Ms. Susan MacIntosh Agent for Pasteuria Bioscience, Inc. MacIntosh & Associates, Inc. 1203 Hartford Avenue Saint Paul, MN 55116

MAY 1 7 2012

TATES ENVIRONMENTAL PROTECTION

Re:

Pasteuria Bioscience, Inc.; Soyacyst LF

EPA Registration No. 85004-9

UNITE

Non-Fast Track Amendment to Modify the Product Formulation & Certification of Limits and

Add Two Additional Manufacturing Facilities

Submission dated 02/10/2012

Decision No. 460925

Dear Ms. MacIntosh:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Modification of the viability statement (in the Ingredient Statement) from "Contains at least  $1.3 \times 10^7$  spores per g or  $5.9 \times 10^9$  spores per pound" to "Contains at least  $2 \times 10^8$  spores per g or  $9.1 \times 10^{10}$  spores per pound" (master label cover sheet and all sub-labels).
- 2) Modification of the EPA Registration Number from "85004-O" to "85004-9" (master label cover sheet and all sub-labels).
- 3) Addition of the following EPA Establishment Numbers: 100-NC-002 (new), 071617-GA-001 (new), and 70815-GA-001 (old) (master label cover sheet and all sub-labels).

In conjunction with the label amendment, you also updated the confidential statement of formula (CSF) on file for Soyacyst LF. There is now only one valid CSF, basic formulation dated May 16, 2012, for this product registration. All previously accepted Soyacyst LF CSFs have been superseded by the aforementioned CSF.

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, are acceptable provided that you comply with the following terms:

- 1) By October 17, 2013, submit five-batch analyses from batches produced at the two new manufacturing facilities, one from the registered establishment in North Carolina and one from the registered establishment in Brunswick, Georgia.
- 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.

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SYMBOL	7511P	75119			
SURNAME >	KAUSCH	Reynold			
DATE	05   17   2012	5/17/12			

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

Susan MacIntosh EPA Registration No. 85004-9

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these terms. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email (*kausch.jeannine@epa.gov*).

Copies of the associated science review and stamped label are enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D., Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

(3) A-79 Enclosure

<sup>(2)</sup> May 11, 2012 Memorandum

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

## WITH THE ALTERNATE BRAND NAME: SOYACYST ST

Biological control for use on soybean seed against soybean cyst nematode

#### **MASTER LABEL**

SUB-LABEL A: FOR AGRICULTURAL USE AS FOLIAR TREATMENT AND SEED TREATMENT

SUB-LABEL B: FOR AGRICULTURAL USE AS FOLIAR TREATMENT

SUB-LABEL C: FOR SEED TREATMENT

FOR ORGANIC PRODUCTION

Active Ingredient:	Pasteuria nishizawae – Pn1*	33.29%
Other Ingredients:		66.71%
Total:		

<sup>\*</sup>Contains at least 2x10<sup>8</sup> spores per g or 9.1x10<sup>10</sup> spores per pound.

EPA Registration N°: 85004-9

EPA Est. Number: 100-NC-002 or 071617-GA-001 or 70815-GA-001

Manufactured for:



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

### **ACCEPTED**

MAY 1 7 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 85004 - 9

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

## WITH THE ALTERNATE BRAND NAME: SOYACYST ST

Biological control for use on soybean seed against soybean cyst nematode

#### SUB-LABEL A

FOR AGRICULTURAL USE AS FOLIAR APPLICATION
AND SEED TREATMENT

#### SUB-LABEL A

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

#### WITH THE ALTERNATE BRAND NAME: SOYACYST ST

Biological control for use on soybean seed against soybean cyst nematode

#### FOR ORGANIC PRODUCTION

Active Ingredient:	Pasteuria nishizawae – Pn1*	33.29%
Other Ingredients:		66.71%
Total:	0.1.1010	

<sup>\*</sup> Contains at least 2x10<sup>8</sup> spores per g or 9.1x10<sup>10</sup> 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°: 85004-9

EPA Est. Number: 100-NC-002 or 071617-GA-001 or 70815-GA-001

Manufactured for:



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

#### PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

	FIRST AID
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> </ul>
	Call a poison control center or doctor for treatment advice.
	Can a poison control center of 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
- 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:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. 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 or 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.

#### PRODUCT INFORMATION

This product contains a biological nematicide for the control of the following nematode:

Soybean Cyst Nematode

Heterodera glycines

#### FOR USE AS FOLIAR APPLICATION

#### APPLICATION INSTRUCTIONS

Soybean: Apply 1.3 to 64 fluid ounces (fl oz) of SOYACYST LF per 1000 square feet of soybean prior to planting and subsequently in 3 to 4 week intervals. Use the higher application rate on sites with high Soybean cyst nematode populations (greater than 50 Soybean cyst nematodes per 0.4 cup [100cm³] 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 Soybean cyst nematode populations below economic threshold levels.

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

#### DAYS TO HARVEST

There are no restrictions on applying SOYACYST LF up to the time of harvest.

#### **CHEMIGATION**

#### **Basic 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 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, solenoidoperated 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.

## 11/30

#### **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.

#### FOR USE AS A SEED TREATMENT

Treatment of highly mechanically scarred or damaged seed, or seed known to be of low vigor and poor quality, except for the purpose of curative control of existing disease pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat a small quantity of seed using equipment similar to that planned for treating the total seed lot. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Due to seed quality, crop or variety sensitivity, and seed storage conditions beyond the control of manufacturer, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.

