

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 25, 2016

Amy Roberts Senior Regulatory Consultant for Premier Tech Horticulture 1150 18th Street, NW - Suite 1000 Washington, DC 20036

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – Addition of two alternate CSFs Product Name: Pro-Mix with Biofungicide EPA Registration Number: 74267-1 Application Date: November 9, 2015 OPP Decision Number: 511141 and 511142

Dear Ms. Roberts:

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

At this time, the U.S. Environmental Protection Agency (EPA) is not requiring a change to the restricted-entry interval (REI) of 0 hour as it appears on your labeling in the Agricultural Use Requirements Box. The EPA is currently developing guidance and criteria for when it will allow a REI of less than 4 hours and might require a change to the REI for this product in the future. 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 (VFT Blend) dated 06/12/2002
- Alternate CSF #1 (BX Blend) dated 06/12/2002
- Alternate CSF #2 (BRK Blend) dated 06/12/2002
- Alternate CSF #3 (GSX Blend) dated 06/12/2002
- Alternate CSF #4 (HP Blend) dated 06/12/2002
- Alternate CSF #5 (FPX Blend) dated 06/12/2002
- Alternate CSF #6 (NCX Blend) dated 06/12/2002
- Alternate CSF #7 (PGX Blend) dated 06/12/2002
- Alternate CSF #8 (TA Blend) dated 06/12/2002
- Alternate CSF #9 (YP Blend) dated 04/18/2016
- Alternate CSF #10 (BRK20 Blend) dated 04/18/2016

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Any CSFs other than those listed above are superseded/no longer valid.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 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 me by phone at (703) 347-0163 or via email at murasaki.seiichi@epa.gov

Sincerely,

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

Enclosure: Accepted Label

Product Label:	
Package Size:	
Date:	

PRO-MIX with Biofungicide – Master Label (8 pages) 3.8 cu.ft. compressed and 2.8 cu.ft. loose fill bag November 9, 2015 – label version (11) Fast Track Amendment add minor text

## (FRONT PANEL)

# **PRO-MIX** with Biofungicide

(Alternate Brand Names: SOGEMIX 'VT-M' with Biofungicide; PRO-MIX 'FPX' with Biofungicide; PRO-MIX 'VFT' with Biofungicide; PRO-MIX 'BX' with Biofungicide; PRO-MIX 'BRK' with Biofungicide; SOGEMIX VT-M with Biofungicide; PRO-MIX FPX with Biofungicide; PRO-MIX VFT with Biofungicide; PRO-MIX BX with Biofungicide; PRO-MIX BRK with Biofungicide; PRO-MIX BIOFUNGICIDE; PRO-MIX BX BIOFUNGICIDE, PRO-MIX BRK BIOFUNGICIDE; PRO-MIX HP BIOFUNGICIDE; PRO-MIX LP-15 BIOFUNGICIDE; PRO-MIX PGX BIOFUNGICIDE; PRO-MIX FPX BIOFUNGICIDE; PRO-MIX BRK20 BIOFUNGICIDE; PRO-MIX YP BIOFUNGICIDE )

## ACTIVE INGREDIENT:

Bacillus subtilis, MBI 600 (not less than 1 X 10<sup>5</sup> viable spores per gram of media)......0.001% **OTHER INGREDIENTS:** 99.999%

Optional Text:

- PROFESSIONAL
- PROFESSIONAL GROWING MEDIUM
- GROWING MEDIUM WITH BIOFUNGICIDE
- FINE-GRADE PLUG GROWING MEDIUM
- SPHAGNUM PEAT-BASED GROWING MEDIA
- FOR GREENHOUSE OR GLASSHOUSE USE
- VEGETABLE, FRUIT & TOBACCO GROWING MEDIUM
- VEGETABLE TRANSPLANT GROWING MIX WITH BIOFUNGICIDE
- WITH SUBTILEX®
- (Logo) Research (Investigacion), Quality Control (Control de Calidad)
- (Logo) TECHNOLOGIES PREMIER TECH
- (website) pthorticulture.com
- Other Ingredients, depending on blend can include:
- (Canadian) (Sphagnum) Peat Moss, fine granulation (or short fiber) (60-85% by volume)
- Vermiculite, horticulture or fine granulation
- Coir horticulture grade
- Perlite, horticulture or plug grade
- Dolomitic and Calcitic Limestone (pH adjuster)
- ENDOMYCORRHIZAE Inoculum (Glomus intraradices)
- Wetting Agent

