

84059-5

04-06-2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

APR 06 2012

Keith Pitts  
Regulatory Manager  
Marrone Bio Innovations  
2121 Second Street, Suite B-107  
Davis, CA 95618

RE: Product Name: MOI-401 EP  
EPA Reg. No: 84059-5  
Applications for Notification Dated: March 6, 2012 addition to add  
Alternate Brand Name: Zequanox™ EP as per PR Notice 98-10.

Dear Mr. Pitts:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (PRN) 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped as "**Notification Accepted**" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at [paden.mary@epa.gov](mailto:paden.mary@epa.gov).

Sincerely,

*Sheryl K. Reilly*  
Sheryl K. Reilly, Ph.D., Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention  
Division (7511P)

CONCURRENCES

|         |           |  |  |  |  |  |  |
|---------|-----------|--|--|--|--|--|--|
| SYMBOL  | ▶ 7511(P) |  |  |  |  |  |  |
| SURNAME | ▶ Paden   |  |  |  |  |  |  |
| DATE    | ▶ 4-6-12  |  |  |  |  |  |  |

March 6, 2012

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

ATTN: Ann Sibold

**“Notification of alternate name change for MOI-401 EP (EPA Reg. No. 84059-5);  
addition of a new alternate name, Zequanox<sup>TM</sup> EP.”**

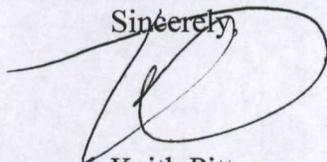
*“This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the CSF of this product. I understand that it is a violation of 1 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand 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.”*

Dear John:

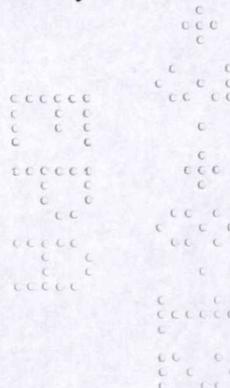
Attached is a revised label for MOI-401 TGAI (84059-4), in which the aforementioned modification has been made.

Please let me know if you need additional information. As always, thank you for your assistance and guidance. With best wishes,

Sincerely,



Keith Pitts  
Vice President, Regulatory Affairs



# MOI-401 EP

Notification Accepted

(Alternate name: Zequanox EP)

Date: 04/06/2012

Biological Quagga and Zebra Mussel Control

Reviewer: *M. J. Glavin*

**ACTIVE INGREDIENT:**

*Pseudomonas fluorescens* strain CL145A cells\* .... 14.6%

**OTHER INGREDIENTS:**..... 85.4%

**TOTAL:** ..... 100.0%

\*Contains no more than 1.0x10<sup>5</sup> CFU/mL of *Pseudomonas fluorescens* strain CL145A cells.  
One gallon of ZEQUANOX EP contains 20.47 ounces of active ingredient (or one liter contains 153 grams of active ingredient)

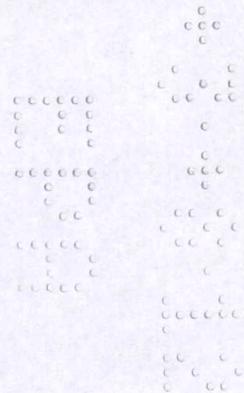
### KEEP OUT OF REACH OF CHILDREN CAUTION

| FIRST AID   |   |
|---|---|
| <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> |
| HOT LINE NUMBER   |   |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information. |   |

EPA Reg. No.: (84059-L)  
EPA Est. No.: 84059-CA-001  
(Batch)(Lot) No: XXXX  
Net Contents: 264 gallons (1000 liters)  
Use by: (6 months after date of manufacture)

**Manufactured by:** Marrone Bio Innovations, Inc.  
2121 Second St., Suite B-107  
Davis, CA 95618 USA

Patent No. 6,194,194; Canada Patent No. 2,225,436  
ZEQUANOX EP is a registered trademark of Marrone Bio Innovations, Inc. © 2010



714

### PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION:** Harmful if inhaled. Avoid breathing vapor or spray mist. Remove and wash contaminated clothing before reuse.

Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables are available, use detergent and hot water. Keep and wash PPE separately from other laundry.

**ENVIRONMENTAL HAZARDS:** Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other 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

### DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. Applications of ZEQUANOX EP must be under the supervision of Marrone Bio Innovations (MBI).

This label must be in the possession of the user at the time of pesticide application.

