

64137-5

4/5/2004

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060.

United States Environmental Protection Agency 1200 Pennsylvania Avenue Washington, DC 20460-0001		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number EPA Reg. No. 64137-5		2. EPA Product Manager Janet L. Andersen	
4. Company/ Product (Name) Mycostop® Biofungicide		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Verdera Oy c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i) my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section – II			
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. NOTIFICATION <input type="checkbox"/> Other – Explain below.	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) <div style="text-align: center;"> Submit label revision notification per PR Notice 98-10. Revisions are illustrated on the Reference Label. </div> <p><i>This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR § 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR § 152.46 this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.</i></p>		Date Reviewed: <u>4-5-05</u> Reviewed By: <u>[Signature]</u>	
Section – III			
1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify): _____
*Certification must be submitted If "Yes" Unit Packaging Wgt. _____ No. Per Container _____		If "Yes" Packaging Wgt. _____ No. Per Container _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container _____	
		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other _____			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).			
Name Kim Davis, CC, APC, Manager		Title Consultant/Agent	
		Telephone No. (Include Area Code) (970) 353-0611 / kim@regwest.com	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature <u>[Signature]</u>		3. Title Consultant/Agent	
4. Typed Name Kim Davis, CC, APC, Manager		5. Date March 16, 2004	



March 16, 2004

Dr. Janet L. Andersen, Director BPPD
Document Processing Desk – **NOTIF**
Office of Pesticide Programs – **7504C**
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall #2, Room 266A
Arlington, VA 22202-4501

Dear Dr. Andersen:

Subject: Verdera Oy
Mycostop® Biofungicide
EPA Reg. No. 64137-5

On behalf of its client **Verdera Oy**, RegWest Company, LLC is submitting the attached documents in support of a label revision notification for subject product. RegWest Company will act as sole agent in this endeavor.

Attached are the following items:

1. Application for Pesticide: Other
2. One **Reference Label** (illustrates the label revisions)
3. Two **New Labels** (incorporate the label revisions)
4. Two market labels (not representative of the complete stamped accepted label)

The label revisions are illustrated on the **Reference Label**. We are primarily reformatting the label to a booklet-type format, including the chemigation directions in the label (as opposed to supplemental labeling) and designating one paragraph (Potential Growth Enhancement/Yield Increase) as "Except in California."

Please contact me at (970) 353-0611 or kim@regwest.com if you have any questions or require additional information.

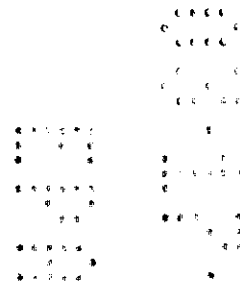
Regards,
RegWest Company, LLC



Kim Davis, CC, APC, Manager
Consultant/Agent

Attachments

pc: VDO



30856 Rocky Road
Greeley, CO 80631-9375
970-353-0611
970-353-0613 Fax
Kim@regwest.com

Mycostop® Biofungicide

FOR TURF and AGRONOMIC, VEGETABLE AND ORNAMENTAL CROPS

Active Ingredients:

Dried spores and mycelium of ray fungus
(*Streptomyces griseoviridis* Strain K61)* 30%

Other Ingredients 70%

*10⁸ cfu (colony forming units) per 1g of product Total 100%

Keep Out of Reach of Children

CAUTION

See back panel for additional precautionary statements.

EPA Reg. No. 64137-5

EPA Est. 64137-FI-1

{Verdera Logo}

0.035 oz. (1g) ☐

0.176 oz. (5g) ☐

0.88 oz. (25g) ☐

NOTIFICATION

Date Reviewed: 4-5-04

Reviewed By: [Signature]

{Back Panel}

MYCOSTOP® BIOFUNGICIDE PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if inhaled. Avoid breathing dust or spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

Personal Protective Equipment

Applicators and other handlers must wear: Long-sleeved shirt and long pants. Waterproof gloves. Shoes plus socks. Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator with any approval number prefix N-95, R-95 or P-95 or HE filter.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are given for washables, use detergent and hot water. 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.
- Users should immediately remove clothing if pesticide gets inside, then thoroughly wash and put on clean clothing.
- Immediately remove personal protective equipment after handling this product. If gloves are worn wash the outside of gloves before removing. As soon as possible thoroughly wash and change into clean clothing.

