style="text-align: center;">Monisha Harris</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <p style="text-align: center;">HYPO-CHLOR® 5.25%</p>	PM# <p style="text-align: center;">AD/32</p>	
5. Name And Address Of Applicant (Include ZIP Code) Veltek Associates, Inc. 15 Lee Boulevard Malvern, Pennsylvania 19355 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

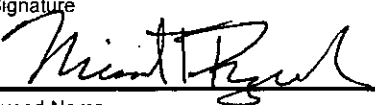
Submission of Label Notification to correct omitted Directions for Use Statement and to modify front panel reference statement.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: mreynolds@tsgusa.com, via phone (202) 828-8967, or via fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other _____ <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received _____ (Stamped) _____
2. Signature 	3. Title Regulatory Consultant to Veltek Associates, Inc.	
4. Typed Name <p style="text-align: center;">Micah T. Reynolds</p>	5. Date <p style="text-align: center;">January 17, 2013</p>	



Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Senior Regulatory Consultant

January 17, 2013

Veltek Associates, Inc.
Submission of Label Notification for
HYPO-CHLOR® 5.25%: EPA Reg. No. 68959-5

Ms. Monisha Harris (**PM-32**)
Antimicrobials Division (**NOTIF**)
Office of Pesticide Programs (**7510P**)
U.S. Environmental Protection Agency
Document Processing Desk
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

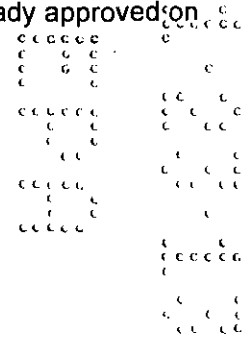
Dear Ms. Harris:

Technology Sciences Group, Inc., on behalf of Veltek Associates, Inc. (Veltek), is submitting the enclosed label notification to modify the reference statement on the front panel, to correct address information for a distributor, and to correct an omission in the Directions for Use section. When this product was first submitted for registration, the draft label inadvertently omitted the fungicidal use instructions in the Directions for Use section. The enclosed label version corrects that omission.

The fungicidal effectiveness for this product was evaluated in AD's efficacy review, DER D400629 (dated July 10, 2012), wherein fungicidal data (MRID No. 48753004) supporting Veltek's HypoChlor 0.25% (EPA Reg. No. 68959-7) product were bridged to this product and a similar Veltek product, HypoChlor 0.52% (68959-6). Further, an optional marketing claim for fungicidal effectiveness was previously approved for this product; therefore, addition of the previously omitted Directions for Use statement is consistent with claims already approved on the label.

Please find enclosed the following documents supporting this amendment:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One redline copy of the proposed label with changes indicated;
- 3) Three (3) clean copies of the proposed label.

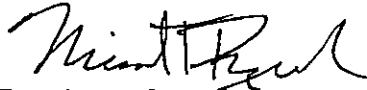


4/8

Veltek Associates, Inc.
HypoChlor 5.25% Label Notification
EPA Reg. No. 68959-5
January 17, 2013
Page 2 of 2

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,



Regulatory Consultant to Veltek Associates, Inc.

Enclosures

cccccc
c c c c c
c c c c c
cccccc
c c c c c
c c c c c
cccccc
c c c c c
cccccc
c c c c c
cccccc
c c c c c
cccccc
c c c c c

5/8

HYPO-CHLOR 5.25% ^{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.....5.25%

Other Ingredients:

*Water94.75%

Total100.00%

*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: (US XXoz or gallons)

EPA Reg. No.: 68959-5

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

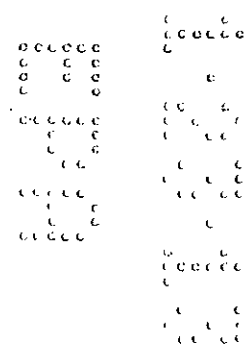
In Canada, distributed by:

Canada Clean Room (CCR) www.ccrkanata.com

200 Terrance Matthews

Kanata, On. K2M 2C6

Made in USA VAI {corporate logo}



6/8

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. 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.

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: Use this product while wearing personal protection such as eye protection goggles or face shield, protective clothing and chemical resistant gloves. Use with adequate ventilation and spray away from eyes and face. HYPO-CHLOR 5.25% ^{MC} is ready to use, or it may be diluted to 0.52%, as desired by the user, as follows:

Amount of Product	Amount of Water
6 1/2 ounces (190mL)	1/2 gallon (1.9L)
12 3/4 ounces (380mL)	1 gallon (3.79L)

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 5.25% ^{MC} 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 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 at room temperature 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: 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 indoor or outdoor drain.

Container Disposal: Non-refillable container. Do not use this container to hold materials other than 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.

{back/side/bottom panel}

Reorder #: vai xxabc, Rev mm/yy

User Information
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

Optional Label Claims:

HYPO-CHLOR 5.25% ®^{MC} is bactericidal. The results of AOAC Efficacy Tests show that HYPO-CHLOR 0.52% ®^{MC} 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 5.25% ®^{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 5.25% ®^{MC} 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.