## KEEP OUT OF REACH OF CHILDREN CAUTION

#### See Additional Precautionary Statements on Side Panel

#### EPA Reg. No. 74267-1

## EPA Establishment No. 74267-CAN-01/02/03/04/06

For identification of establishment number, refer to the manufacturing identification, which is ink-jet printed within white bar. This indicates year/month/day/manufacture location/manufacture shift, military time and product identification. For example: 2015/11/01 3 12:45 BX. Manufacturing locations are coded as: Factory Code:

- 1 for Riviere-du-Loup, Quebec compressed products (EPA Establishment No. 74267-CAN-01)
- 2 for Riviere-du-Loup. Quebec loose fill products (EPA Establishment No. 74267-CAN-02)
- 3 for Richer, Manitoba (EPA Establishment No. 74267-CAN-03)
- 4 for Northal, Alberta (EPA Establishment No. 74267-CAN-04)

6 for Rexton, New Brunswick (EPA Establishment No. 74267-CAN-06)

## ACCEPTED

## Apr 25, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 74267-1

## (SIDE PANEL)

## **PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals. CAUTION:** Avoid contact with eyes. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling.

**Personal Protective Equipment**: Applicators and other handlers must wear long-sleeved shirt and long pants, and shoes plus socks. As a general precaution when exposed to living microbial products such as this, applicators (persons opening bags and/or filling potting machines) must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Follow manufacturer's instructions for cleaning / maintaining PPE. Keep and wash PPE separately from other laundry.

**Environmental Hazards:** For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to inter-tidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water.

**User Safety Recommendations:** Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

FIRST AID							
<ul> <li>Hold eye open and rinse slowly and gently with water for 15 – 20 minute</li> <li>Remove contact lenses, if present, after the first 5 minutes, then con eye.</li> </ul>							
	<ul> <li>Call a poison control center or doctor for treatment advice.</li> </ul>						

# **PRO-MIX** with Biofungicide

GROWING MEDIUM WITH BIOFUNGICIDE FINE-GRADE PLUG GROWING MEDIUM SPHAGNUM PEAT-BASED GROWING MEDIA FOR GREENHOUSE OR GLASSHOUSE USE VEGETABLE, FRUIT & TOBACCO GROWING MEDIUM VEGETABLE TRANSPLANT GROWING MIX WITH BIOFUNGICIDE

**PRO-MIX with Biofungicide** has been enriched with Subtilex® (active ingredient: *Bacillus subtilis* MBI 600), a biofungicide that prevents root diseases. The *Bacillus subtilis* bacteria colonize developing root systems, and suppress disease-causing organisms, such as *Pythium, Fusarium, Rhizoctonia, Alternaria* and *Aspergillus*, which attack root systems. The bacteria also act as a biostimulant developing with the growing root system. As a result, a vigorous root system is (then) established that results in more uniform plant stands after transplanting and crop response. (*Optional Text:* As a result, a vigorous root system is established that results in more uniform plant stands after transplanting in the field and in greater crop yields).

## PRO-MIX Biofungicide Custom Blends

PRO-MIX With Biofungicide is a custom blended growing medium designed to meet your growing needs.