First Aid

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 by mouth to mouth if possible.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes.
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. Have the product container or label with you when calling a poison control center or doctor or going for treatment. [You may also contact 1-800-424-9300 for emergency medical treatment information.]

{Note: the first aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

[Emergency Information

For spill, leak, fire, exposure or accident call CHEMTREC at 1-800-424-9300.]

Environmental Hazards

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 by disposal of equipment wash waters.

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 handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the 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. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours. Exception: If the product is soil injected or soil incorporated, 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.

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:

- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Dust/mist filtering respirator with MSHA/NIOSH-approval number prefix TC-21C or a NIOSH-approved respirator with any approval number prefix N-95, R-95 or P-95 or HE filter.

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 and greenhouses. Do not enter treated area without protective clothing until sprays have dried.

ORNAMENTAL AND VEGETABLE USES

Mycostop is used for the control of seed rot, root and stem rot and wilt caused by *Fusarium*, *Alternaria* and *Phomopsis* of container grown ornamentals, vegetables and tree and forest seedlings. Mycostop has also shown suppression of *Botrytis* Gray Mold and root rots of *Pythium*, *Phytophthora* and *Rhizoctonia* in the greenhouse.

Mycostop can be used as a seed treatment for seed or soil-borne damping off and early root rot of vegetables, herbs and ornamentals planted in the field or greenhouse.

{Inside Top Panel}

**Disease Control
Seed Treatment**

- Mycostop can be applied as a seed treatment in vegetables, herbs, ornamentals, trees and conifers at the following rates:
 - Lettuce: 0.03 oz. Mycostop/lb. seed (2 g/kg)
 - Ornamentals, dill, leguminous plants, parsley, root crops, spinach, tomatoes, trees and conifers: 0.08 oz. Mycostop/lb. seed (5 g/kg)
 - Brassica species (Cole crops), herbs, leeks and onions: 0.13 oz. Mycostop/lb. seed (8 g/kg)
- Mycostop may be mixed with seed in a planter box. As a planter box treatment, fill box half full of seed, add half the required amount of Mycostop and thoroughly mix with a stick or paddle. Add remainder of seed and Mycostop and thoroughly mix.
- To mix in a small container such as a jar, add the required amount of Mycostop, shake until the seeds become coated with powder, then pour into planter box.
- Sow treated seed without delay, but at least within a week if kept cool and dry.
- Do not treat damp or wet seed with Mycostop powder.

- Do not treat seeds of Dusty Miller or melons with Mycostop.

Mycostop has also been proven effective when used as a 0.01% [(5 g/13 gal.)(0.18 oz./13 gal.)(5 gal./50 liters)] to 0.1% [(5 g/1.3 gal.)(0.18 oz./1.3 gal.)(5 g/5 liters)] seed soak where soaking seed for 5-15 minutes immediately prior to planting is practical. Because many ornamentals and vegetables have not been tested using a seed soak, the grower should first check emergence on a small quantity of seed.

Incorporation In Potting Media

Mycostop can be mixed into potting media at a rate of 1-2 g/cubic yard. Apply Mycostop in a concentrate spray to the growth media when the media is being mechanically blended or rake in by hand in beds. It is important that Mycostop be evenly incorporated to assure best performance. Use potting media containing Mycostop within 2 days after incorporation. Do not store above 85°F. A drench or spray application of Mycostop is recommended within 2-6 weeks as described below under *Soil Spray or Drench Applications*.

Transplant Dip or Cutting Dip

Mycostop may be applied by dipping roots of transplants or cuttings (including bare root seedlings) such as carnations, in a suspension shortly before planting. A suspension of 0.01% [(5 g/13 gal.)(0.18 oz./13 gal.)(6 g/50 liters)] to 0.1% [(5 g/1.3 gal.)(0.18 oz./1.3 gal.)(5 g/5 liters)] is recommended. Use the higher rate for high disease pressure.

