

85004-8

06/13/2012

1/11

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 D C 20460

EPA
Registration
Number

85004-8

Date of Issuance

JUN 13 2012

NOTICE OF PESTICIDE

☒ Registration
☐ Reregistration
(under FIFRA as amended)

Term of
Issuance

Unconditional

Name of Pesticide Product

NAVIVA LF

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 or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the Environmental Protection Agency (EPA or the Agency). In order to protect health and the environment the Administrator on his or 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 registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms:

1. Revise the EPA Registration Number to read as follows "EPA Reg No 85004-8"
2. 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 final printed labeling.

Signature of Approving Official

Keith A. Matthews, Director
Biopesticides and Pollution Prevention Division

Date

13 June 2012

CONCURRENCES

SYMBOL	7511P	7511P	2511P				
SURNAME	KANSCH	Ryly	Matthews				
DATE	06/11/2012	6/12/12	13 June 12				


Pasteuria Bioscience, Inc
EPA Reg No 85004-8

- 3 Submit/cite all data, which are required to support NAVIVA Tech, within the time frames required by the terms of EPA Registration Number 85004-4 These data must be determined by EPA to be acceptable
- 4 Submit the following data on NAVIVA LF by the due dates specified below These data must be determined by EPA to be acceptable

Study Type	Required Data/Information	Due Date
Discussion of Formation of Unintentional Ingredients (Guideline Number 885 1300)	Provide information and/or additional data to address EPA s comments regarding contaminant screens (specifically see page 10 of the March 2 2012 EPA Memorandum)	December 13 2012
Analysis of Samples (Guideline Number 885 1400)	Submit an analysis of samples for four additional batches	June 13 2013

The March 2, 2012 EPA Memorandum and a stamped copy of the label are enclosed for your records

Sincerely,



Keith A Matthews, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosures (3)
NAVIVA LF Accepted Label
A 79 Enclosure
March 2 2012 EPA Memorandum

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NAVIVA LF

Biological control for use on specified food and non-food crops
against reniform nematode

🌿 FOR ORGANIC PRODUCTION

Active Ingredient	<i>Pasteuria</i> spp (<i>Rotylenchulus reniformis</i> nematode) – Pr3*	33 2900%
Other Ingredients		66 7100%
Total		100 0000%

* Contains at least 1.3×10^7 spores per g or 5.9×10^9 spores per pound

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary and first aid statements on the back panel

Net Contents 2.5, 5, 10 gallons

EPA Registration N° 85004-I
EPA Est Number

Manufactured for

 **PASTEURIA**
bioscience

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

Batch code _____

ACCEPTED

JUN 13 2012

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
FPA Reg No 85004-8

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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	<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 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 Pesticide Information Center (NPIC) at 1-800-858-7378 seven days a week, 6 30 am to 4 30 pm Pacific Time During other times, 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

[Containers with capacities of 5 gallons or less] For terrestrial uses, 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 disposing of equipment wash waters or rinsate

[Containers with capacities greater than 5 gallons] 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.

For terrestrial uses, 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 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 State or Tribal agency responsible for pesticide regulation.

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 on specified food and non-food crops:

Reniform Nematode

Rotylenchulus reniformis

USE RESTRICTIONS

Consult your extension agent or manufacturing representative before mixing this product with fertilizer or seed.

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APPLICATION INSTRUCTIONS

Apply 0.13 – 6.4 fluid ounces (fl oz) of NAVIVA LF per 100 square feet of the crop (see Table 1) prior to planting and subsequently in 3 to 4 week intervals. Use the higher application rate on sites with high Reniform nematode populations (greater than 50 Reniform nematodes per 0.4 cup [100 cm³] 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 Reniform nematode populations below economic threshold levels.

Table 1 Amounts of NAVIVA LF applied to food and non-food crops

Food and Non-food Crops	Scientific Name	Amount of NAVIVA LF per 100 Square Feet of Crop Area (fl oz)
Food Crop		
Onion garlic	Allium	0.13 – 6.4
Beet	Beta	
Broccoli collards mustard rape seed	Brassica	
kale brussel sprouts cauliflower	Brassica cont'd	
turnip kohlrabi cabbage	Brassica cont'd	
Peppers (all sweet hot bell etc.)	Capsicum	
Cucumber melons	Cucumis	
Gourd pumpkin squash	Cucurbita	
Soybean	Glycine	
Cotton	Gossypium	
Sunflower	Helianthus	
Lettuce	Lactuca	
Tomato	Lycopersicon	
Mints	Mentha	
Beans	Phaseolus	
Peas	Pisum	
Beans	Vigna	
Non-Food Crop		
Begonia	Begonia	0.13 – 6.4
Spiderplants spiderflower spiderweed	Cleome	
Hibiscus sorrel	Hibiscus	
Impatiens jewelweeds	Impatiens	
Asters	Aster	
Tobacco flowering tobacco	Nicotiana	
Marigold	Tagetes	
Zinnia	Zinnia	

NAVIVA LF 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 NAVIVA LF 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 plant root-zone and to flush the irrigation lines of any remaining product. After application of NAVIVA LF and subsequent treatment with water, minimizing irrigation for several weeks following treatment may improve Reniform nematode control. For areas under intense irrigation, repeat applications may be necessary to maintain Reniform nematode populations below an economic threshold.

DAYS TO HARVEST

There are no restrictions on applying NAVIVA LF 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 flow outlet end of the fill pipe and the top or 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 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

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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 NAVIVA LF

PESTICIDE DISPOSAL

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

CONTAINER HANDLING

[Plastic containers with capacities equal to or less than 5 gallons] 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 and drain for 10 seconds after the flow begins to drip Fill the container 1/4 full with water and recap Shake for 10 seconds Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal Drain for 10 seconds after the flow begins to drip 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 ordinance If burned, stay out of smoke

[Plastic containers with capacities greater than 5 gallons] 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 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 ordinance If burned, stay out of smoke

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 in accordance with the Directions for 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 this label To the extent consistent with applicable law, user assumes all risks of use, storage or handling not in accordance with accompanying directions