- **BX Blend.** The BX Blend (PRO-MIX BX Biofungicide) is a 'General Purpose' peat-based (professional) growing medium formulated (designed) for the cultivation of horticultural plants. This growing medium (It) contains a blend of select Canadian Sphagnum peat moss, perlite, vermiculite, dolomitic and calcitic limestone. This formulation is lightweight, uniform and provides conditions necessary to establish plant growth. PRO-Mix 'BX' with Biofungicide is suitable for a wide variety of plants.
- **BRK Blend.** The BRK Blend (PRO-MIX BRK Biofungicide) is a medium-weight, Peat/Barkbased growing medium designed for the cultivation of horticulture plants. Processed pine bark adds weight and reduces water retention of media while (quality) Sphagnum peat moss is lightweight and possesses high water-holding ability (ensures the optimal balance between air and water). This combination forms a base for a "general use" growing medium that provides conditions necessary to establish plant growth, particularly when container stability and lowwater retention are required.
- BRK20 Blend. The BRK20 Blend (PRO-MIX BRK20 Biofungicide) is a peat-bark based growing medium with bark content at 20% by volume. Processed medium sized bark adds weight, improves drainage and does not compete for nitrogen with plants. The result is a 'general use' growing medium that has a lower bulk density and holds more water compared to PRO-MIX BRK. PRO-MIX 'BRK20' is suitable for a wide variety of greenhouse plants, perennials and potting applications
- **HP Blend.** The HP Blend (PRO-MIX HP Biofungicide) is a 'High Porosity' peat-based growing medium designed for the cultivation of horticultural plants. This lightweight and porous growing medium provides conditions necessary to establish plant growth, especially when growing situations require medium with high air-capacity and low water-retention. This

formulation is excellent for use with water sensitive crops, propagation of plant cuttings and /or low-light growing conditions.

- LP15 Blend. PRO-MIX LP15 BIOFUNGICIDE is a multipurpose peat-based, perlite professional growing medium designed for growers that prefer a low amount of aggregate and no vermiculite. PRO-MIX LP15 is suitable for a wide range of greenhouse and transplanting applications.
- **FPX Blend.** The FPX Blend (PRO-MIX FPX Biofungicide) is a fine peat/perlite-based growing medium for germinating ornamental and vegetable seeds in small cell plug trays. It contains a base blend of short-fiber Sphagnum peat moss and fine perlite for easy filling of trays with minimal bridging. When in use, this blend retains less water than peat/vermiculite blends.
- **PGX Blend.** The PGX Blend (PRO-MIX PGX Biofungicide) is a peat-based growing medium designed for germinating ornamental and vegetable seeds. This fine textured blend contains a base of short-fiber Sphagnum peat moss and fine grade vermiculite and is well suited for traditional seeding and plug-system applications.
- **TA Blend.** The TA Blend (PRO-MIX TA Biofungicide) is a peat-based growing medium formulated for germinating and growing-on of Tobacco and Agriculture transplants. This blend is ideal for use with trays/flats cultivated in subirrigated float systems and conventional irrigation methods. This fine textured blend is user-friendly for filling small cell trays and flats with automated equipment or by hand.
- VFT Blend. The VFT Blend is a peat-based growing medium formulated for germinating and growing-on of vegetable, fruit and tobacco transplants. This blend is designed for use with trays/flats cultivated in subirrigated float systems and conventional irrigation methods. (*Optional Text:* This formulation contains a blend of ingredients that allow oxygen and water to move freely for uniform seed germination and plant growth. This fine textured blend is user-friendly for filling small cell trays and flats with automated equipment or by hand. USES: Vegetable Transplants, Fruit Transplants, Tobacco Transplants, Germination of Tobacco and Vegetable Seeds, Float Trays, Subirrigation systems.)
- **YP Blend.** The YP Blend (PRO-MIX YP Biofungicide) is a specialized growing medium for young plants produced in vacuum formed cells and pots larger than 30 mm. It is also suitable for rooting cuttings in trays and transplanting plugs in regular containers and trays. PRO-MIX® YP provides a rooting environment which supports healthy and strong early plant growth. Its precise blend of fibrous blonde Sphagnum peat moss, coir fiber and horticulture grade perlite resists compaction and promotes plant rootball development.

To determine the best PRO-MIX Biofungicide custom blend for your growing needs, consult the following base-formula table. For technical assistance, plant compatibility information and crop culture guidelines, contact PREMIER GROWER SERVICES – USA and Mexico: (800) 424-2554; Canada: (800) 667-5366.

