85004-3 6/16/2010 1 of 12

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:	Date of Issuance:
85004-3	JUN 16 2010
Term of Issuance:	Conditional, Time-Limited
Name of Pesticide Product:	*Pasteuria usgae* – Liquid Formulation

NOTICE OF PESTICIDE:

__X__ 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 her 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 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:	Date:
W. Michael McDavit, Acting Director Biopesticides and Pollution Prevention Division	JUN 16 2010

EPA Form 8570-6

CONCURRENCES

SYMBOL ▶	7511P	7511P	7511P					
SURNAME ▶	KAUSCH	Reynolds						
DATE ▶	06/15/2010	6/15/10	6/16/10					

☆ U.S. Government Printing Office: 2005 206-899 (mac)

3. Submit/cite all outstanding data, determined by the Agency to be acceptable and required to support the manufacturing-use product, *Pasteuria usgae* – BL1 (source of this end-use product's active ingredient), 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 (OCSPP 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 *Pasteuria usgae* 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
Product Identity (OCSPP Guideline 885.1100)	Currently, full recognition of *Pasteuria usgae* is still pending with the Judicial Commission of the International Committee for Systematic Bacteriology. Once *Pasteuria usgae* has been recognized and removed from the category *Candidatus*, documentation indicating official recognition must be provided to the Agency.	As soon as the specified information becomes available

4. Submit the following data and/or information, determined by the Agency to be acceptable, in the time frames listed:

Study Type	Required Data/Information	Due Date
Storage Stability (OCSPP 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.	June 18, 2011
Corrosion Characteristics (OCSPP 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.	June 18, 2011

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 the conditions for data submission (as indicated in points 3 and 4 on page 2) 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

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

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

PASTEURIA USGAE – LIQUID FORMULATION

Biological control for use on turf and strawberries against sting nematode

FOR ORGANIC PRODUCTION

Active Ingredient:	*Pasteuria usgae**	0.0033%
Other Ingredients:	.....	99.9967%
Total:	.....	100.0000%

* Contains at least 1.3×10^7 spores per g or 5.8×10^9 spores per pound.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary statements on the back panel

EPA Registration N°: 85004-3
EPA Est. Number: 70051-CA-001

Manufactured for:

PASTEURIA bioscience

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

Net Contents:

Batch Code:

ACCEPTED

JUN 16 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 85004-3

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing spray mist. 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 on skin or clothing:	• 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:	• 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)

Applicators and other handlers must wear:

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

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 wash waters or rinsate.

DIRECTIONS FOR USE

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

Do not use this product until you have read the entire label. 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 requirement specific to your State and Tribe, consult the agency responsible for pesticide regulations.

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.

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:

- 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 sprays have dried.

PRODUCT INFORMATION

This product contains a biological nematicide for the control of the following nematode for most turf grass and strawberry 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 strawberry or turf grass pesticides.

APPLICATION INSTRUCTIONS

Turf Grass: Apply 0.1 to 5 gallons of ***Pasteuria usgae* – Liquid Formulation** per 100 square feet of turf prior to, during, and after turf green-up in 3 to 4 week intervals. Use the higher application rates on sites with high sting nematode populations (greater than 60 sting nematodes per 0.4 cup [100 cm^3] 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 in (2 – 3 cm) in length. For best control, a minimum of 3 sequential applications is required. For warm-season grasses, these applications 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.

***Pasteuria usgae* – Liquid Formulation** may be diluted in water to attain proper distribution across the turf areas to be treated. This product may be applied using standard calibrated ground spray-application equipment or applied via chemigation through the existing irrigation system if it is properly designed for such applications. Agitation in the mix tank is recommended for any application requiring dilution of the formulated product with water prior to application. When mixing, fill the tank one-half full with water, add ***Pasteuria usgae* – Liquid Formulation** slowly to the tank with hydraulic or mechanical agitation, and continue to fill with water. For diluted product applications, apply product in the appropriate amount of water to treat the root-zone of the turf without flushing the product beyond the root-zone (this can vary with soil type and turf-root density/depth).

Apply 0.10 inch water immediately following all applications to move the *Pasteuria* spores into the turf root-zone, except when the product is diluted more than 50% with water for the application (such as chemigation). After application of ***Pasteuria usgae* – Liquid Formulation** and subsequent treatment with water (as needed), 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.

Strawberry: Apply 0.1 to 5 gallons of ***Pasteuria usgae* – Liquid Formulation** per 100 square feet of strawberry bed prior to planting and subsequently in 3 to 4 week intervals. Use the higher application rate on sites with high sting nematode populations (greater than 50 sting nematodes per 0.4 cup [100cc] of soil) or areas with extensive nematode damage such as stunted plants, dying plants, or heavily stunted root systems compared to unaffected plants in the same field. For best control, a minimum of 3 sequential applications is required. Monthly applications throughout the year may help maintain sting nematode populations below economic threshold levels.

***Pasteuria usgae* – Liquid Formulation** may be diluted in water to attain proper distribution across the area to be treated. This product may be applied using standard calibrated ground spray-application equipment and incorporated to a 4 inch depth prior to bed formation or applied via chemigation through the irrigation system after bed formation (pre-planting). Agitation in the mix tank is recommended for any application requiring dilution of the formulated product with water prior to application. When mixing, fill the tank one-half full with water, add ***Pasteuria usgae* – Liquid Formulation** slowly to the tank with hydraulic or mechanical agitation, and continue to fill with water. For diluted product applications, apply product in the appropriate amount of water to treat the root-zone of the crop without flushing the product beyond the root-zone of the crop (this can vary with soil type and crop stage).

Apply enough water following all applications to move the *Pasteuria* spores into the strawberry root-zone and to flush the irrigation lines of any remaining product. After application of ***Pasteuria usgae* – Liquid Formulation** and subsequent treatment with water, minimizing irrigation for several weeks following treatment may improve sting nematode control. For areas under intense irrigation, repeat applications may be necessary to maintain sting nematode populations below an economic threshold.

DAYS TO HARVEST

There are no restrictions on applying ***Pasteuria usgae* – Liquid Formulation** up to the time of harvest.

CHEMIGATION

General Requirements:

1) Apply this product only through sprinkler (including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move) and drip (trickle) irrigation systems. Do not apply this product through any other type of irrigation system
2) Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.
3) If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers, or other experts.
4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.
5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make any necessary adjustments should the need arise.

Requirements for Chemigation Systems Connected to Public Water Systems:

1) Public water supply means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of 25 individuals daily at least 60 days throughout the year.
2) Chemigation systems connected to the public water systems must contain a functional, reduced-pressure zone (RPZ), backflow preventer or the functional equivalent in the water supply upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top of the overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
3) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
4) The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Requirements for Sprinkler Chemigation:

1) The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

5) The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Requirements for Drip Chemigation:

1) The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4) The system must contain functional inter-locking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5) The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump), effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

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 *Pasteuria usgae* - Liquid Formulation.

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. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 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 over onto 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. The 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.

WARRANTY STATEMENT

Pasteuria Bioscience, Inc. (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. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.