



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 5, 2019

Keeva Shultz
Authorized Agent to Biocontrol Technologies, S.L.
Wagner Regulatory Associates, Inc.
P.O. Box 640
Hockessin, DE 19707

Subject: Pesticide Registration Improvement Act (PRIA) Labeling and Confidential Statement of Formulation Amendment – Add an Alternate Supplier for the Active Ingredient and an Alternate Producer for the Product to the Basic Confidential Statement of Formula (CSF) and Add an Alternate #1 CSF with an Alternate Supplier for the Active Ingredient and an Alternate Producer for the Product and Make Other Changes to the Labeling Requested by the EPA (e.g., Update the Units for the Viability Statement)
Product Name: T34 Biocontrol
EPA Registration Number: 87301-1
Application Date: 06/14/2019
OPP Decision Number: 552825

Dear Ms. Shultz:

The amended labeling and Confidential Statement of Formulations (CSFs) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is 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 06/14/2019
- Alternate CSF #1 dated 06/14/2019

Any CSFs other than those listed above are superseded/no longer valid.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

The enclosed science memorandum dated December 3, 2019 states that additional microbial contaminant testing (analysis of samples) of *Listeria monocytogenes*, *Shigella*, and *Vibrio* is required for any proposed future food uses for *Trichoderma asperellum* strain T34. Subsequent to the completion of the science memorandum, the Agency determined that you are only required to submit microbial contaminant testing for *L. monocytogenes* and may provide scientific rationale in place of testing for *Shigella* and *Vibrio*. Please note that this microbial contaminant testing is required for each manufacturing facility.

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 Alex Boukedes by phone at (703) 347-0305 or via email at boukedes.alexandra@epa.gov.

Sincerely,



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

\

Enclosure: Label and science memo dated 12/03/2019



[Text and logos in brackets are optional.]

T34 BIOCONTROL**ACCEPTED**

12/05/2019

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 87301-1**ABN: Asperello T34 BIOCONTROL****Biological Fungicide Wettable Powder**

For the suppression of root diseases caused by Fusarium, Rhizoctonia, Pythium and Phytophthora in ornamental plants in greenhouses.

READ THE LABEL BEFORE USING**ACTIVE INGREDIENT:***Trichoderma asperellum*, strain T34 (dried conidia)* 12.00 %**OTHER INGREDIENTS:** 88.00 %**TOTAL:** 100.00%*Contains 3×10^{11} colony forming units per Kg of product.**KEEP OUT OF REACH OF CHILDREN****CAUTION**

First Aid	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
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 further treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor.
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, call the Poison Control Center 1-800-222-1222 . For general information on this product, contact the National Pesticides Information Center at 1-800-858-7378 , Monday through Friday, 8 a.m. to 12 p.m. PST, or at http://npic.orst.edu .	

Manufactured for:Biocontrol Technologies, S.L.
Avgda. Madrid, 215-217, entresòl A
08014 Barcelona, SpainBatch number: _____
EPA Reg. No: 87301-1

EPA Est. No: _____

Net Weight: 3.75 oz. (100 g)/17.64 oz. (500 g)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals – CAUTION. Causes moderate eye irritation. Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust and spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Personal Protective Equipment (PPE): Applicators and other handlers must wear long-sleeved shirt, long pants, shoes plus socks, protective eyewear, and a minimum of a NIOSH-approved particulate filtering facepiece respirator with any R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any R or P filter; OR a NIOSH-approved powered air-purifying respirator with an HE filter. (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 for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations:

Users should:

- 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: Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

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

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 only apply to uses of this product that are covered by the Worker Protection Standard.

For enclosed environments:

There is a restricted entry of four (4) hours for this product when applied as a soil application via soil drench, in-furrow spray, transplant starter solution, dip, soak, or chemigation when used in enclosed environments such as glasshouses and greenhouses.

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:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

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 treated areas until sprays have dried.

PRODUCT INFORMATION: T34 BIOCONTROL is a biofungicide that protects ornamental and carnation plants and increases their defenses against *Fusarium oxysporum* f. sp. dianthi. The active ingredient is the beneficial fungus *Trichoderma asperellum*, strain T34.

PRODUCT USE: T34 BIOCONTROL is a preventative biofungicide for control of ornamental plants diseases. The active ingredient is the beneficial fungus *Trichoderma asperellum*, strain T34 which grows onto plant roots as they develop and provides protection against plant root pathogens such as *Fusarium*, *Rhizoctonia*, *Pythium*, and *Phytophthora*.

The utilization of T34 BIOCONTROL is recommended after a security period (7-10 days) of substrate sterilization, fumigation, solarization or biofumigation.

T34 BIOCONTROL, preventively applied, protects plants from diseases due to its capacity to colonize the growing media and the plant roots and because of its strong action against pathogenic microorganisms and the induction of plant resistance responses.

T34 BIOCONTROL germinates and grows in a wide range of soils and substrates, and around the roots of many crops to which it facilitates the absorption of several nutrients. It develops in a variety of pHs (6-8) and soil temperatures 68-95°F (20-35°C), but its optimal growth temperature is 77-86°F (25-30°C).

T34 BIOCONTROL has a suppressive effect on the soil-born pathogen *Fusarium oxysporum*, since it directly competes for space and/or nutrients and can parasitize the pathogenic fungus.

