

100-1522

3/11/2014

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MAR 11 2014

Ms. Susan MacIntosh
Regulatory Consultant for Syngenta Crop Protection, LLC
MacIntosh & Associates, Inc.
1203 Hartford Avenue
Saint Paul, MN 55116-1622

Re: Your applications dated August 6, 2013 to change a label statement related to packaging consistent with Pesticide Registration (PR) Notice 98-10

Product Name	EPA Reg. No.	OPP Decision Number
SOYACYST™ WP PLUS	100-1522	482130
SOYACYST™ TECH PLUS	100-1523	482129
SOYACYST™ ST PLUS	100-1524	482131

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.

Should you wish to retain the reference to Pasteuria Bioscience, Incorporated'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.

CONCURRENCES

SYMBOL	7511P	7511P	2511P				
SURNAME	KAUSCH	Baicus	Mendez				
DATE	03/11/2014	3/11/14	3/11/14				

2/10

Susan MacIntosh
EPA Registration Nos. 100-1522, -1523, and -1524

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

Sincerely,




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

9 11 21
KIMBERLY NESCI
CHIEF, MICROBIAL PESTICIDES BRANCH
BIOPESTICIDES AND POLLUTION PREVENTION DIVISION

5/10

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	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
	Application for Pesticide – Section I		

1. Company/Product Number 100-1522	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Soyacyst WP Plus	PM# 92	
5. Name and Address of Application (Include ZIP Code) Syngenta Crop Protection, LLC 410 Swing Road Greenboro, NC 27409 <input checked="" 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 change in packaging and label statements, per PR Notice 98-10, Section II.E. 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 <small>If "Yes" Unit Packaging wgt. No. per Container</small>	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <small>If "Yes" Package wgt No. per container</small>	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 10, 25 or 50 (25 Kgs) Lbs + 55 lbs	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 /SYN	Telephone No. (Include Area Code) 651-340-1262
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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 	3. Title Regulatory Consultant for PBI /SYN	6. Date Application Received (Stamped)
4. Typed Name Susan MacIntosh	5. Date 6 August 2013	

9/10

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 1×10^{11} spores per gram or 4.5×10^{12} spores per pound.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional precautionary and first aid statements [on the back panel] [below] [on label] [in booklet]

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: 03/11/2014

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:

57/10

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.

FIRST AID

If inhaled:

- 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

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.

6/10

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.

9/10

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.

10/10

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.