

85004-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

09/03/2009

AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

85004-2

Date of Issuance:

SEP 03 2009

Term of
Issuance:Conditional,
Time-Limited

Name of Pesticide Product:

Econem™

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Pasteuria Bioscience, Incorporated
12085 Research Drive, Suite 185
Alachua, FL 32615

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA registration number.

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 (FIFRA).

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 is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you do the following terms and conditions:

1. The subject registration will automatically expire on midnight March 1, 2012.
2. Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

-Continued on Page 2-

Signature of Approving Official:

WAM

W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division

Date:

9-3-09

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	KAUSCH	Reynolds						
DATE	09/02/2009	9/2/09						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Pasteuria Bioscience, Incorporated
EPA Registration No. 85004-2

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3. Submit/cite all data required to support the manufacturing-use product, *Pasteuria usgae* – BL1, which is used to create this product, within the time frames required by the terms and conditions of EPA Registration Number 85004-1:

Study Type	Required Data/Information	Due Date
Analysis of Samples (OPPTS Guideline 885.1400)	The preliminary analysis of samples provided to the Agency revealed a wide range of concentrations, with many replicates containing 1–2 orders of magnitude fewer <i>Pasteuria usgae</i> spores than the minimum specified on the Confidential Statement of Formula and product label (i.e., 1×10^6 spores per milliliter). A follow-up explanation, attempting to address this variability, mentioned several factors that contributed to this inconsistency and discussed how the concentration of spores could be adjusted during the manufacturing process, if necessary. Despite this additional information, a new five-batch analysis, with all batches from production level, must be submitted to the Agency.	May 1, 2011
Manufacturing Process (OPPTS Guideline 885.1200)	The original manufacturing process did not describe quality control measures taken to confirm that <i>Pasteuria usgae</i> was the only <i>Pasteuria</i> species present in the master stock. A follow-up explanation, which demonstrated that batches are screened for the presence of other microbes and screened against sting nematodes to confirm the presence of <i>Pasteuria usgae</i> , still did not provide sufficient information to indicate that screening for other <i>Pasteuria</i> species is conducted during the manufacturing process. Other <i>Pasteuria</i> species, specifically those that parasitize saprophytic (non-plant pathogenic) nematodes, must be screened for during the manufacturing process. Pasteuria Bioscience, Incorporated must integrate quality control measures that screen for <i>Pasteuria</i> species that parasitize saprophytic nematodes, either immediately after freezing or after making seed stock, into their current manufacturing process and provide a written description of these measures to the Agency.	October 1, 2009
Product Identity (OPPTS Guideline 885.1100)	Currently, full recognition of <i>Pasteuria usgae</i> is still pending with the Judicial Commission of the International Committee for Systematic Bacteriology. Once <i>Pasteuria usgae</i> has been recognized and removed from the category <i>Candidatus</i> , documentation indicating official recognition must be provided to the Agency.	As soon as the specified information becomes available
Storage Stability (OPPTS Guideline 830.6317)	The storage stability study for the technical grade of the active ingredient (TGAI)/manufacturing-use product (MP) has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency. Within the discussion of these results, the test substance must be described so as to ensure that this data requirement has been fulfilled for both the TGAI and the MP (i.e., reference that the TGAI is equivalent to the MP for <i>Pasteuria usgae</i> – BL1).	June 1, 2010

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Pasteuria Bioscience, Incorporated
EPA Registration No. 85004-2

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4. Submit the following data and/or information in the time frames listed:

Study Type	Required Data/Information	Due Date
Analysis of Samples (OPPTS Guideline 885.1400)	The preliminary analysis of samples provided to the Agency revealed a wide range of concentrations of <i>Pasteuria usgae</i> spores. A new five-batch analysis, with all batches from production level, must be submitted to the Agency.	August 1, 2011
Storage Stability (OPPTS Guideline 830.6317)	The storage stability study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency.	September 1, 2010
Corrosion Characteristics (OPPTS Guideline 830.6320)	The corrosion characteristics study for this end-use product has been cited as ongoing. When the study has been completed and the results have been compiled, these data must be submitted to the Agency.	September 1, 2010

5. Submit two (2) copies of the final printed labeling before you release the product for shipment.
Refer to the A-79 enclosure for further description of a final printed label.

