

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 12, 2016

Patrick McCain Senior Regulatory Product Manager, Seedcare Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419

 Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – Add an Alternate Confidential Statement of Formula (CSF) and Update the Warranty, Storage and Other Language on the Labeling Product Name: Soyacyst[™] ST Plus EPA Registration Number: 100-1524 Application Dates: April 21, 2015 & June 26, 2015 OPP Decision Numbers: 503845 & 506529

Dear Mr. McCain:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSFs:

- Basic CSF dated 06/02/2016
- Alternate CSF dated 04/01/2015

Any CSFs other than those listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling

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or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 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 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, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ann Sibold by phone at (703) 305-6502 or via email at sibold.ann@epa.gov.

Sincerely,

HA AND

Jeannine Kausch, Acting Product Manager 92 Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

(Master)

SOYACYST[™] ST Plus [Alternate Brand Name: Clariva® pn]

Nematicide

A biological seed treatment product for protection against listed nematodes on soybeans and sugarbeets

Active Ingredient:	
Pasteuria nishizawae – Pn1*	
Other Ingredients:	85.000%
Total:	
* Contains at least 1.0 x 10^{10} spores per mL or 3.8 x 10^{13} spores per gallon of product.	

KEEP OUT OF REACH OF CHILDREN

CAUTION

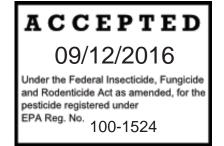
See additional precautionary and first aid statements in booklet [on label].

EPA Reg. No. 100-1524

EPA Est.

Net Contents

[Batch code to be marked directly on containers that are nonrefillable. Batch code not required for refillable containers.]



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 further treatment advice. 	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.		
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal) Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call 1-800-888-8372		

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if inhaled. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

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 NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C.

Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

User Safety Requirements

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. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards [less than 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 Hazards [greater than or equal to 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.

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.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

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

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

Store between a range of 32°F to 100°F.

Do not use this product until you have read the entire label.

Keep unprotected persons out of treatment areas until seeds have dried or been packaged.

PRODUCT INFORMATION

This product contains a biological nematicide for protection against the following nematodes:

Soybean Cyst Nematode Sugarbeet Cyst Nematode Heterodera glycines Heterodera schachtii

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.

Dilute SOYACYST[™] ST Plus with water and apply directly to dry seed or mix with inoculants and/or other seed treatment coatings (e.g., colorants, polymers, etc.), registered insecticides and fungicides. All seed treatment coatings such as colorants and/or polymers must be cleared as an inert for pre-harvest use. See 40 CFR 180.920. 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.

Continuous agitation or mixing of the slurry mixture is necessary to prevent settling out of the solution. Clean out any unused product from the treater after treating or maintain constant agitation if the leftover slurry will be maintained overnight. **Do not store Clariva pn mixed in slurries for more than 72 hours.**

NOTE: This product does not contain dye. Treated seed must be treated with a dye cleared as an inert for preharvest use. See 40 CFR 180.920. All seed treated 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 protection against soybean cyst nematode, apply 0.9 to 33.8 fl oz of SOYACYST[™] ST Plus per 100 lb (25 to 1000 mL per 45.4 kg) of soybean seed.

SUGARBEET

For protection against sugarbeet cyst nematode, apply 0.034 to 1.35 fl oz (1.0 to 40 mL) of SOYACYST[™] ST Plus product per unit (100,000 seeds) of sugarbeet seed.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store between a range of 32°F to 100°F. Reclose container of unused portions of SOYACYST[™] ST Plus.

Pesticide Disposal

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

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Do not contaminate equipment and facilities during cleanup procedures and disposal of wastes.

Container Handling [less than or equal to 5 gallons]

Non-refillable 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, or by other procedures approved by state and local authorities.

Container Handling [greater than 5 gallons]

Non-refillable 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, or by other procedures approved by state and local authorities.

Container Handling [greater than 5 gallons]

Refillable container. Refill this container with pesticide 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 person refilling. To clean container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

DO NOT USE CONTAINER FOR FOOD, FEED OR DRINKING WATER.

SOYACYST[™] [Clariva®], the ALLIANCE FRAME, the SYNGENTA Logo, and the PURPOSE ICON are Trademarks of a Syngenta Group Company.

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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for: Syngenta Crop Protection, LLC P. O. Box 18300 Greensboro, North Carolina 27419-8300

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