Soil Spray or Drench Applications

Mycostop may be applied to bedding plants, foliage plants, flowering plants, trees, conifers, forest seedlings, woody ornamentals, vegetable transplants or vegetables grown for production. Examples of ornamental crops include carnation, gerbera, African violet, cyclamen, geranium, pine and others. Examples of vegetable crops include cabbage, cucumbers, melons, peppers, tomatoes and others.

- **Soil Spray** – Uniformly apply Mycostop at a rate of 1-2g/100 sq. ft. (0.035–0.07 oz./100 sq. ft.) over the area to be treated. For example, use 0.2-0.5 gal. (1-2 liters) of 0.1% suspension [(5g/1.3 gal.)(0.18 oz./1.3 gal.)(5 g/5 liters)] per 100 sq. ft. Follow with normal irrigation or sufficient water (1/8–1/4 inch) within 6 hours to move Mycostop into the plant root zone.
- **Drench** – Uniformly apply Mycostop at a rate of 1-2 g/100 sq. ft. (0.035–0.07 oz./100 sq. ft.) over the area to be treated. Apply sufficient water during application to move Mycostop into the root zone.
- **Small Seedling Production** – Apply Mycostop at a rate of 2-4 g per 1000 sq. ft. [(0.07-0.14 oz./1000 sq. ft.)(2-4 g/100 sq. meters)] over the area to be treated.

Repeat spray or drench application every 2-6 weeks as needed for disease control. Use the higher rate and more frequent application for high disease pressure and for larger plants.

Band or In-Furrow Application

Apply 0.5-1.0 lb. Mycostop/treated acre (0.5-1.0 Mycostop kg/treated hectare) shortly before or at the time of planting in 15-50 gals. of water. A 7-inch band is recommended for banded applications. Lightly incorporate into the top 2-3 inches of soil. An in-furrow application of Mycostop may also be made at the same rates. Spray all the soil that surrounds and covers the seed.

Side-Dress Application

Apply 0.5-1.0 lb. Mycostop/treated acre (0.5-1.0 Mycostop kg/hectare) in 25-100 gals. of water as a side-dress application to the plant bed. Direct spray to base of plant and root zone. Repeat treatment every 2-4 weeks or as needed.

Botrytis Suppression

A Mycostop spray of 0.1% [(5 g/13 gal.)(0.18 oz./13 gal.)(5 g/50 liters)] will help suppress *Botrytis* infection. Direct spray to susceptible leaves, flowers and fruits to point of run-off. Apply every 2-3 weeks or as needed depending on disease pressure.

Mixing Instructions

To make a suspension of Mycostop, mix in a small volume of water such as 0.25-1.0 gallon and let stand for approximately 30 minutes. Agitate as needed to get product evenly dispersed before diluting to final volume. Do not tank mix Mycostop with any pesticides or with concentrated fertilizers.

Potential Growth Enhancement/Yield Increase*

Mycostop has been shown to promote the growth and yield of plants even in healthy crops. For*potential growth enhancement use a rate of 1 g/500 sq. ft. (0.035 oz./500 sq. ft.) and repeat monthly during the life of the crop. *Except in California.

AGRONOMIC USES

Mycostop is used for the control of seed rot, root and stem rot and wilt diseases caused by *Fusarium* in agronomic crops such as cotton, corn (field), soybeans, wheat, sorghum, beans, peas and tree and forest seedlings.

Seed Treatment

- Mycostop is applied as a seed treatment at a dose rate of 4-8 oz./100 lb. of seed (2.5-5.0 g/kg). Apply as a planter box treatment by mixing Mycostop with the seed before planting. For best results, fill planter box half full of seed, add half the required amount of Mycostop and thoroughly mix with a stick or paddle. Add remainder of seed and Mycostop and thoroughly mix.
- Good results can also be obtained by mixing Mycostop with seed in a separate container, then pouring into planter box.
- Sow treated seed without delay, but at least within a week, if kept cool and dry.

[Soil Spray Applications]**Mixing Instructions**

To make a suspension of Mycostop, mix in a small volume of water such as 0.25-1.0 gallon and let stand for approximately 30 minutes. Agitate as needed to get product evenly dispersed before diluting to final volume. Do not tank mix Mycostop with any pesticides or with concentrated fertilizers.