If these conditions are 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.

A stamped copy of the label is enclosed for your records.

Sincerely,



W. Michael McDavit, Associate Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (2):

- Econem™ Accepted Label
- A-79 Enclosure

ECONEM™

Biological management of sting nematodes in turf

Active Ingredient:	<i>Pasteuria usgae</i> *	0.0020%
Other Ingredients:		99.9980%
Total:		100.0000%

* Contains at least 1×10^4 spores per g or 4.5×10^6 spores per pound.**KEEP OUT OF REACH OF CHILDREN****CAUTION**

See additional precautionary statements on the back panel

EPA Registration Number: 85004-2

EPA Est. Number: 70815-GA-001

Manufactured for:

 **PASTEURIA**
bioscience

12085 Research Dr., Suite 185
Alachua, FL 32615
(386) 462-0008
www.pasteuriabio.com/

ACCEPTED

SEP 03 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 85004-2

Net Weight:

Batch Code:

Pasteuria Bioscience, Inc.

August 27, 2009

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. 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.

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none"> • 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 inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time. After 4:30 pm Pacific Time, call your poison control center at 1-800-222-1222.	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

The PPE requirements that follow apply to both Worker Protection Standard (WPS) uses (in general, agricultural-plant uses are covered under the Worker Protection Standard (40 CFR Part 170)) and Non-WPS uses.

Applicators and other handlers must wear:

- Protective eyewear

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks

Mixers/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 manufacturer's instructions for cleaning and maintaining PPE. If no instructions are available, use detergent and hot water for washables. Keep and wash PPE separately from other laundry.

ENGINEERING CONTROLS

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6)), the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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 cleaning equipment or disposing of equipment washwaters.

DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation. Do not use this product until you have read the entire label.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box apply only to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours unless wearing the appropriate personal protective equipment.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water), is:

- Protective eyewear
- Coveralls
- Waterproof gloves
- Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until product has been integrated into soil through irrigation.

PRODUCT INFORMATION

This product contains a biological nematicide for the control of the following nematode for most turf grass uses:

Sting Nematode

Belonolaimus longicaudatus

USE RESTRICTIONS

Consult your extension agent or manufacturing representative before mixing this product with fertilizer or seed. Do not mix this product with other turf grass pesticides.

APPLICATION INSTRUCTIONS

Turf Grass: Apply 2 to 10 pounds of **Econem™** per 1000 square feet of turf prior to, during, and after turf green-up in 3 to 4 week intervals using calibrated, standard granule application equipment such as a drop-spreader. For best control, a minimum of 3 sequential applications is required. For warm-season grasses, these green-up periods may be in early spring and again in late summer or early fall; for cool-season grasses, this may be late summer or early fall. Monthly applications throughout the year may help maintain sting nematode populations below economic threshold levels.

Use the higher application rates on sites with high sting nematode populations (greater than 60 sting nematodes per 0.4 cup (100 cm³ of soil) or areas with extensive nematode damage such as bare turf areas, dying turf areas, or turf with root systems less than 0.8 – 1.2 inch (2 – 3 cm) in length.

Apply 0.10 inch water immediately following all applications. After application of **Econem™** and subsequent treatment with water, minimizing irrigation for several weeks following treatment may improve sting nematode control. For areas under intense irrigation or experiencing excessive rainfall, repeat applications may be necessary to maintain sting nematode populations below an economic threshold.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in a cool, dry place. Reclose containers of unused portions of Econem.

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 HANDLING

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

WARRANTY STATEMENT

Pasteuria Bioscience, Incorporated (PBI) warrants that this product conforms to its label description and is suitable for its intended use if stored and used strictly in accordance with the Directions for Use under normal conditions of use. To the extent consistent with applicable law, PBI makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. To the extent consistent with applicable law, user assumes all risks of use, storage or handling not in strict accordance with accompanying directions.