

85004-1

06/02/2009

1/6

UNITED STATES ENVIRONMENTAL PROTECTION 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:

85004-1

Date of Issuance:

6-2-09

Term of
Issuance:

Conditional,
Time-Limited

Name of Pesticide Product:

Pasteuria usgae - BL1

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.

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.

The registration application referred to above, submitted in connection with registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions:

1. The subject registration will automatically expire on midnight December 1, 2011.
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:

WMA

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

Date:

6-2-09

EPA Form 8570-6

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	KAUSCH	KAUSCH					
DATE	06/02/2009	6/2/09					

3. 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, 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

4. 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.

3/6

Pasteuria Bioscience, Incorporated
EPA Registration No. 85004-1

-3-

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,

A handwritten signature in black ink that reads "W. Michael McDavit". The signature is written in a cursive, flowing style.

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

Enclosures (2):
- *Pasteuria usgae* – BL1 Accepted Label
- A-79 Enclosure

4/6

PASTEURIA USGAE – BL1
For manufacturing or formulating use only

ACTIVE INGREDIENT: <i>Pasteuria usgae</i> *	0.01%
OTHER INGREDIENTS:	99.99%
TOTAL:	100.00%

* Contains at least 1×10^6 spores per gram

KEEP OUT OF REACH OF CHILDREN
CAUTION

See additional precautionary statements on the back panel

EPA Registration Number: 85004-1
EPA Est. Number: 84691-PA-001

Produced for:



12085 Research Dr., Suite 185
Alachua, FL 32615

+1 (386) 462-0008
www.pasteuriabio.com/

Net Contents: _____

ACCEPTED

JUN 02 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 85004-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wear a long-sleeved shirt, long pants, waterproof gloves, shoes, socks, and dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95 when handling this product. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

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.
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.	

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 EPA.

DIRECTIONS FOR USE

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

For formulation into a nematicide for use on turf. This product may be used to formulate products for any additional uses not listed on the manufacturing-use product label, if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store refrigerated (~4°C). Reclose container of unused portions of *Pasteuria usgae* – BL1.

PESTICIDE DISPOSAL

To avoid wastes, use all material in this container by application according to label directions. If waste 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

Refillable container. Refill this container with *Pasteuria usgae*-BL1 only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into a disposal facility or pesticide disposal program. Fill the container partially 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 over onto its other end and tip it back and forth several times. Empty the rinsate into a disposal facility or store rinsate for later disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.