

85004-14

7/10/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 10 2013

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

Re: PBI; SOYACYST ST Plus™
EPA Registration No. 85004-14
PRIA: Non-Fast Track Formulation Amendment (B680)
Non-PRIA: Label Notification and Minor Formulation Amendment

| Type of Application | Date of Original Application | OPP Decision Number |
|--|------------------------------|---------------------|
| Label Notification (Brand Name, Package Size, and Establishment Number Modifications) | April 17, 2013 | 479493 |
| PRIA Formulation Amendment (Update Certified Limits & Consolidate Previously Approved Formulations) | April 24, 2013 | 478280 |
| Minor Formulation Amendment (Add Producer to End-Use Product) | June 6, 2013 | 480027 |

Dear Ms. MacIntosh:

The formulation amendments referred to above, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable. There is now only one valid confidential statement of formula (CSF) for this product registration: a basic formulation dated July 1, 2013. All previously accepted SOYACYST ST Plus™ CSFs (including basic and alternate formulations) have been superseded by the aforementioned CSF.

Additionally, in an application originally dated April 17, 2013 (OPP Decision No. 479493), PBI notified the EPA that it added an alternate brand name, an additional package size, and another establishment number (i.e., where the product is made) to the SOYACYST ST Plus™ label. The EPA conducted a preliminary screen of this request for its applicability under Pesticide Registration Notice 98-10 and determined that the action requested falls within the scope of this particular document. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed in our records. Submit two (2) copies of final printed labeling before the product, as modified, is sold or distributed [40 C.F.R. § 156.10(a)(6)].

CONCURRENCES

| SYMBOL | 7511P | 7511P | 7511P | | | | |
|---------|------------|---------|---------|--|--|--|--|
| SURNAME | KAUSCH | Borges | Ulls | | | | |
| DATE | 07/10/2013 | 7/10/13 | 7/10/13 | | | | |

Susan MacIntosh
EPA Registration No. 85004-14

Lastly, should you wish to retain the reference to PBI's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product 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 your product's label, 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)

Please read instructions on reverse before completing form.

Form Approved OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

Application for Pesticide – Section I

| | | |
|--|--|--|
| 1. Company/Product Number 85004-14 <i>RU</i> | 2. EPA Product Manager Kimberly Nesci | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Soyacyst ST Plus | PM# 92 | |
| 5. Name and Address of Application (Include ZIP Code) Pasteuria Bioscience, Inc. 12085 Research Dr Alachua, FL 32615 <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: EPA Reg. No. _____ Product Name _____ | |

Section II

| | |
|--|--|
| <input type="checkbox"/> Amendment – Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification – Explain below. | <input type="checkbox"/> 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 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No * Certification must be submitted | Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container | Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container | 2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____ |
| 3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | 4. Size(s) Retail Container 1.25, 2.5, 5, 15, 20 or 50 gallons | 5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input checked="" type="checkbox"/> Paper glued <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 Susan MacIntosh | Title Regulatory Consultant for PBI | Telephone No. (Include Area Code) 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. | | 6. Date Application Received (Stamped) |
| 2. Signature <i>Susan MacIntosh</i> | 3. Title Regulatory Consultant for PBI | |
| 4. Typed Name Susan MacIntosh | 5. Date 17 April 2013 | |

4/10

SOYACYST™ ST Plus

Biological control for use on soybean seed against soybean cyst nematode

WITH the ALTERNATE BRAND NAME:

Clariva™ pn

Biological control for use on soybean seed against soybean cyst nematode

| | | |
|--------------------|-------------------------------------|----------|
| Active Ingredient: | <i>Pasteuria nishizawae</i> – Pn1 * | 15.000% |
| Other Ingredients: | | 85.000% |
| Total: | | 100.000% |

* Contains at least 1.0 x 10¹⁰ spores per mL or 4.5 x 10¹¹ spores per gal.

KEEP OUT OF REACH OF CHILDREN CAUTION

See additional precautionary and first aid statements on the back panel

Net Contents: 1.25, 2.5, 5, 15, 20 or 50 Gallons

EPA Registration Number: 85004-14

EPA Est. Number: 100-NC-002 or 71617-GA-001 or 70815-GA-001 or 70992-CHE-007
or 100-NE-001

Manufactured [by] [for]:



Notification Accepted

Date: 07/10/2013

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 spray mist. Remove and wash contaminated clothing before reuse.

| FIRST AID | |
|---|---|
| If inhaled: | <ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for treatment advice. |
| HOT LINE NUMBER | |
| <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 |
|---|
| <p>Users should:</p> <ul style="list-style-type: none"> • 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: 1.25 and 2.5 gallons]

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 sizes: 5, 15, 20, and 50 gallons]

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 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 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 seeds beyond planting time.

To achieve improved application coverage to the seed, dilute SOYACYST™ ST 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™ ST 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™ ST 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 0.9 to 33.8 fl. oz. of SOYACYST™ ST Plus per 100 Lbs (25 to 1000 mL per 45.4 kg) of soybean seed.

FOR USE AS A COMMERCIAL SEED TREATMENT

To achieve improved application coverage to the seed, dilute SOYACYST™ ST Plus 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™ ST 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™ ST 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 0.9 to 33.8 fl. oz. of SOYACYST™ ST Plus per 100 Lbs (25 to 1000 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 between a range of 32°F to 100°F. Reclose container of unused portions of SOYACYST™ ST 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

[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 ordinances. 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 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.