LIST OF I	NGREDIENTS PER BLEND						
	Canadian Sphagnum Peat Moss (75-85%) • Vermiculite – horticultural grade• Perlite –						
BX	horticultural grade						
	• Dolomitic and Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide (Bacillus subtilis)						
HP	Canadian Sphagnum Peat Moss (65-75% by volume)      Perlite – horticultural grade      Dolomitic						
	and Calcitic limestone (pH adjuster) • Wetting Agent• Biofungicide (Bacillus subtilis)						
LP15	<ul> <li>Canadian Sphagnum Peat Moss (80-90% by volume)</li> <li>Perlite – horticultural grade</li> </ul>						
LPID	• Dolomitic and Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide (Bacillus subtilis)						
	Canadian Sphagnum Peat Moss (45-55% by volume)      Processed Pine bark      Perlite –						
BRK	horticultural grade • Dolomitic and Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide						
	(Bacillus subtilis)						
BRK20	Canadian Sphagnum Peat Moss (70-80%)      Processed Pine Bark      Perlite – horticultural grade						
DKKZU	• Dolomitic and Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide (Bacillus subtilis)						
	Canadian Sphagnum Peat Moss (80-90% by volume)      Vermiculite – fine grade      Dolomitic and						
FPX	Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide (Bacillus subtilis)						
PGX	Canadian Sphagnum Peat Moss (75-85% by volume)      Vermiculite – fine grade      Dolomitic and						
FGA	Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide (Bacillus subtilis)						
	Canadian Sphagnum Peat Moss (45-55% by volume)      Coir – horticultural grade      Perlite –						
YP	horticultural grade • Dolomitic and Calcitic limestone (pH adjuster) • Wetting Agent • Biofungicide						
	(Bacillus subtilis)						

## Optional Text/Table:

PRO-MIX Base Formula	Sphagnum Peat Moss	Perlite	Vermiculite	Bark	Coir	Limestone	Wetting Agent	BIOFUNGICIDE
вх	 75-85%/vol.							
HP	 65-75%/vol.							
LP-15	 80-90%/vol.							
BRK	 40-50%/vol.			*1  35-45%/vol.				
BRK	 70-80%/vol.			*1  15-25%/vol.				
FPX	 80-90%/vol.	 plug-grade						
PGX	 75-85%/vol.		 plug-grade					
ТА	 80-90%/vol.		 plug-grade					
VFT	 75-85%/vol.		 plug-grade					
YP	 45 - 55%/vol.							

\*1 – Processed pine

#### Optional Text/Table:

To determine the best PRO-MIX With Biofungicide custom blend for your growing needs, consult the following table. For technical assistance, plant compatibility information and crop culture guidelines, contact PREMIER GROWER SERVICES – USA and Mexico: (800) 424-2554.

Blend	Bedding Trays	Hanging Baskets*	Potted Plants*	Perennials & Hardy Mums	Cuttings*	Seed Germination	Float Trays	Subirrigation Systems
BX Blend	1	1	1	1	1	1		1
BRK Blend	1		1	1				1
BRK20 Blend	1		1	×				✓
HP Blend	1	×	1	×	×			✓
FPX Blend						1	~	*
LP15 Blend	×	V	~	v	~			
PGX Blend						1	1	1
TA Blend						1	1	×
VFT Blend						1	1	1
YP Blend	1				1	1		

\* Intended for annuals, bulbs, flowering and/or foliage plants

\*\* Intended for the propagation of cuttings, such as flowering, foliage, herbaceous and woody plants.

## **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. 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.

### 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 intervals (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

There is a zero (0) restricted entry interval for this product.

### **PREPARATION:**

Open package at the time of seeding, potting or transplanting. Potting benches and equipment should be located in a clean, weed-free area. Add water to **PRO-MIX Biofungicide** until slightly moist to the touch. Transplant cuttings, plugs, seedlings, etc. in moistened medium taking care to avoid compaction (do not press down around seed or root systems). After transplanting, add water to settle medium. Place newly transplanted trays and pots in a suitable growing area within the greenhouse.

