68539-3

## 2/22/2013 UNIT STATES ENVIRONMENTAL PROTECTIC GENCY

FEB 2 2 2013

Ms. Jamie Aggas Regulatory Coordinator BioWorks, Inc. 100 Rawson Road, Suite 205 Victor, NY 14564

Re: BioWorks, Inc. (BioWorks); T-22G Biological Fungicide EPA Registration No. 68539-3 Minor Label ("Fast Track") Amendment Submissions dated 06/22/2012, 12/06/2012, 02/19/2013, and 02/20/2013 Decision No. 467058

Dear Ms. Aggas:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting inconsistencies and typographical errors.
- 2) Removal of the alternate brand name, TurfShield<sup>®</sup> Granules Biological Fungicide.
- 3) Addition of the following labeling text to account for small containers:

"See attached label booklet for First Aid, Precautionary Statements, Storage and Disposal Instructions and Directions for Use."

- 4) Enclosure of the User Safety Recommendations in their own box.
- 5) Modification of the Environmental Hazards statements to comport with information presented in Chapter 8, Section III(A) of the Label Review Manual (revised September 2012).
- 6) Replacement of "Use Before" with "Expires" (re: product stability).
- 7) Removal of the turf reference from the second sentence in the Product Information section.
- 8) Addition of BioWorks' phone number and Internet address to the contact information.
- 9) Modification of certain application rates to accommodate smaller container sizes (e.g., 2.5 6.0 lb / ½ acre instead of 5.0 12.0 lb / acre).
- 10) Revision of some crop group names and commodity listings in accordance with 40 C.F.R. § 180.41.
- 11) Addition of the following statement to the Pesticide Storage section:

"Product keeps best under refrigeration."

				CONCURRENC	ES	 	
YMBOL	7511P	7511P	7571P				
URNAME	KAUSCH	Boys	Mir				
	02/20/2013	2/20/13	2122/13				

PA Form 1320-1A (1/90)

Ms. Jamie Aggas EPA Registration No. 68539-3

- 12) Modification of the Container Handling statements for the 10-lb unit (packaged in polyethylene bag and placed in corrugated carton) to comport with Chapter 13 of the Label Review Manual (revised January 2012).
- 13) Modification of two statements in the Notice to Buyer and Seller section to comport with information presented in Chapter 12, Section IX of the Label Review Manual (revised November 2007).
- 14) Addition of a consumer access number for CHEMTREC.
- 15) Addition of information presenting where the product is made and BioWorks' company logo.

Some of these changes were proposed with a notification request (Decision No. 468013) that was dated June 18, 2012. Such changes are now considered to be part of this label amendment.

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email (*kausch.jeannine@epa.gov*).

A stamped copy of the label is enclosed for your records.

Sincerely,

Kimberly Nesci, Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

Enclosures: (1) T-22G Biological Fungicide Accepted Label (2) A-79 Enclosure

2



(<u>Alternate Brand Names</u>: RootShield® Granules Biological Fungicide; T-22 G Granules Biological Fungicide) **ACCEPTED** 

**ACTIVE INGREDIENT** 

### KEEP OUT OF REACH OF CHILDREN CAUTION

	FIRST AID			
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.			
HOT LINE	NUMBER: Have the product container or label with you when calling a poison control center or			
	oing for treatment. You may also contact 1-800-222-1222 for emergency medical treatment			
information.				

[See attached label booklet for First Aid, Precautionary Statements, Storage and Disposal Instructions and Directions for Use]

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. 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 protective eyewear, long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks. Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization. Follow manufacturer's directions 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:**

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. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

#### **ENVIRONMENTAL HAZARDS:**

For terrestrial uses: Do not apply directly to water, 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 washwaters or rinsate.

EPA Reg. No.:	68539-3
EPA Est. No.:	068539-NY-001

Manufactured by: BioWorks, Inc., 100 Rawson Road, Ste. 205, Victor, NY 14564 (800) 877-9443

www.bioworksinc.com Net Weight: Lot No.:

Expires: (Date will be 184 days after production)

MASTER LABEL

T-22G Biological Fungicide; EPA Reg. No. 68539-3 Amendment to add mandatory statement and tuber vegetables - version (12) dated December 6, 2012

FEB 2 2 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 68539-3

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected workers may be in the area during application. For any requirement specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

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

No REI is required as this product is soil incorporated, and the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

#### PRODUCT INFORMATION

T-22G Biological Fungicide is a preventative biological fungicide for control of soilborne plant pathogens and plant root diseases. The active ingredient is a microbe, *Trichoderma harzianum* Rifai strain T-22, which when applied as an inoculant to soil or planting mixes, grows onto plant roots as they develop and provides protection against plant root pathogens such as *Pythium, Rhizoctonia, Fusarium, Cylindrocladium* and *Thielaviopsis*.

T-22G Biological Fungicide can be used in combination with or in rotation with other fungicides, insecticides, miticides, fertilizers or micronutrients in accordance with the more restrictive of label limitations and precautions.

