

85004-12

07/18/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

Table with 4 columns: Product Name, EPA Reg. No., Label Modifications, and OPP Decision Number. Rows include SOYACYST™ TECH, SOYACYST™ TECH+, SOYACYST™ LF, SOYACYST™ WP PLUS, and SOYACYST™ TECH PLUS.

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)].

CONCURRENCES


Table for CONCURRENCES with columns for SYMBOL, URNAME, and DATE, containing handwritten entries like 7511P, KAUSCH, and 07/17/2013.

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](mailto:kausch.jeannine@epa.gov)).

Sincerely,



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



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

- Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide – Section I**

|  |  |  |
|--|--|--|
| 1. Company/Product Number<br>85004-12 <i>RE</i>  | 2. EPA Product Manager<br>Kimberly Nesci   | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Soyacyst WP Plus  | PM#<br>92  |  |
| 5. Name and Address of Application (Include ZIP Code)<br>Pasteuria Bioscience, Inc.<br>12085 Research Dr<br>Alachua, FL 32615<br><input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:<br>EPA Reg. No. _____<br>Product Name _____ |  |

**Section II**

Amendment – Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_

Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application.

Notification – Explain below.  Other – Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 Notification of new brand names, per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section III**

|   |  |   |  |
|---|--|---|--|
| Child-Resistant Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No<br><br><b>* Certification must be submitted</b>   | Unit Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No<br><br>If "Yes"<br>Unit Packaging wgt.      No. per Container | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input checked="" type="checkbox"/> No<br><br>If "Yes"<br>Package wgt      No. per container | 2. Type of Container<br><input checked="" type="checkbox"/> Metal<br><input checked="" type="checkbox"/> Plastic<br><input type="checkbox"/> Glass<br><input type="checkbox"/> Paper<br><input type="checkbox"/> Other (Specify) _____ |
| 3. Location of Net Contents Information<br><input checked="" type="checkbox"/> Label <input type="checkbox"/> Container   | 4. Size(s) Retail Container<br>10, 25 or 50 Lbs or 25 Kg   | 5. Location of Label Directions<br><input checked="" type="checkbox"/> On Label<br><input type="checkbox"/> On Labeling accompanying product            |  |
| 6. Manner in Which Label is Affixed to Product<br><input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____<br><input checked="" type="checkbox"/> Paper glued<br><input type="checkbox"/> Stenciled |  |   |  |

**Section IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

|                         |  |   |
|-------------------------|--|---|
| Name<br>Susan MacIntosh | Title<br>Regulatory Consultant for PBI | Telephone No. (Include Area Code)<br>651-340-1262 |
|-------------------------|--|---|

**Certification**  
 I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

|  |   |  |
|--|---|--|
| 2. Signature<br><i>Susan MacIntosh</i> | 3. Title<br>Regulatory Consultant for PBI | 6. Date Application Received (Stamped) |
| 4. Typed Name<br>Susan MacIntosh       | 5. Date<br>17 April 2013                  |  |

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MacIntosh & Associates, Inc.



Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington DC, 20460

April 20, 2013

Re: Label Notification: Brand name changes to 6 products

Dear Dr. Nesci,

Pasteuria Bioscience Inc. (PBI, Establishment No. 85004), a wholly owned Syngenta company, respectfully submits six notifications for brand name changes to six different products, all under the Soyacyst product line. For some of the products an additional package size is also being added. As Syngenta prepares to take over the PBI registrations, the first step is to modify these brand names, which is being completed prior to the actual request for registration transfer, as suggested at a recent meeting with EPA (PBI-SYN-EPA March 26, 2013 meeting).

The table below summarizes these brand name and package size changes reflected in the attached label copies. In each case, EPA Form 8570-1 is attached to a copy of the original label with the modified language highlighted in yellow plus a clean copy of the revised label. To avoid confusion, each notification is in a separately labeled manila envelop.

| Current Brand Name       | Alternative Brand Name | Additional package size | EPA Registration No. |
|--------------------------|------------------------|-------------------------|----------------------|
| Soyacyst™ Tech           | Clariva™ pn MUP        | 25 Kgs                  | 85004-6              |
| Soyacyst™ Tech+          | Clariva™ pn Tech+      | none                    | 85004-7              |
| Soyacyst™ LF/Soyacyst ST | Clariva™ pn LF         | 15 gallons              | 85004-9              |
| Soyacyst Tech Plus™      | Clariva™ pn Technical  | 25 Kgs                  | 85004-13             |
| Soyacyst WP Plus™        | Clariva™ pn WP         | 25 Kgs                  | 85004-12             |
| Soyacyst ST Plus™        | Clariva™ pn            | 15 gallons              | 85004-14             |

This notification of new brand names and package size additions is submitted per PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and

40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please let me know if you have any questions regarding the information included herein. A self-addressed, stamped postcard is included for each of these notifications, to notify me that these notifications are acceptable.

