

NOV 19 2004

John Dubeck
Agent for 3M Corporation
1001 G Street, N. W., Suite 500 West
Washington, DC 20001

RE: "Sodium Pyrithione"
EPA Reg. Symbol 10350-56
Your Notification Dated 10/21/04

The Notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to correct the incorporation rate into sponges from 0.06% to 0.6%, is acceptable with the following comments.

1. According to the registrant, the prior stamped label incorrectly listed the incorporation rate as 0.06% due to a registrant error that was never rectified. Evidence was presented in this notification that the maximum intended rate is 0.6%, and that the actual incorporation rate ranges from 0.06 to 0.6%.
2. The "First Aid" statements for this product were never revised as required by the PR Notice 2001-1.
3. Therefore, with your very next label amendment, add the minimum concentration to be incorporated into the sponge, as per your efficacy data, and add the correct "First Aid" Statements. These can only be done by the amendment process.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

33

287

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
MI11159/01/09N

Application for Pesticide - Section I

1. Company/Product Number 3M/10350-56	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sodium Pyrethione	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) 3M 3M Center, Building 220-2E-02 St. Paul, MN 55144-1000 <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.)

-- Notification of correction of typographical error in label Directions for Use per PR Notice 98-10.
 -- 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.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	<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) of Retail Container Shipped, stored and handled in bulk		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"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other (_____)	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Susan M. Price	Title Sr. Regulatory Affairs Specialist	Telephone No. (Include Area Code) (651) 733-3461
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 for misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Registration Counsel/Agent	
4. Typed Name John D. Dubeck	5. Date October 21, 2004	

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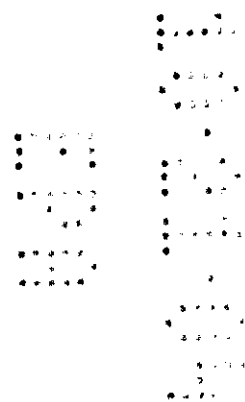
WRITER'S DIRECT ACCESS

John B. Dubeck
(202) 434-4125
dubeck@khlaw.com

October 21, 2004

Via Messenger

Mr. Marshall Swindell (ATTN: Tony Kish)
Product Manager Team 33
Regulatory Management Branch I
Antimicrobial Division (7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Room 266A, Crystal Mall, Building 2
1801 South Bell Street
Arlington, VA 22202-4501



**Re: Notification to Correct Typographical Error in Directions for Use,
Regarding Sodium Pyrithione, EPA Reg. No. 10350-56**

Dear Marshall:

On behalf of 3M, we are submitting this Notification to correct a typographical error that we have just discovered on the approved label for the above referenced product. The product is incorporated into a line of cellulose sponges, *i.e.*, a treated article, to provide antimicrobial protection.

Under the provisions of PR Notice 98-10 we are required to correct the typographical error by Notification because it occurs in the Directions for Use section of the label. Specifically, we found last week a decimal error in the statement of the maximum amount of residual pyrithione ion that may be contained in the sponge. The stamped approved label, dated March 23, 2000, contains the figure 0.06 weight % on a dry basis. The intended label directions, proposed for sodium pyrithione as part of an application for registration submitted on May 20, 1999, called for a maximum level of 0.6 weight %.

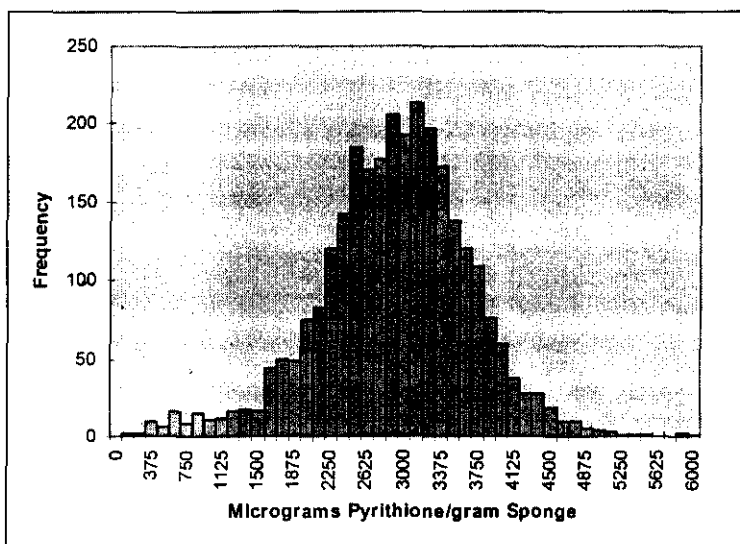
In order to avoid any delays or confusion, we would like to discuss the history of the registration and point out when the error occurred. As described above, the original application was submitted in May of 1999. On October 13, 1999, 3M received a letter from you requesting that a number of changes be made to the label, most of which were required by the reregistration process for Sodium Omadine (*i.e.*, sodium pyrithione). No change was required in the specified

Marshall
 October 21, 2004
 Page 2

maximum level of pyrrithione in the sponge. On December 21, 1999 we submitted new labels containing all the required changes.