Do not exceed label dosage rates. This product cannot be used with any product containing a label prohibition against such mixing. This product is not compatible with chemicals that contain the following active ingredients: imazilil, propicanazole, tebuconazole, and triflumizole. Do not apply T-22G Biological Fungicide immediately before these pesticides are used. Where early season seed rot and seedling diseases are expected, use chemically treated seed or other appropriate measures for stand establishment and T-22G Biological Fungicide for root disease control.

Note: T-22G Biological Fungicide contains live spores of a microbe that must be used prior to disease onset. T-22G Biological Fungicide becomes active in soil or on plants when temperatures are above 50°F and is not effective while temperatures remain cold. T-22G Biological Fungicide can be applied to sterilized or fumigated soil but must be applied after sterilization or fumigation.

This biological fungicide is for use in soil applications (in soil furrow and potting soil) for all listed crops.

#### **USE RESTRICTIONS**

Do not apply this product as a broadcast application. Cover applied product with soil or otherwise incorporate it into soil.

# DO NOT APPLY to sugarcane, pechay, rice, mushrooms, kiwi, tobacco, barley, oats, lemon, apple, and chickpea. Not for use on aquatic crops.

#### **APPLICATION INSTRUCTIONS**

#### APPLY VIA GROUND APPLICATION ONLY.

MASTER LABEL

$\left( \right)$		(		
CROPS ON WHICH	I T-22G BIOLOGICAL FUNG USE	CIDE MAY BE USED: APPLICATION RATE of T- 22G BIOLOGICAL FUNGICIDE		
Berries and Small Fruits: Blackberries, Blueberries, Currants, Elderberries, Gooseberries, Huckleberries, Loganberries, Raspberries, Strawberries, Grapes	In-furrow	2.5 – 6.0 lb / ½ acre		
<b>Bulb Vegetables:</b> Garlic, Leeks, Onions, Shallots	In-furrow	2.5 – 6.0 lb / ½ acre		
<b>Cereal Grains:</b> Buckwheat, Corn (grain, sweet corn, popcorn, high oil)	In-furrow	2.5 – 6.0 lb / ½ acre		
<b>Citrus Fruits:</b> Citrus Hybrids, Grapefruit, Kumquat, Limes, Oranges, Pummelos	In-furrow	2.5 – 6.0 lb / ½ acre		
Cucurbit Vegetables: Cucumbers, Melons (i.e. Chinese waxgourd, Citron melon, Muskmelons, or Watermelon), Gourds Pumpkins, Squash	In-furrow	2.5 – 6.0 lb / ½ acre		
Flowers, Bedding Plants, and Ornamentals	In-furrow Greenhouse planting mix Nursery planting mix Nursery bed application	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0  lb /  cubic yd soil mix 1.0 - 3.0  lb /  cubic yd soil mix 0.5 - 7.5  lb / 1000  sq ft, incorporate with rake or tiller		
<b>Fruiting Vegetables:</b> Eggplant, Sweet and Hot Peppers, Tomatillos, Tomatoes	In-furrow Greenhouse planting mix	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0 lb / cubic yd soil mix		
Herbs and Spices	In-furrow Greenhouse planting mix	2.5 – 6.0 lb / ½ acre 1.0 – 3.0 lb / cubic yd soil mix		
Mints	In-furrow Greenhouse planting mix	2.5 – 6.0 lb / ½ acre 1.0 – 3.0 lb / cubic yd soil mix		
Leafy and Brassica (Cole) Leafy Vegetables: Arugula, Celery, Chervil, Endive, Fennel, Lettuce (head and leaf), Parsley, Radicchio, Rhubarb, Spinach, Swiss Chard, Broccoli, Brussels Sprouts, Cabbage, Cauliflower, Collards, Kale, Kohlrabi,	In-furrow Greenhouse planting mix Nursery bed application	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0  lb /  cubic yd soil mix 0.5 - 7.5  lb / 1000  sq ft, incorporate with rake or tiller		

5/8

#### MASTER LABEL

T-22G Biological Fungicide; EPA Reg. No. 68539-3 Amendment to add mandatory statement and tuber vegetables - version (12) dated December 6, 2012 Page 3 of 6