Sincerely,



Susan MacIntosh

President

On behalf of Pasteuria Bioscience, Inc.™

A Syngenta Company

MacIntosh & Associates, Inc.

1203 Hartford Ave

Saint Paul, MN 55116-1622

Tel. +1.651.340.1262

Cell +1.612.720.9260

Email: [macintosh.associates@me.com](mailto:macintosh.associates@me.com)

Cc: Kelly Smith, Ph.D., Head, Pasteuria Bioscience, Inc.

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### SOYACYST™ WP Plus

Biological control for use on soybean seed against soybean cyst nematode

**WITH the ALTERNATE BRAND NAME:**

### Clariva™ pn WP

Biological control for use on soybean seed against soybean cyst nematode

CAN BE USED  FOR ORGANIC PRODUCTION

|                    |                                    |        |
|--------------------|------------------------------------|--------|
| Active Ingredient: | <i>Pasteuria nishizawae</i> – Pn1* | 100.0% |
| Other Ingredients: |                                    | 0.0%   |
| Total:             |                                    | 100.0% |

\* Contains at least  $1 \times 10^{11}$  spores per gram or  $4.5 \times 10^{12}$  spores per pound.

### KEEP OUT OF REACH OF CHILDREN

### CAUTION

See additional precautionary and first aid statements on the back panel

Net Weight: 10, 25 or 50 Lbs or 55 (25 Kgs) Lbs

EPA Registration Number: 85004-12

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

Manufactured [by] [for]:



Notification Accepted

Date: 07/18/2013

Reviewer: J. KAUSCH

12085 Research Dr.  
Alachua, FL 32615

(386) 462-0008  
www.pasteuriabio.com

™ Soyacyst is a trademark of Pasteuria Bioscience, Inc.

Clariva™, the ALLIANCE FRAME, the SYNGENTA Logo, and the PURPOSE ICON are Trademarks of a Syngenta Group Company

Batch Code:

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

## CAUTION

Harmful if inhaled. Avoid breathing dust or 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>  |   |
| <p>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.</p> |   |

### 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

[Environmental hazards statements for the following container sizes: 10 and 25 pounds]

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 water or rinsate.

[Environmental hazard statements for the following container size: 50 or 55 (25 Kgs) pounds]

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 water or rinsate.

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.**

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 is a biological nematicide for the control of specific plant-parasitic nematodes. The product is to be applied as a seed treatment prior to planting. The degree of control and nematode suppression depends upon the timing, rate, nematode species and soil type. Mobility of this product in the soil is influenced by the amount of rainfall/irrigation and the soil type. It will only control those nematodes that come into contact with the bacterium. This product is 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 ON FARM SEED TREATMENT

Do not use treated seed for food or feed purposes or process for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seed beyond planting time.

To achieve improved application coverage to the seed, dilute SOYACYST™ WP Plus 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™ WP Plus 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™ WP Plus 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.

### SOYBEAN

For control of soybean cyst nematode, apply 0.09 to 3.5 oz. of SOYACYST™ WP Plus per 100 Lbs (2.5 to 100 grams per 45.4 kg) of soybean seed.

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## FOR USE AS A COMMERCIAL SEED TREATMENT

To achieve improved application coverage to the seed, dilute SOYACYST™ WP Plus 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™ WP Plus 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™ WP Plus 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.

NOTE: This product does not contain dye. All seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for humans or feed for animals.

The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information: "This seed has been treated with *Pasteuria nishizawae* - Pn1. Do not use for food, feed or oil purposes."

### SOYBEAN

For control of soybean cyst nematode, apply 0.09 to 3.5 oz. of SOYACYST™ WP Plus per 100 Lbs (2.5 to 100 grams per 45.4 kg) of soybean seed.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

#### PESTICIDE STORAGE

Store between a range of 32°F and 100°F. Reclose container of unused portions of SOYACYST™ WP Plus.

#### 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

Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

**LIMIT OF WARRANTY AND LIABILITY**

This product conforms to the description on this label and is reasonably fit for the purpose set forth on this label when used according to the label directions and under the specified label conditions. To the extent consistent with applicable law, the manufacturer disclaims any and all other express or implied warranties of merchantability and fitness for particular purpose. Buyer and all users assume all risks and responsibility for loss or damage if this product is used, stored, handled or applied under any condition not reasonably foreseeable or beyond the manufacturer's control, or not as explicitly set forth in this label. To the extent consistent with applicable law, THE LIMIT OF THE MANUFACTURER'S LIABILITY SHALL BE THE PURCHASE PRICE FOR THE QUANTITY INVOLVED. To the extent consistent with applicable law, IN NO EVENT SHALL THE MANUFACTURER BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.