**Mode of Action:** Zebra and quagga mussels filter the product out of water and process the active ingredient as a food source. When the zebra and quagga mussels digest the product, the active ingredient disrupts the epithelial cells lining their digestive system causing mussel mortality. Since the ZEQUANOX EP efficacy is dependent on zebra and quagga mussel feeding activity and metabolism, which is affected by such factors as water temperature and mussel breeding activity, site assessments must be conducted to ensure appropriate timing of product application.

**Treatment sites for MOI-401 EP:** Treatments of ZEQUANOX EP are limited to enclosed and other confined static or flowing water infrastructures infested with zebra and/or quagga mussels. Treatment area must be a completely enclosed pipe or water conveyance system or concrete chamber with a defined inlet or outlet. Application of ZEQUANOX EP assumes the full flow and volume of water through the treated pipe or water conveyance system or concrete chamber with a defined inlet or outlet. Enclosed and other confined static or flowing water infrastructures include water storage chambers and tanks, pipes, general plumbing and equipment, and other water conveyance structures associated with civil infrastructure such as the cooling water systems and contained water storage chambers of power plants, pump stations, irrigation systems, industrial and manufacturing facilities (e.g. automobile and steel), and dams. **Treatment of open water, such as infested ponds, lakes, reservoirs, rivers and streams, or other unconfined aquatic systems, with ZEQUANOX EP is prohibited.**

**Method of Application:** Apply ZEQUANOX EP by injecting the product from a tote using chemical metering pumps directly into the enclosed system. This is similar equipment commonly used for chemical injection in water and wastewater treatment. Application is based on volumetric flow rates. For enclosed and confined systems (e.g. cooling and service water lines

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and fire suppression systems), treated water flow rates and chemical injection rates are measured by using equipment such as flow meters and calibration columns. Use turbidity measurements before, during and after application as a surrogate to measure actual applied product.

**Maximum Rate of Application of MOI-401 EP:** Up to 0.026 oz/gallon (200 mg/L) active ingredient for up to 24 hours total per month.

**Limitations on Discharge of Treated Water:** Prior to treatment, site assessments must be conducted to ensure that the concentration of treated water from mussel infested infrastructure does not exceed an EEC (expected environmental concentration) of 0.00013 oz/gallon (1 mg/L) active ingredient no more than a 200 yard radius of the discharge or dilution zone of the treated infrastructure.

**Monitoring Discharge of Treated Water:** Water samples pre-, during, and post-treatment will be collected below the discharge location and above the treatment location to be analyzed for *Pseudomonas* concentrations and for turbidity. Number of samples and sampling frequency will be determined by Marrone Bio Innovations prior to treatment and described in the pre-notification.

**Treatment Scenarios:** Apply ZEQUANOX EP by one or both treatment scenarios, depending on the system, level of infestation, stage within mussel lifecycle, time of year and sensitivity of the system to abrasion/occlusion from invasive mussels:

1) Rehabilitation Level Treatment.

Rehabilitation treatments are conducted at high concentrations to remove adult mussel infestations. A rehabilitation treatment can be followed by a settlement maintenance treatment to protect facilities sensitive to any shell debris. (The settlement maintenance treatment scenario is described in the next section below entitled, "Settlement Maintenance Treatment"). The purpose of the rehabilitation treatment is to kill and/or remove attached adult mussels from infested systems. These treatments would be at concentrations near or at the maximum rate of 0.026 oz/gallon (200 mg/L) active ingredient for no more than 12 hours in a continuous 24 hour period. Cold water environments, such as the Great Lakes region, typically have only 2-3 zebra and/or quagga mussel lifecycles per year and require one rehabilitation treatment per year. Warm water environments, such as the Lower Colorado River, have up to 7 zebra and/or quagga mussel lifecycles per year. Rehabilitation level treatments are typically done once per year, but cannot occur more than twice per year.

2) Settlement Maintenance Level Treatments

Settlement maintenance is an on-going, lower dose treatment during the mussel spawning season and prevents juvenile mussels from settling and growing to the adult stage within the system and is similar, in function, to chlorine treatments. It is performed to protect pipes and orifices that are more susceptible to damage by mussel settlement, and prevents shell debris from clogging equipment or abrasion damage to equipment. Settlement maintenance treatments cannot exceed 0.0067 oz/gallon (50 mg/L) active ingredient for up to 12 hours per treatment and can be done no more than two times per month per treatment site.

**Calculation of Application Rates:**

For all applications, prior to product application, dilute ZEQUANOX EP into double contained plastic injection tank, tote, or similar container appropriate for use for chemical application into water. For every 0.26 gallon (1 liter) of ZEQUANOX EP added to plastic container add between 0.13 to 0.92 gallons (0.5 to 3.5 liters) of non-chlorinated water to achieve a concentration of 10.2 to 5.8 oz/gallon (76.5 to 43.7 g/L). Mix well. Once ZEQUANOX EP is diluted, follow application instructions as described below.