The December 21st labels still contained the specification of 0.6% by weight for maximum bound pyrrithione ion. The letter we enclosed with the label, however, indicated in a footnote that the maximum pyrrithione level should be 0.06 weight %. This appears to be where the decimal error began. Apparently, some time between December of 1999 and March of 2000 a new final label was provided to EPA changing maximum level on the label to agree with the letter, and that label became the stamped approved label. The change should never have been made because the error was in the letter, not the label.

Registration of sodium pyrrithione was part of a larger effort to register 3M's cellulose sponge as a pesticide. The sponge is now an article treated with sodium pyrrithione as a preservative. As part of the product chemistry package for the sponge application, analytical data on the pyrrithione ion content in 2,869 production batches of sponge were provided. These data showed a mean level of pyrrithione ion of 0.28 weight percent, a maximum level of 0.59 weight % and a minimum of 0.07 weight %. The production data were also presented in the sponge application in a graph, which is shown to the right. Clearly, the choice of 0.6 weight % as a maximum makes sense, and the 0.06% figure must be an error.



Further confirmation that EPA and 3M intended that the 0.6 weight % figure be the maximum can be found in the Notice of Filing published in the *Federal Register* for food contact uses of the sponge. A copy of the notice is enclosed for your convenience. The notice was published by EPA on September 20, 2000, 6 months after 3M received its registration for the Sodium Pyrrithione used in the sponge (65 FR 56895-56901, Sept. 20, 2000). The notice describes the sponge as containing a mean level of zinc pyrrithione of 0.35% by weight, which is equivalent to 0.28% by weight pyrrithione ion. As you remember, zinc in the sponge captures and holds the pyrrithione ion.

For your convenience, we have also enclosed a copy of the Notice of Pesticide Registration and label dated March 23, 2000 for Sodium Pyrrithione and the most recent version of the stamped approved label which contains a minor change in language approved in November of 2000. We have also enclosed one copy of the revised label with the change

587

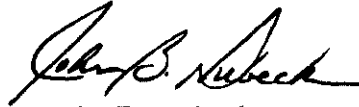
KELLER AND HECKMAN LLP

Marshall
October 21, 2004
Page 3

highlighted in yellow and two copies of the revised label without highlighting. The only change we now wish to make in the label by notification is "0.06" to "0.6", i.e., correction of the typographical error.

Please feel free to contact me at the above number or Andy Jovanovich at 202-434-4156 if you have any questions.

Sincerely,



John B. Dubeck

Enclosures

cc: Susan M. Price, 3M

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Applicators and other handlers must wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approved number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number TC-14G) or a NIOSH approved respirator with an organic vapor cartridge or canister with any N, R, P or HE pre-filter.

Use protective eyewear (face shield, goggles, or safety glasses). Wear protective clothing (long sleeve shirt, long pants, socks plus shoes). Use chemical resistant rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove contaminated PPE and clothing and wash before reuse. Wash the outside of gloves before removing. Follow the manufacturers instructions for cleaning and maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Do not apply this product in a way that will contact workers or other persons.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

This pesticide is a chelating agent and should not be used with other chelating agents or with chlorine.

CHEMICAL HAZARDS

Do not store with or mix with strong oxidizing agents.

Sodium Pyrrithione

An end-use product to preserve zinc-chitosan modified cellulose sponges.

ACTIVE INGREDIENTS:

Sodium 2-pyridinethiol-1-oxide	41.0%
OTHER INGREDIENTS	59.0%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

- IF IN EYES** — Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.
- IF ON SKIN** — Wash with plenty of soap and water. Get medical attention.
- IF INHALED** — Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
- IF SWALLOWED** — Call a Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

Note To Physician: Convulsions, if persistent, may be controlled by careful intravenous use of short-acting barbituates.

DIRECTIONS FOR USE

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

This product may only be used to treat sponges made of zinc-chitosan modified cellulose for residual preservative effects. It inhibits the growth of mold, mildew and bacteria that cause odor, staining and degradation of the sponge.

Use 0.83 lbs (10.5 oz.) to 25 lbs (2.5 gal) of product diluted to 1000 gallons with water to produce a wash solution containing 100-3,000 ppm sodium pyrrithione. Use upper concentrations to penetrate thick articles such as large sponge blocks. Thoroughly soak material to be treated. No residence time is required. Excess wash solution may be recovered for recycling immediately. Additional product should be added as required during recovery and recycling to maintain target sodium pyrrithione concentration. The finished sponge shall contain a maximum amount of bound residual pyrrithione ion of 0.6 Wt. % on a dry basis.

WARRANTY: 3M warrants that this product conforms to the chemical description on the label and is reasonably fit for purposes stated on such label.

EPA Reg. No. 10350-56
EPA Est. No 10350-



St. Paul, MN 55144

Net Contents: 6000 gallons

687

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage. Do not store above 130 degrees F (55 degrees C). Keep container tightly closed when not in use. Do not store with strong oxidizing agents.

Pesticide Disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes can not be disposed of by use according to label instructions, contact you State Pesticide or Environmental control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal. Triple rinse container. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

727