

85004-6

5/16/2012

1045

MAY 16 2012

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

Re: Pasteuria Bioscience, Inc.; Soyacyst Tech  
 EPA Registration No. 85004-6  
 Non-Fast Track Amendment to Modify the Manufacturing Process & Certification of Limits  
 and Add Two Additional Manufacturing Facilities  
 Submission dated 02/10/2012  
 Decision No. 460914

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  $1 \times 10^8$  spores per gram" to "Contains at least  $6 \times 10^9$  spores per gram."
- 2) Modification of the EPA Registration Number from "85004-A" to "85004-6."
- 3) Addition of the following EPA Establishment Numbers: 70051-CA-001 (new), 88913-CHK-001 (new), and 85004-FL-001 (old).

In conjunction with the label amendment, you also updated the confidential statement of formula (CSF) on file for Soyacyst Tech. There is now only one valid CSF, basic formulation dated May 15, 2012, for this product registration. All previously accepted Soyacyst Tech CSFs have been superseded by the aforementioned CSF.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 16, 2013, submit five-batch analyses from batches produced at the two new manufacturing facilities, one from the registered establishment in California and one from the registered establishment in the Czech Republic.
- 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.

## CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	KRUSCH	Reynolds	Reynolds					
DATE	05/16/2012	5/16/12	5/16/12					

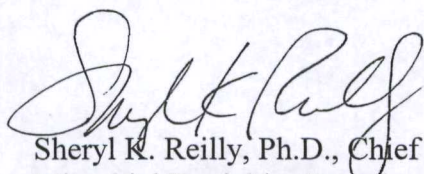


Susan MacIntosh  
EPA Registration No. 85004-6

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](mailto: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)

Enclosures: (1) Soyacyst Tech Accepted Label  
(2) May 11, 2012 Memorandum  
(3) A-79 Enclosure

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## SOYACYST TECH

For manufacturing or formulating use only

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<b>ACTIVE INGREDIENT:</b> <i>Pasteuria nishizawae</i> – Pn1*	99.88%
<b>OTHER INGREDIENTS:</b> .....	0.12%
<b>TOTAL:</b>	100.00%

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\* Contains at least  $6 \times 10^9$  spores per gram

### KEEP OUT OF REACH OF CHILDREN CAUTION

See precautionary and first aid statements on the back panel

Net Contents: 10, 20 or 55 gallons

EPA Registration Number: 85004-6

EPA Est. Number: 70051-CA-001 or 88913-CHK-001 or 85004-FL-001

Manufactured for:



**ACCEPTED**

**MAY 16 2012**

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 85004-6

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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.

<b>FIRST AID</b>	
<b>If inhaled:</b>	<ul style="list-style-type: none"><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>
<b>HOT LINE NUMBER</b>	
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.	

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

**DIRECTIONS FOR USE**

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

For formulation into a nematicide for soybean crop uses, either as a foliar spray or for soybean seed treatment. This product may be used to formulate products for any additional uses not listed on the manufacturing-use product label, if the formulator, user

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group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

### **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 Tech.

#### **PESTICIDE DISPOSAL**

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

#### **CONTAINER HANDLING**

Refillable container. Refill this container with SOYACYST Tech only. Do not reuse this container for any other purpose.

Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into an approved waste disposal facility or manufacturing equipment. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into an approved waste disposal facility or manufacturing equipment, or store rinsate for later disposal. Repeat this procedure two more times.

[For Plastic containers:] Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

[For Metal containers:] Then offer for recycling if available or reconditioning if appropriate or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

### **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.

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