T34 BIOCONTROL near plant roots builds a physical barrier against pathogens, induces systemic resistance (ISR) and increases the synthesis of plant defense proteins.

GREENHOUSE POTTING MIX OR SOIL DRENCH: GREENHOUSE CARNATIONS IMPORTANT INFORMATION

FOR USE ONLY AS AN AGRICULTURAL FUNGICIDE

CROPS: carnation plants, greenhouse

APPLICATION AND DOSE:

Dissolve the specific amount of T34 BIOCONTROL in a small amount of water and shake to obtain good product dispersion. Add this solution to the irrigation tank, with the total volume of water necessary to water the plants, stirring continuously to ensure a homogeneous application of the product.

Apply T34 BIOCONTROL in the penultimate irrigation of the day, to ensure that no other residual product remains in the irrigation system. This will also minimize the wash-out risk and guarantee suitable diffusion in the substrate.

METHOD OF APPLICATION:

1. Spray of the growing media for propagation

Apply T34 BIOCONTROL, spraying, at a dose of 0.35 ounces (10 grams) of T34 BIOCONTROL per 35 ft.³ (1 m³) of substrate before potting or at a dose of 0.02 ounces (0.5 grams) per 10.8 ft.² (1 m²) of surface area immediately after sowing seeds or rooting cuttings.

2. Root bath

Before planting, we recommend dipping the roots of the carnation cuttings several hours or overnight in a solution of water with 0.0004 ounces or 0.002 teaspoons (0.01 grams) of T34 BIOCONTROL in 2.1 pints (1L) of water.

3. Irrigation of container-grown crops

Apply the T34 BIOCONTROL by irrigation at 0.175 ounces (5 grams) of T34 BIOCONTROL per 1,000 pots of 2.1 pints (1L) at the planting day. Repeat the application one week later if plants were not treated during propagation with T34 BIOCONTROL. Apply 0.175 ounces (5 grams) of T34 BIOCONTROL per 1,000 pots of 2.1 pints (1L) every 2-3 months as follow-up treatment and also prior to a risk situation or after plants are stressed.

MAXIMUM TOTAL DOSE:

The maximum concentration recommended for the dilution of T34 BIOCONTROL is 1.3 oz./gal. (10 g/L) water.

COMPATIBILITY: Do not use or mix T34 BIOCONTROL with other products. It is recommended to avoid treatments with chemical fungicides 10 days after or before the application of T34 BIOCONTROL, since T34 BIOCONTROL is incompatible with broad spectrum fungicides and specific fungicides against ascomycetes and basidiomycetes. The application of T34 BIOCONTROL is compatible with all liquid fertilizers and with the use of insecticides and acaricides and fungicides specific against oomycetes.

CHEMIGATION:

- Apply this product only through [choose one or more of the following types of systems: sprinkler including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move; flood (basin); furrow; border or drip (trickle)] irrigation & system(s). Do not apply this product through any other type of irrigation system.
- Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.
- If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.
- Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.
- A person knowledgeable of the chemigation system and responsible for its operation or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

- Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.
- Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone (RPZ), back flow preventer or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.
- The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- Do not apply when wind speed favors drift beyond the area intended for treatment.
- Continuous agitation is recommended in the pesticide supply tank.
- T34 BIOCONTROL should be applied continuously for the duration of the water application.
- Refer to “Application and Dose” instructions for specific mixing and dilution instructions.

FLOOR (BASIN), FURROW, AND BORDER CHEMIGATION

- Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from back flow if water flow stops.
- Systems utilizing a pressurized water and pesticide injection system must meet the following requirements:
 - The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
 - The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
 - The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
 - The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
 - The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
 - Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
 - T34 BIOCONTROL should be applied continuously for the duration of the water application.
 - Refer to “Application and Dose” instructions for specific mixing and dilution instructions.

DRIP (TRICKLE) CHEMIGATION

- The system must contain a functional check valve, vacuum relief valve and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from back flow.
- The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- The system must contain functional inter-locking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- Systems must use a metering pump such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- Continuous agitation is recommended in the pesticide supply tank.

- T34 BIOCONTROL should be applied continuously for the duration of the water application.
- Refer to “Application and Dose” instructions for specific mixing and dilution instructions.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original container in a cool dry place. When kept at 40°F (4°C), the viability of the product provides effective doses for up to one year.

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

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. Offer for recycling, if available or dispose of empty bag in sanitary landfill or by incineration.

NOTICE TO BUYER AND SELLER: The directions for use of this product are believed to be adequate and must be followed carefully, it is impossible to eliminate all risks inherently associated with the use of this product. To the extent consistent with applicable law, the products sold to you are furnished “as is” by Premier Horticulture Ltd. The manufacturer and the seller are subject only to the manufacturer’s warranties, if any, which appear on the label of the product sold to you. Except as warranted by this label, Premier Horticulture Ltd., the manufacturer, or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability, fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. To the extent consistent with applicable law, Buyer’s or user’s exclusive remedy, and Premier Horticulture, Ltd., the manufacturer’s or the seller’s total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of Premier Horticulture Ltd., the manufacturer, or the seller is authorized to amend the terms of this warranty disclaimer or the product’s label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, Premier Horticulture Ltd., the manufacturer or the seller shall not be liable for consequential, special, or indirect damages resulting from the use, handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may have to such damages.

Spanish Patent ES 2 188 385 B1

European Patent EP 1 400 586 B1

USA Patent US 7 553 657 B2