#### 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.

To achieve improved application coverage to the seed, dilute SOYACYST LF 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. Do not mix SOYACYST LF 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 SOYACYST LF 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 (<a href="http://www.pasteuriabio.com/">http://www.pasteuriabio.com/</a>).

#### SOYBEAN

For control of soybean cyst nematode, apply 2 to 12 fluid ounces of SOYACYST LF per 100 Lbs (60-150 mL per 45.4 kg) of soybean seed.

#### FOR USE AS A COMMERICAL SEED TREATMENT

To achieve improved application coverage to the seed, dilute SOYACYST LF 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. Do not mix SOYACYST LF 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 SOYACYST LF 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 (<a href="https://www.pasteuriabio.com/">http://www.pasteuriabio.com/</a>).

#### SOYBEAN

For control of soybean cyst nematode, apply 2 to 12 fluid ounces of SOYACYST LF per 100 Lbs (60–150 mL per 45.4 kg) of soybean seed.

#### 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 SOYACYST LF.

#### 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**

[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.

May 16, 2012

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

#### SUB-LABEL B

FOR AGRICULTURAL USE AS FOLIAR APPLICATION

#### SUB-LABEL B

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

#### FOR ORGANIC PRODUCTION

Active Ingredient:	Pasteuria nishizawae – Pn1*	33.29%
Other Ingredients:		66.71%
Total:		

<sup>\*</sup> Contains at least 2x10<sup>8</sup> spores per g or 9.1x10<sup>10</sup> 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 No: 85004-9

EPA Est. Number: 100-NC-002 or 071617-GA-001 or 70815-GA-001

Manufactured for:



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

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artific respiration, preferably mouth-to-mouth if possible.</li> </ul>		FIRST AID .
<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	If inhaled:	• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

# 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
- 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:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. 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 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 or 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

#### PRODUCT INFORMATION

This product contains a biological nematicide for the control of the following nematode:

Soybean Cyst Nematode

Heterodera glycines

#### APPLICATION INSTRUCTIONS

**Soybean:** Apply 1.3 to 64 fluid ounces (fl oz) of SOYACYST LF per 1000 square feet of soybean prior to planting and subsequently in 3 to 4 week intervals. Use the higher application rate on sites with high Soybean cyst nematode populations (greater than 50 Soybean cyst nematodes per 0.4 cup [100cm³] 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 Soybean cyst nematode populations below economic threshold levels.

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

#### DAYS TO HARVEST

There are no restrictions on applying SOYACYST LF up to the time of harvest.

#### **CHEMIGATION**

#### **Basic 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 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, solenoidoperated 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.

#### 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 SOYACYST LF.

#### 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**

[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.

Proposed Label for Soyacyst LF Sub-Label B

#### 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.

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

## WITH THE ALTERNATE BRAND NAME: SOYACYST ST

Biological control for use on soybean seed against soybean cyst nematode

SUB-LABEL C

FOR SEED TREATMENT

#### SUB-LABEL C

#### SOYACYST LF

Biological control for use on soybean against soybean cyst nematode

## WITH THE ALTERNATE BRAND NAME: SOYACYST ST

Biological control for use on soybean seed against soybean cyst nematode

#### FOR ORGANIC PRODUCTION

Active Ingredient:	Pasteuria nishizawae – Pn1*	
Other Ingredients:		
Total:		1.3

<sup>\*</sup> Contains at least 2x10<sup>8</sup> spores per g or 9.1x10<sup>10</sup> 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 Number: 85004-9

EPA Est. Number: 100-NC-002 or 071617-GA-001 or 70815-GA-001

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

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

Move person to fresh air.
<ul> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

#### 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
- 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:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. 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 or Tribe, consult the State or Tribe 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.

#### PRODUCT INFORMATION

This product contains a biological nematicide for the control of the following nematode:

Soybean Cyst Nematode

Heterodera glycines

#### FOR USE AS A SEED TREATMENT

Treatment of highly mechanically scarred or damaged seed, or seed known to be of low vigor and poor quality, except for the purpose of curative control of existing disease pests, may result in reduced germination and/or reduction of seed and seedling vigor. Treat a small quantity of seed using equipment similar to that planned for treating the total seed lot. Conduct germination tests on a small portion of seed before committing the total seed lot to a selected seed treatment. Due to seed quality, crop or variety sensitivity, and seed storage conditions beyond the control of manufacturer, no claims are made to guarantee the germination of carry-over seed or propagating material for all crop seed.

#### 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.

To achieve improved application coverage to the seed, dilute SOYACYST LF 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. Do not mix SOYACYST LF 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 SOYACYST LF 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 (<a href="http://www.pasteuriabio.com/">http://www.pasteuriabio.com/</a>).

#### **SOYBEAN**

For control of soybean cyst nematode, apply 2 to 12 fluid ounces of SOYACYST LF per 100 Lbs (60–150 mL per 45.4 kg) of soybean seed.

#### FOR USE AS A COMMERICAL SEED TREATMENT

To achieve improved application coverage to the seed, dilute SOYACYST LF 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. Do not mix SOYACYST LF 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 SOYACYST LF 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/).

Proposed Label for Soyacyst ST Sub-label C

#### SOYBEAN

For control of soybean cyst nematode, apply 2 to 5 fluid ounces of SOYACYST LF per 100 Lbs (60–150 mL per 45.4 kg) of soybean seed.

#### 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 SOYACYST LF.

#### 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**

[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

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