CROPS	USE	APPLICATION RATE of T- 22G BIOLOGICAL FUNGICIDE	
Mustard Greens			
Asparagus	In-furrow Greenhouse planting mix Nursery bed application	2.5 – 6.0 lb / ½ acre 1.0 – 3.0 lb / cubic yd soil mix 0.5 – 7.5 lb / 1000 sq ft, incorporate with rake or tiller	
Legume Vegetables (Succulent or Dried): Beans (soybean, snap, dry), Lentils, Peas	In-furrow	2.5 – 6.0 lb / ½ acre	
<b>Oilseed Crops:</b> Cotton, Canola, Safflower, Sunflower	In-furrow	2.5 – 6.0 lb / ½ acre	
Pome Fruits: Pears, Quince	In-furrow Greenhouse planting mix Nursery planting mix Trees and shrubs	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0  lb /  cubic yd soil mix 1.0 - 3.0  lb /  cubic yd soil mix 0.2 - 8.0  oz /  transplant hole and incorporate	
Root and Tuber Vegetables: Beets, Sugar Beets, Carrots, Celeriac, Chicory, Horseradish, Parsnip, Radish, Rutabaga, Salsify, Turnips, Ornamental Root and Tuber Vegetables	In-furrow Planting hole	1.0 - 3.0 lb / cubic yd soil mix 0.2 - 8.0 oz / transplant hole and incorporate	
Potatoes, Sweet Potatoes, Yams, Jerusalem Artichoke, Cassava, Ginger			
Shadehouse and Outdoor Nursery Crops: Deciduous trees (i.e. Maple, Oak), Ornamentals, Pine	In-furrow Shadehouse or outdoor nursery use Nursery planting mix Nursery bed application Trees and shrubs	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0  lb /  cubic yd soil mix, incorporate with rake or tiller 1.0 - 3.0  lb /  cubic yd soil mix 0.5 - 7.5  lb / 1000  sq ft, incorporate with rake or tiller 0.2 - 8.0  oz /  transplant hole and incorporate	
<b>Stone Fruits:</b> Apricots, Cherries, Nectarines, Peaches, Plums, Prunes	In-furrow Greenhouse planting mix Nursery planting mix Trees and shrubs	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0  lb /  cubic yd soil mix 1.0 - 3.0  lb /  cubic yd soil mix 0.2 - 8.0  oz /  transplant hole and incorporate	
<b>Tree Nuts:</b> Almonds, Beech Nuts, Brazil Nuts, Butternuts, Cashews, Chestnuts, Filberts, Hickory Nuts, Macadamia	In-furrow Greenhouse planting mix Nursery planting mix Trees	$2.5 - 6.0 \text{ lb} / \frac{1}{2} \text{ acre}$ 1.0 - 3.0  lb /  cubic yd soil mix 1.0 - 3.0  lb /  cubic yd soil mix 0.2 - 8.0  oz /  transplant hole and	

6/8

amia I rees T-22G Biological Fungicide; EPA Reg. No. 68539-3 Amendment to add mandatory statement and tuber vegetables - version (12) dated December 6, 2012 Page 4 of 6

CROPS	USE	ArPLICATION RATE of T- 22G BIOLOGICAL FUNGICIDE
Nuts, Pecans, Pistachios, Walnuts		incorporate

**IN-FURROW SOIL TREATMENT**: Apply T-22G Biological Fungicide from a granular applicator at the rate of 2.5 - 6.0 pounds per  $\frac{1}{2}$  acre. Apply granules using a metering device, such as a Gandy applicator or equivalent, mounted to deliver granules into the furrow just behind the furrow opener. Apply in furrow at seeding or to established crops as a side dress and incorporate into soil.

**GREENHOUSE PLANTING MIX AMENDMENT**: Mix T-22G Biological Fungicide with planting mixes at a rate of 1-3 pounds per cubic yard (loose) mix. Thoroughly incorporate T-22G Biological Fungicide into planting mixes during mix preparation or at pot filling.

**NURSERY PLANTING MIX AMENDMENT AND NURSERY BED APPLICATION**: For nursery planting mixes, apply T-22G Biological Fungicide at the rate of 1-3 pounds per cubic yard (loose) mix. For nursery beds, incorporate T-22G Biological Fungicide at a rate of 0.5-7.5 pounds per 1000 square feet of bed by raking or tilling. Application of irrigation water will help move T-22G Biological Fungicide into the soil. If soil is fumigated or steam sterilized, apply T-22G Biological Fungicide after treatment.

**TREES AND SHRUBS**: Apply T-22G Biological Fungicide to the planting hole at a rate of 0.2 - 8.0 ounces and incorporate into the planting soil or soil mix.

#### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store in a cool, dry place. Do not store near food or feed commodities. Do not store at temperatures above 75°F for prolonged periods. Product keeps best under refrigeration. Keep container tightly closed when not in use.

**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.

(10 lb unit packaged in polyethylene bag and placed into corrugated carton) Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer for recycling if available, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If outer box is contaminated, dispose of in the same manner as required for the bag.

(40 lb bag, 500 lb bag, 1000 lb bag) Completely empty bag into application equipment. Then offer for recycling if available, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**NOTICE TO BUYER AND SELLER**: Seller warrants that this product conforms to the description on this label and is reasonably fit for the purposes stated on this label when used and stored in accordance with the directions for use. This warranty does not extend to use of this product contrary to label directions or under conditions not reasonably foreseeable by the Seller, and Buyer and User assume the risk of any such use. To the extent consistent with applicable law, Seller disclaims all other warranties, express or implied, including any warranty of fitness or merchantability. To the extent consistent with applicable law, Seller shall not be liable for consequential, special or indirect damages resulting from use or handling of this product; and Seller's sole liability and Buyer's and User's exclusive remedy shall be limited to refund of the purchase price.

This product is sold only for uses stated on its label.

Country: United States of America

[In Case of Emergency, Call CHEMTREC: (800) 424-9300]

[Manufactured in the United States of America (USA) by: BioWorks Inc. [Company Logo]]