

10350-56

11-9-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 09 2000

Sue Price
Regulatory Affairs Specialist
3M
3M Center, Building 290-04-01
St. Paul, MN 55144-1000

**Mailed To: Andy Jovanovich, Agent for 3M
c/o Keller & Heckman
1001 G Street, N.W., Suite 500
Washington, DC 20001**

**RE: "Sodium Pyrithione"
EPA Reg. Symbol 10350-56
Your Amendment Dated 7/25/2000**

The amendment referred to above, submitted in connection with registration under section 3 (c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to delete the restriction statement, "Not for production of sponges that may contact food in non-residential use sites", is acceptable provided that you comply with the requirement listed below. The subject of this amendment is for the use of this product to treat non-residential (ie., commercial, institutional), food contact 3M sponges. These sponges are treated with sodium pyrithione which converts to zinc pyrithione in the sponge. This "Me Too" use is not considered a significant expansion of zinc pyrithione food contact uses already approved by FDA.

Requirement - Submit/cite all data required for registration and/or reregistration of your product under FIFRA section 3 (c) (5) and section 4 when the Agency requires all registrants of similar products to submit such data.

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

Note that certain outstanding zinc pyrithione TGAI data may be needed to support indirect food contact uses (including sponges) involving zinc pyrithione. This missing data may be a requirement of the "Zinc Omadine RED" which is under finalization now. You should stay in contact with your active ingredient supplier to make sure they will support any outstanding data needed for your use.

CONCURRENCES							
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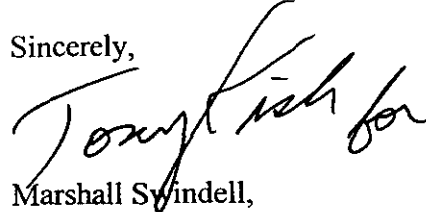
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A stamped copy of the accepted label is attached for your records.

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)

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DATE							

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 Pyrithione

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 pyrithione. 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 pyrithione concentration. The finished sponge shall contain a maximum amount of bound residual pyrithione ion of 0.06 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-

ACCEPTED
with COMMENTS
in EPA Letter Dated:



NOV 09 2000 St. Paul, MN 55144

Net Contents: 6,000 gallons

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

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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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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