*Enclosed, and other confined static and flowing water infrastructure*

Rehabilitation Level Treatment: For adult zebra and quagga mussels control in enclosed and confined static and flowing water in infested infrastructures, e.g. water storage chambers or tanks and pipes and any water conveyance structures, associated with civil infrastructure such as, power plants, pumping stations, irrigation systems, industrial and manufacturing facilities (e.g. automobile and steel) and dams , inject diluted ZEQUANOX EP contained in the appropriate chemical injection tank (container) into flowing water at a point with heavy mixing with standard chemical injection metering pump to reach a completely mixed and homogeneous suspension of up to 0.026 oz/gallon (200 mg/liter) concentration of active ingredient.. Maintain continuous injection with the chemical metering pump production for 6 to 12 hours or until up to 0.026oz/gallon (200 mg/L) active ingredient is reached in a static environment. For non-flowing, static, application conditions, product should be held in the contained treatment system for the total treatment time of 12 to 18 hours. To maintain a completely mixed and dispersed concentration, use a submersible pump or other mixing unit. To achieve the maximum desired concentration, calculate the injection rate (volumetric dose) based on the total volumetric water flow rate (or volume) and diluted product concentration.

Settlement Maintenance Level Treatment: For settlement prevention control of juvenile and planktonic zebra and quagga mussel life stages (veliger life stage) in enclosed and confined static and flowing water in infested infrastructures, e.g. water storage chambers and tanks and pipes and any water conveyance structures associated with civil infrastructure such as, power plants, pumping stations, irrigation systems, industrial and manufacturing facilities (e.g. automobile and steel) and dams, inject diluted ZEQUANOX EP contained in the appropriate chemical injection tank (container) at a location with heavy mixing with standard chemical injection metering pump to reach a completely mixed and homogeneous suspension of up to 0.0067 oz/gallon (50 mg/L) concentration of active ingredient. Maintain continuous injection with the chemical metering pump production for 1 to 6 hours until up to 0.0067oz/gallon (50 mg/L) active ingredient is reached in a static environment. For non-flowing, static, application conditions, product should be held in the contained treatment system for the total treatment time of 6 hours. To achieve the necessary concentration, calculate the injection rate (volumetric dose) based on the total volumetric water flow rate (or volume) and diluted product concentration. Repeat injection up to two times a month, dependent on viable veliger density, continuously through mussel spawning season.

*Product measurement in treated system*

Perform turbidity measurements to determine when the desired completely mixed homogenous concentration of ZEQUANOX EP active ingredient is achieved and to the required ZEQUANOX EP active ingredient concentration. In order to correlate target turbidity to desired active ingredient concentration, add the necessary volume of diluted MOI-401-EP to achieve the target concentration into a known volume of water contained in a plastic or glass container and mix. Read turbidity of this mixture – this is the target turbidity for desired completely mixed homogenous concentration. If turbidity concentrations exceed label or pre-notification intended

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use, applicator will adjust chemical metering pump or shut down application system entirely to prevent exceeding the expected environmental concentration upon discharge.

Prior to any treatment, site assessments must be conducted to ensure that the concentration of treated water from mussel infested infrastructure does not exceed an EEC (expected environmental concentration) of 0.00013 oz/gallon (1 mg/L) active ingredient no more than a 200 yard radius from the discharge or dilution zone of the treated infrastructure.

Water samples pre-, during, and post-treatment will be collected below the treated discharge location and above the treatment location to be analyzed for *Pseudomonas* and for turbidity). Number of samples and sampling frequency will be determined by Marrone Bio Innovations prior to treatment and included in the pre-notification.

After application, allow 2 to 4 weeks, respectively, at warm (ca. > 68°F (20°C)) to cold (ca. < 50 F (10°C)) water temperatures before determining the final mortality achieved, via biobox monitoring or similar industry practice, from each treatment.

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Store in original container at less than -4°F (-20°C) for up to 53 days after date of manufacture.

**Pesticide Disposal:** To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**Container Disposal:** Triple rinse container promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

**WARRANTY**

To the extent consistent with applicable law, the seller makes no warranty, expressed or implied, of merchantability, fitness or otherwise concerning use of this product. To the extent consistent with applicable law, the user assumes all risks of use, storage or handling that are not in strict accordance with the accompanying directions.