#### JUL 18,2013

Ms. Susan MacIntosh Authorized Agent for Pasteuria Bioscience, Inc. (PBI) MacIntosh & Associates, Inc. 1203 Hartford Avenue Saint Paul, MN 55116-1622

Re: Your applications originally dated April 20, 2013 to update and/or add primary brand names, alternate brand names, EPA Registration Numbers, EPA Establishment Numbers, and package sizes consistent with Pesticide Registration (PR) Notice 98-10

Product Name	EPA Reg. No.	Label Modifications	OPP Decision. Number
SOYACYST <sup>™</sup> TECH	85004-6	Update Primary Brand Name, Add Alternate Brand Name & Add Package Size	478154
SOYACYST <sup>™</sup> TECH+	85004-7	Update Primary Brand Name, Add Alternate Brand Name, Update EPA Registration Number & Add EPA Establishment Number	478155
SOYACYST <sup>™</sup> LF	85004-9	Update Primary and Alternate Brand Names, Add Alternate Brand Name, Add Package Size, & Update EPA Establishment Numbers	478157
SOYACYST <sup>™</sup> WP PLUS	85004-12	Update Primary Brand Name, Add Alternate Brand Name, Add Package Size, and Update EPA Registration Number	479653
SOYACYST <sup>™</sup> TECH PLUS	85004-13	Update Primary Brand Name, Add Alternate Brand Name, Add Package Size, and Update EPA Registration Number	479641

#### Dear Ms. MacIntosh:

The Biopesticides and Pollution Prevention Division is in receipt of your applications, as indicated above, for notification under PR Notice 98-10. The EPA conducted a preliminary screen of these requests for their applicability under PR Notice 98-10 and determined that the actions requested fall within the scope of this particular document. Our records have been duly noted, and the labels submitted with these applications have been stamped "Notification Accepted" and will be placed in our records. Submit two (2) copies of final printed labeling (for each product) before the products, as modified, are sold or distributed [40 C.F.R. § 156.10(a)(6)].

		·		CONCURRENC	ES		
YMBOL	7511 P	75119	75110				
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Susan MacIntosh EPA Registration No. 85004-6, -7, -9, -12, and -13

Should you wish to retain the reference to PBI's website on your labels, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the products would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 C.F.R. § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on the labels of your products, claims made on the website may not substantially differ from those claims approved through the registration/amendment process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration/amendment, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email (kausch.jeannine@epa.gov).

Sincerely,

Kimberly Nesci, Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) a completing form.

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Form	Approved	`

.. No. 2070-0060. Approval expires 2-28-95

OPP Identifier Number

#### United States

Registration
Amendmen

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<b>\$EPA</b>		vvasningto	on, DC 20460		⊠ O			·
		Applica	tion for Pest	icide – Se	ection	1		
1. Company/Product Number				2. EPA Pro		anager	•	osed Classification
85004-9 4. Company/Product (Name)				Kimberly N PM#	iesci		× No	ne Restricted
Soyacyst LF / Soyacyst ST				92				·
<ol> <li>Name and Address of Applica Pasteuria Bioscience, Inc.</li> </ol>	tion <i>(Include ZII</i>	P Code)						FIFRA Section 3(c)(3) emposition and labeling
12085 Research Dr				to:				p
Alachua, FL 32615				EPA Reg.	No			
Check if this is a r	new address			Product Na	ame			· · · · · · · · · · · · · · · · · · ·
			Section	ı II				
Amendment – Explain belo	w.					labels in respon		
Resubmission in response	to Agency letter	dated		_		r dated blication.		
Notification – Explain below						ain below.		
Explanation: Use additional p		sary. (For	section I and Sec	ction II.)			<u> </u>	
Notification of new brand nar	nes, per PR N	otice 98-	10. This notifica	ation is con				
EPA regulations at 40 CFR 1 formula of this product. I und								
further understand that if this	notification is	not cons	istent with the t	erms of PR	Notice	98-10 and 40	CFR 15	52.46, this product
may be in violation of FIFRA	and I may be	subject to	<del></del>		penaltie	s under section	ns 12 a	nd 14 of FIFRA.
			Section	1 (()				
Child-Resistant Packaging	Unit Packagin	<u> </u>	Water Soluble	Packaging		2. Type of Cont	ainer	· · · · · ·
Yes	Yes	9	Yes			Metal		
<b>⋉</b> No	<b>⋉</b> No		<b>⋉</b> No			<b>≭</b> Plastic		·
* Certification must						Glass		6 6 C C
be submitted	lf "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt	No. per container		Paper		cccc
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3. Location of Net Contents Infor	mation		Retail Containe	r		5. Location of		
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1. Contact Point (Complete items	s directly below	for identifi	cation of individua	al to be cont	acted, if			
Name Susan MacIntosh		Title	ulatory Consultar	nt for PRI		Telephone 651-340-1	•	lude Area Code)
Ousan washiosh			ification			1 00 1-0-40-17		6. Date Application
certify that the statements		this form	and all attachme					Received
l acknowledge any knowi both under applicable law.	ingly talse or mi	sieading st	tatement may be	punisnable l	oy fine o	i imprisonment	υſ	(Stamped)
2. Signature			3. Title					
Summ Mandotal			Regulatory Con	sultant for P	BI			
Typed Name     Susan MacIntosh			5. Date 17 April 2013			•		

