

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:

Date of Issuance:

JUN 1 3 2012

85004-5 Term of

Issuance:

Unconditional

Name of Pesticide Product:

NAVIVA ST

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 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. 85004-5."
- 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 2014

Pasteuria Bioscience, Inc. EPA Reg. No. 85004-5

3. Submit the following data on NAVIVA ST 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

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 ST Accepted Label

⁻ A-79 Enclosure

⁻ March 2, 2012 EPA Memorandum

NAVIVA ST

For seed treatment use only

FOR ORGANIC PRODUCTION

ACTIVE INGREDIENT: Pasteuria spp. (Rotylenchulus reniformis nematode) - P.	r3* 99.88%
OTHER INGREDIENTS:	<u>00.12%</u>
TOTAL:	100.00%

^{*} Contains at least 1x10⁸ spores per gram

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary and first aid statements on the back panel

Net Contents: 10, 20 or 55 gallons

EPA Registration Number: 85004-L

EPA Est. Number:

ACCEPTED

JUN 1 3 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 85004 - 5

Manufactured for:



12085 Research Dr., Suite 185 Alachua, FL 32615 +1 (386) 462-0008 www.pasteuriabio.com/

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 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 in eyes:	 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	Take off contaminated clothing.			
or	• Rinse skin immediately with plenty of water for 15-20 minutes.			
clothing:	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 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

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 the 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.

EXCEPTION: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

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:

- · Water proof gloves
- Coveralls
- Shoes plus socks

NON- AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product 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 treatment areas until seeds have dried or been packaged.

This product contains a biological nematicide for the control of the following nematode on specified food and nonfood crops:

Reniform Nematode

Rotylenchulus reniformis

FOR USE AS A PRE-PLANT SEED TREATMENT

Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seeds beyond planting time. See Table 1. for crops and application amounts.

To achieve improved application coverage to the seed, dilute NAVIVA ST with water and apply directly to dry seed or mix with inoculants and/or other registered seed treatment coatings (e.g., colorants, polymers, etc.), insecticides and fungicides (Table 1). Do not mix NAVIVA ST with any product containing a label prohibition against such mixing. When tank-mixing with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both NAVIVA ST and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates. Please consult Pasteuria Bioscience, additional information Inc. for (http://www.pasteuriabio.com/).

FOR USE AS A COMMERICAL SEED TREATMENT

To achieve improved application coverage to the seed, dilute NAVIVA ST with water and apply directly to dry seed or mix with inoculants and/or other registered seed treatment coating (e.g., colorants, polymers, etc.), insecticides and fungicides (Table 1). Do not mix NAVIVA ST with any product containing a label prohibition against such mixing. When tank-mixing with any other registered seed treatment insecticide and/or fungicide, always read and follow all use directions, restrictions, and precautions of both NAVIVA ST and the tank mix partner(s). The resulting tank mix must be in accordance with the more restrictive label limitations and precautions. Do not exceed label dosage rates. Please consult Pasteuria Bioscience, Inc. for additional information (http://www.pasteuriabio.com/).

MIXING INSTRUCTIONS

Mix NAVIVA ST as follows:

- Step 1. Add water to the mix tank and provide gentle agitation.
- Step 2. Determine the amount of NAVIVA ST required (see Table 1.) based on the amount and type of crop seed to be treated. Then, add NAVIVA ST to mix tank.
- Step 3. If tank mixing, add other spray materials to mix tank.
- Step 4. Agitate until fully mixed and/or dissolved and avoid excessive foaming.
- Step 5. Promptly apply seed treatment mixture to seed.

Table 1. Amounts of NAVIVA ST applied to food and non-food crop seeds

Table 1. Amounts of NAVIVA ST applied to food and non-food crop seeds Scientific Amount of NAVIVA ST per 100				
Food and Non-food Crops	Name	lbs seed (fl. oz.)*		
Food Crop				
Onion, garlic	Allium			
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	2.4 - 243 fl oz		
Cucumber, melons	Cucumis]		
Gourd, pumpkin, squash	Cucurbita			
Soybean .	Glycine			
Cotton	Gossypium			
Sunflower	Helianthus	1		
Lettuce	Lactuca			
Tomato	Lycopersicon			
Mints .	Mentha			
Beans	Phaseolus			
Peas	Pisum			
Beans	Vigna			
Non-Food Crop				
Begonia	Begonia			
Spiderplants, spiderflower, spiderweed	Cleome	7		
Hibiscus, sorrel	Hibiscus			
Impatiens, jewelweeds	Impatiens	2.4 – 243 fl oz		
Asters	Aster			
Tobacco, flowering tobacco	Nicotiana			
Marigold	Tagetes			
Zinnia	Zinnia			

^{*}Based on 0.25 - 25 mg/seed (3000 seed / lb)

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 NAVIVA ST.

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

Refillable container. Refill this container with NAVIVA ST 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 application equipment or 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 over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or mix tank, 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. 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.