(*Optional Text:* Select trays and flats that provide adequate drainage and fill completely with moistened medium, taking care not to compact. Do not pack down. Compaction reduces air space and can adversely affect germination and seedling growth. Sow seeds according to seed packet directions and irrigate with water. Place newly sown trays in suitable growing area and maintain air/medium temperatures that favor plant species grown. Sow seeds, transplant cuttings, seedlings, ect. in moistened medium taking care to avoid compaction (do not press down around seed or root

systems). Be sure that all flats and trays have adequate drainage. After seeding/transplanting, add water to settle medium. Place newly sown/transplanted trays and pots in a suitable growing area within the greenhouse.)

**IMPORTANT:** PRO-MIX Biofungicide is suitable for fruit and vegetable seedlings, and transplants. Do not use for plants bearing fruit. PRO-MIX Biofungicide is for use in protected growing environments only (e.g. glasshouse or greenhouse): <u>not</u> for use in non-protected environments (e.g. non-contained nurseries or slat houses).

## FERTILIZATION:

Initial plant development will occur without immediate fertilization. It is essential to initiate a fertilization program at the emergence of the first set of true leaves, this will ensure plants receive adequate nutrients. Select a fertilization program that is appropriate for the plant species grown, stage of development and water nutrient content. If you frequently analyze media nutrient levels and plant tissue throughout the production cycle, you can insure plants receive proper nutritional requirements.

## WATER MANAGEMENT:

An essential part of crop culture is water management. When plants require water, irrigate the crop early in the day. This will allow plant foliage and medium surface to dry. Also, medium temperature can warm to normal level by evening. Irrigate thoroughly so water 'runs through' to prevent salt accumulation and to ensure uniform wetting and drying of containers throughout the crop. If preferred, additional wetting agent can be applied during the crop cycle at irrigation to reduce surface tension of water for more thorough water penetration and movement throughout the root zone.

## **APPLICATION INFORMATION:**

- Store product away from excessive heat
- Use **PRO-MIX Biofungicide** "as is" from package. Add water to moisten.
- Thoroughly moisten medium to "water-in" plants after transplanting and placing in the greenhouse.
- Do not add fertilizers when sowing seeds.
- Use for plants requiring a growing pH between 5.0 and 7.0.
- Do not sterilize or pasteurize **PRO-MIX Biofungicide**.
- Do not store wet growing media, as pH will tend to climb from activation of limestone.

• Store products in sealed bags to (preserve quality) (avoid intrusion from water, pathogens, pesticides and weeds).

• Pesticides and chemical growth regulator treatments can be used in combination with **PRO-MIX Biofungicide** and will provide extended protection throughout the growing season. (*Optional Text:* The biofungicide-enriched media can be used with pesticide and chemical treatments and will provide extended protection throughout the growing season.)

• Rotate product inventory to practice 'First In – First out'. Product performance is best when used within 12 months of manufacturing date. (see manufacturing date on package: yyyy/mm/dd.)

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Do not contaminate water by cleaning of equipment or disposal wastes.

**STORAGE:** Store in a dry place.

**PRODUCT DISPOSAL:** Wastes resulting from the use of this product may be disposed on site, or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of bag in trash or by incineration, if allowed by State and local authorities.

### QUALITY GUARANTEE

PREMIER HORTICULTURE is committed to quality. All PRO-MIX professional products are made with high-quality components. If for any reason you are not completely satisfied with the quality of this product, you may return this package to the seller and PREMIER HORTICULTURE guarantees to replace it or refund its purchase price, at your choice. As usual with similar products, all other remedies and liabilities including, liability for direct or consequential damages, warranties of merchantability and fitness for a particular purpose are excluded.

# PRODUCT OF CANADA

Manufactured for: PREMIER HORTICULTURE, INC. 200 Kelly Rd, Unit E-1 Quakertown, PA 18951 For additional information, call: (215) 529-1290 or (800) 525-2553 www.pthorticulture.com

#### Manufactured by:

PREMIER HORTICULTURE LTEE / LTD 1 Avenue Premier Rivière-du-Loup, Canada G5R 6C1 For additional information, call: (514) 631-6700 or (800) 667-5366

SUBTILEX is a registered trademark of BASF Corporation and the strain of *Bacillus subtilis* is a product of BASF Corporation.