#### SOYACYST<sup>TM</sup> LF

Biological control for use on soybean against soybean cyst nematode

# WITH the ALTERNATE BRAND NAME: Clariva<sup>TM</sup> pn LF

Biological control for use on soybean against soybean cyst nematode

# WITH THE ALTERNATE BRAND NAME: SOYACYSTTM 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:	2.1.10	100.000/

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

EPA Registration No: 85004-9

EPA Est. Number: 100-NC-002 or 70051-CA-001 or 88913-CHK-001

Manufactured for:

# **PASTEURIA** bioscience

**Notification Accepted** 

Date: 07 | 18 | 2013

Reviewer: J. KAUSCH

12085 Research Dr. Alachua, FL 32615

(386) 462-0008 www.pasteuriabio.com

TM SOYACYST™ is a trademark of Pasteuria Bioscience, Inc.

Clariva $^{\text{TM}}$ , the ALLIANCE FRAME, the SYNGENTA Logo, and the PURPOSE ICON are Trademarks of a Syngenta Group Company

#### SOYACYSTTM LF

Biological control for use on soybean against soybean cyst nematode

# $\frac{\text{WITH THE ALTERNATE BRAND NAME:}}{\text{CLARIVA}^{\text{TM}} \text{ pn LF}}$

Biological control for use on soybean against soybean cyst nematode

# WITH THE ALTERNATE BRAND NAME: SOYACYST TM 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<sup>TM</sup> LF

Biological control for use on soybean against soybean cyst nematode

# WITH the ALTERNATE BRAND NAME: Clariva<sup>TM</sup> pn LF

Biological control for use on soybean against soybean cyst nematode

# WITH THE ALTERNATE BRAND NAME: SOYACYST<sup>TM</sup> 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:		

<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 or 15 gallons

EPA Registration N°: 85004-9

EPA Est. Number: 100-NC-002 or 70051-CA-001 or 88913-CHK-001

Manufactured for:



12085 Research Dr. Alachua, FL 32615

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#### 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> <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 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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, 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.

#### 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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/).

#### **SOYBEAN**

For control of soybean cyst nematode, apply 2 to 12 fluid ounces of SOYACYST<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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/).

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#### 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<sup>TM</sup> 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.

#### SOYACYST<sup>TM</sup> LF

Biological control for use on soybean against soybean cyst nematode

# $\frac{\text{WITH the } \underline{\text{ALTERNATE BRAND NAME:}}}{\text{Clariva}^{\text{TM}} \text{ pn } LF}$

Biological control for use on soybean against soybean cyst nematode

#### SUB-LABEL B

FOR AGRICULTURAL USE AS FOLIAR APPLICATION

#### SUB-LABEL B

#### SOYACYST<sup>TM</sup> LF

Biological control for use on soybean against soybean cyst nematode

# WITH the ALTERNATE BRAND NAME: Clariva<sup>TM</sup> pn 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 or 15 gallons

EPA Registration No: 85004-9

EPA Est. Number: 100-NC-002 or 70051-CA-001 or 88913-CHK-001

Manufactured for:



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

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Proposed Label for SOYACYST<sup>TM</sup> LF Sub-Label B

# 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> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

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#### 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.

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#### **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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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, 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.

#### 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<sup>TM</sup> 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<sup>TM</sup> LF

Biological control for use on soybean against soybean cyst nematode

# WITH THE ALTERNATE BRAND NAME: SOYACYSTTM ST

Biological control for use on soybean seed against soybean cyst nematode

SUB-LABEL C

FOR SEED TREATMENT

#### SUB-LABEL C

#### SOYACYST<sup>TM</sup> LF

Biological control for use on soybean against soybean cyst nematode

# WITH THE ALTERNATE BRAND NAME: SOYACYST<sup>TM</sup> 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:		100.00%

<sup>\*</sup> Contains at least 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 or 15 gallons

EPA Registration Number: 85004-9

EPA Est. Number: 100-NC-002 or 70051-CA-001 or 88913-CHK-001

Manufactured for:



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

TM SOYACYST is a trademark of Pasteuria Bioscience, Inc.

#### 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.	

#### **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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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/).

#### **SOYBEAN**

For control of soybean cyst nematode, apply 2 to 12 fluid ounces of SOYACYST<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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**

Proposed Label for SOYACYST™ ST Sub-label C

For control of soybean cyst nematode, apply 2 to 5 fluid ounces of SOYACYST<sup>TM</sup> 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.

Proposed Label for SOYACYST<sup>TM</sup> ST Sub-label C

#### 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.