TURF

Use Mycostop for the control of seed rot, root rot and stem rot and wilt diseases caused by *Fusarium* in turf. Apply 0.4-0.5 lb. Mycostop per acre (0.4-0.5 kg/hectare) in 50-150 gal. (190-570 liters) of water. Repeat treatment every 4 to 6 weeks as needed depending on disease pressure.

Band or In-Furrow Application

Apply 0.5-1.0 lb. Mycostop/treated acre (0.5-1.0 kg Mycostop/treated hectare) shortly before or at the time of planting in 25-50 gal. of water. A 7-inch band is recommended for banded applications. Lightly incorporate into the top 2-3 inches of soil. An in-furrow application of Mycostop can also be made at the same rates. Spray all the soil that surrounds and covers the seed.

Integrated Disease Control Programs

Mycostop may be used in integrated disease control programs. However, it should not be tank mixed with any pesticide. Mycostop may be used the same day, if registered and if not prohibited, with benomyl, thiophanate methyl, metalaxyl, vinclozolin, fosetyl-Al and propamocarb hydrochloride. Pesticides not compatible with Mycostop have a 4-day interval between applications.

Drip Irrigation – Chemigation**General**

1. Apply Mycostop only through drip irrigation system(s). Do not apply Mycostop through any other type of irrigation system.
2. A pesticide supply tank is recommended. Continuous agitation of Mycostop in the supply tank is required. Begin application of Mycostop during the beginning of irrigation.

For Agronomic Crops

- Use Mycostop at 0.5-1.0 lb./treated acre (0.5-1.0 kg/treated hectare).
- Apply in sufficient water to move into root zone.
- Repeat every 2-6 weeks as needed for disease control

For Vegetable and Ornamental Crops

- On an area basis, use Mycostop at 1.0-2.0 g/100 sq. ft. [(0.035-0.07 oz./100 sq. ft.)(1.0-2.0 g/10 sq. meters)]. On an individual plant basis, use Mycostop at 1.0-5.0 g (0.03-0.17 oz.) per 200 plants.
 - Use higher rate and more frequent application for large plants and pots, and for high disease pressure.
 - Apply in sufficient amount of water to move into root zone. Repeat every 2-6 weeks as needed for disease control.
3. Crop injury, lack of effectiveness or illegal pesticide residues in the crop can result from nonuniform distribution of treated water.
 4. If you have any questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.
 5. A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of a responsible person, shall shut the system down and make necessary adjustments should the need arise.

(Inside Bottom Panel)

Special Instructions for Use of Public Water Sources

1. 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 from public water systems are in place.
2. 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.
3. Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) 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 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.
4. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
5. 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.
6. 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.
7. 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.

Special Instructions for Drip Irrigation (Chemigation) Systems

1. 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 backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. 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.
4. The system must contain a functional interlocking control to automatically shut off the pesticide injection pump when the water pump motor stops.
5. 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.
3. 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.

STORAGE AND DISPOSAL

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

Storage: Mycostop consists of living microbes that are packed in moisture- and air-proof unit packages. Store in a cool (below 8°C, 46°F), dry place. Use all contents in packet the same day. Do not store opened packets since product will lose its activity. **Pesticide Disposal:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal:** Completely empty packet into application equipment, then dispose of empty packet 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 USER

Verdera Oy warrants only that this product conforms to the product description on this label and is reasonably fit for the purposes set forth in the Directions for Use when used in accordance with them. However, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the use, storage or handling of the product contrary to the label instructions, all of which are beyond the control of Verdera Oy. All such risks shall be assumed by the user. In no case shall Verdera Oy be liable for indirect or consequential damages resulting from the use, storage or handling of this product. VERDERA OY MAKES NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

8 7 8

Use Before {Date}

**Verdera Oy
Riihitontuntie 14 A
P.O. Box 1
02201 Espoo, FINLAND**

**EPA Reg. No. 64137-5
EPA Est. 64137-FI-1
Made in Finland
VO-1203-EPA0203**

Mycostop® is a registered trademark of Verdera Oy, Finland

- [] Denotes optional/alternate language
{ } Denotes language that does not appear on the market labeling

