

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, SURNAME, and DATE, containing handwritten entries like 7511P, KAUSCH, 07/17/2013, and signatures.

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)



United States
Environmental Protection Agency
 Washington, DC 20460

- Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number 85004-13 <i>RG</i>	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Soyacyst Tech 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

- 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 <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 10, 25 or 50 Lbs or 25 Kgs	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
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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 <i>Susan MacIntosh</i>	3. Title Regulatory Consultant for PBI	6. Date Application Received (Stamped)
4. Typed Name Susan MacIntosh	5. Date 17 April 2013	



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

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

SOYACYST™ TECH PLUS

For manufacturing or formulating use only

WITH the ALTERNATE BRAND NAME:

Clariva™ pn Technical

For manufacturing or formulating use only

ACTIVE INGREDIENT: <i>Pasteuria nishizawae</i> – Pn1*	100.0%
OTHER INGREDIENTS:	0.0%
TOTAL:	100.0%

* Contains at least 1.0 x 10¹¹ spores per gram or 4.5 x 10¹² spores per pound.

KEEP OUT OF REACH OF CHILDREN CAUTION

See precautionary and first aid statements on the back panel

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

EPA Registration Number: 85004-13

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. 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>	

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 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 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 at room temperature (20-22°C). Reclose container of unused portions of SOYACYST™ Tech Plus.

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

Nonrefillable container. Do not reuse or refill this container. 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.