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



AUG 2 1 2013

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Cheryl Wagner
Wagner Regulatory Associates, Inc.
Agent for Biocontrol Technologies, S.L.
P.O. Box 640
7460 Lancaster Pike, Suite #9
Hockessin, DE 19707

Re:

T34 Biocontrol

EPA Reg. No. 87301-1

Submission dated April 18, 2013

Dear Ms. Wagner:

The Agency has reviewed your request to amend the subject product registration. The amendment includes the following changes to the product's label:

- Addition of alternative brand names.
- Revisions to description under product name, distributor, and product use section (p.4).

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

- Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5)
 when the Agency requires all registrants of similar products to submit such data.
- Submit your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of a final printed label.

If these conditions are not complied with, then the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label and A-79 are enclosed for your records. If you have questions, please contact Michael Glikes by phone at (703) 305-6231 or by email at glikes.michael@epa.gov.

Sincerely,

Kimberly Nesci, Chief

Microbial Pesticides Branch

Biopesticides & Pollution Prevention Division

Enclosures: A-79; Product Label

T34 BIOCONTROL ABN: PRO-MIX PUR Trichoderma [inoculum]

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:	100.90%
*The wettable powder formulation containing 10.83 % or 1v:	10 ¹² colony forming units per Kg of dry weig

KEEP OUT OF REACH OF CHILDREN

CAUTION

First Aid		
If swallowed	 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	 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	 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	 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 emergency information, call the National Pesticides Information Center at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific Time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.

Distributed by:

Premier Horticulture Ltd. 127 South Fifth Street, Suite 300 Quakertown, PA 18951

Batch number:	
EPA Reg. No:87301-1	EPA Est, No:

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

ACCEPTED

AUG 2 1 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 8 7301-1

PRECAUTIONARY STATEMENTS

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

Personal Protective Equipment (PPE): Applicators and other handlers must wear long-sleeved shirt, long pants, shoes plus socks, and dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, 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.

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, nursuries, 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, infurrow spray, transplant starter solution, dip, soak, or chemigation when used in enclosed environments such as glasshouses and greenhouses.

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 or dusts have settled.

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 regular 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 form 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.
- PRO-MIX PUR 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.
- PRO-MIX PUR 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.
- · PRO-MIX PUR should be applied continuously for the duration of the water application.
- Refer to "Application and Dose" instructions for specific mixing and dilution instructions.

PRODUCT INFORMATION: PRO-MIX PUR 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: PRO-MIX PUR Trichoderma inoculum 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 PRO-MIX PUR is recommended after a security period (7-10 days) of substrate sterilization, fumigation, solarization or biofumigation.

PRO-MIX PUR, 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.

PRO-MIX PUR 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 77-86°F (20-35°C), but its optimal growth temperature is 77-86°F (25-30°C).

PRO-MIX PUR 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.

PRO-MIX PUR near plant roots builds a physical barrier against pathogens, induces systemic resistance (ISR) and increase the synthesis of plant defence proteins.

DIRECTIONS FOR USE: 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 PRO-MIX PUR 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 PRO-MIX PUR 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 PRO-MIX PUR, spraying, at a dose of 0.35 ounces (10 grams) of PRO-MIX PUR per 35 ft³ (1 m³) of substrate <u>before porting</u> or at a dose of 0.02 ounces (0.5 grams) per 10.8 ft² (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 PRO-MIX PUR in 2.1 pints (1 L) of water.

Irrigation of container-grown crops

Apply the product by irrigation at 0.175 ounces (5 grams) of PRO-MIX PUR per 1000 pots of 2.1 pints (1L) at the planting day. Repeat the application one week later if plants were not treated during propagation with PRO-MIX PUR. Apply 0.175 ounces (5 grams) of PRO-MIX PUR 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 PRO-MIX PUR is 1.3 oz./gal. (10 g/L) water.

COMPATIBILITY: PRO-MIX PUR should not be used or mixed with other products. It is recommended to avoid treatments with chemical fungicides 10 days after or before the application of PRO-MIX PUR, since PRO-MIX PUR is incompatible with broad spectrum fungicides and specific fungicides against ascomycetes and basidiomycetes. The application of PRO-MIX PUR is compatible with all liquid fertilizers and with the use of insecticides and acaricides and fungicides specific against oomycetes.

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: Do not contaminate food or feed by disposal. Wastes resulting from the use of this product may 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