

73049-37

9/15/2009

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

September 15, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Doina Bujor, Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

RE: Product Name: DiTera WP
EPA Reg. No: 73049-37
Application for Label Notification Dated July 20, 2009 to Update Storage and Disposal
Language per PR Notice 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at hudson.diana@epa.gov.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



United States
Environmental Protection Agency
Washington, DC 20460

<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 73049-37	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) DiTera WP	PM# 92	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <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: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION Date Reviewed: <u>9-15-09</u> Reviewed By: <u>D. Hudson</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. (see next page)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" 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			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Other _____	
				<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Doina Bujor	Title Regulatory Manager	Telephone No. (Include Area Code) 347-968-4724
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 	3. Title Regulatory Manager	
4. Typed Name Doina Bujor	5. Date Jul 20, 2009	

Notification of Storage and Disposal Statement (PR Notice 2007-4) for DiTera WP, EPA Reg. No. 73049-37 (continuation from the previous page)

I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§152.46, 56.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.



Doina Bujor
Regulatory manager

July 20, 2009



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July 20, 2009

Sheryl Reilly
Biopesticides & Pollution Prevention Division
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
703-308-8269

RE: DiTera WP (EPA Reg. No. 73049-37) Notification

Dear Ms. Reilly:

Valent BioSciences Corporation is submitting a notification for DiTera WP (EPA Reg. No. 73049-37) in accordance with PR Notice 2007-4 and PR. The changes made to the label are to the Storage and Disposal statement and include the container disposal language for non-refillable rigid container.

Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the red-lined label
- One copy of the clean label.

Please contact me if you have any questions at 847-968-4724 or by e-mail at doina.bujor@valent.com.

Sincerely,

Doina Bujor
Regulatory Manager

NOTIFICATION

Date Reviewed: 9-15-09

Reviewed By: D. Hudson

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**DiTera WP
BIOLOGICAL NEMATOCIDE
WETTABLE POWDER**

ACTIVE INGREDIENT (1):

ABG-9008 Technical Powder Containing Dried Fermentation
Solids and Solubles of *Myrothecium verrucaria**

strain AARC-0255.....100% w/w

(1) "Non-viable"/"killed" microbial composition

*U.S. Patent No. 5,051,255

POTENCY:

62,500 RKU (Root-knot Units) per gram of product.

Potency units should not be used to adjust use rates.

There is no direct relationship between intended activity (potency) and the Percent Active Ingredient by Weight.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 73049-37 _____ Lot No.: _____
EPA Est. No. 33762-IA-1

Registrant:

Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

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Net Contents:

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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.
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 for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-VALENT.	

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION**

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment

Applicators and other handlers must wear:

- * Long-sleeved shirt and long pants.
- * Waterproof gloves.
- * Shoes plus socks.

Follow 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.

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 sensitizations.

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User Safety Recommendations
Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing 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 apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters. Do not apply where run-off is likely to occur.

DIRECTIONS FOR USE

It is a violation 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 regulations.

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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. 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:

- *Coveralls.
- *Waterproof gloves.
- *Shoes plus socks

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STORAGE AND DISPOSAL

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

Pesticide Storage: Keep containers tightly closed when not in use. Store in a cool, dry place. Avoid extreme temperatures.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Do not contaminate water when disposing of equipment washwaters.

Container Disposal: Nonrefillable container. Do not reuse or refill container. Offer for recycling, if available. Completely empty liner by tapping sides and bottom to loosen clinging particles. Dispose of liner in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. Perforate or crush drum and dispose of in the same manner.

Deleted: Do not reuse liner or drum.

GENERAL INFORMATION

DiTera WP controls the following plant nematodes parasitizing food, fiber and ornamental crops: *Meloidogyne* spp. (root-knot nematode), *Heterodera/Globodera* (cyst nematode), *Pratylenchus* spp. (lesion nematode), *Tylenchulus semipenetrans* (citrus nematode), *Trichodorus* spp. (stubby-root nematode), *Paratylenchus* spp. (pin nematode), *Rotylenchulus* spp. (reniform nematode), *Xiphinema* spp. (dagger nematode), *Belonolaimus* spp. (sting nematode), *Criconemoides* spp., *Criconemella* spp. and related genera (ring nematodes), *Tylenchorhynchus* spp. (stunt nematodes), *Hoplolaimus* spp. (lance nematodes), (*Rotylenchus* spp., *Helicotylenchus* spp. (spiral), *Radopholus* spp. (burrowing nematodes), and other plant parasitic nematodes.

GENERAL INSTRUCTIONS

DiTera WP may be applied to the soil as a pre-plant, at planting or post-plant treatment on annual and perennial crops (refer to commodities listed in Table 1). Pre-plant applications should preferably be close to the actual planting times. Unless otherwise specified, DiTera WP must be moved into the root zone for optimum results. This movement may be accomplished by irrigation or mechanical incorporation.

The optimal application time should be determined based on the cultural practices and the nematode population dynamics. For perennial crops, apply DiTera WP just prior to a root flush to protect young roots. Multiple applications may be required for crops with multiple root flushes (for example, grapes, bananas, etc.).

DiTera WP may be applied using ground sprays, or using approved irrigation systems (refer to Chemigation Use Directions), with quantities of water sufficient to provide coverage of the root area of the plants. The amount of water needed per acre will depend on the plant species, biology of the nematode species to be controlled, stage of crop,

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weather, soil moisture conditions, level of nematode infestation, etc. Do not apply by mist sprayer or aerial spray equipment.

MIXING RECOMMENDATIONS

To ensure complete mixing of DiTera WP, spray equipment having both mechanical and by-pass agitation is recommended. Fill tank with 1/2 to 3/4 the desired quantity of water. Start mechanical and hydraulic systems to provide maximum agitation. Add an agricultural wetting agent prior to adding DiTera WP. Add 1/3 to 1/2 of DiTera WP and allow to mix until thoroughly suspended. Add the remaining material slowly while bringing water to the desired volume. Continue agitation. If a concentration greater than 1 lb. DiTera WP per 2 gallons of water is desired, the material should be added in smaller increments with sufficient agitation following each addition. Do not mix more DiTera WP than can be used in a 24-hour period. Rinse and flush spray equipment thoroughly following each use. Use a strainer no finer than 50 mesh in conventional spray systems.

COMPATIBILITY

The DiTera WP application directions refer to the use of the product alone. Data concerning the compatibility of DiTera WP with other agricultural products are not available. Valent does not assume responsibility for unexpected, adverse results due to the tank mixing or simultaneous applications of DiTera WP with other agricultural products including fertilizers.

CHEMIGATION

MIXING AND APPLICATION INSTRUCTIONS

A thoroughly mixed DiTera WP suspension can be applied through irrigation systems described under Chemigation Use Directions, so as to treat the soil around the crop root-zone. It is recommended that the material be used immediately after mixing in order to avoid settling. DiTera WP must be applied as a dedicated irrigation between normal irrigations or at the end of a scheduled irrigation. To minimize excessive dilution or leaching of product from root zone, DiTera WP must be applied in the highest concentration over the shortest time span possible.

Do not apply this product through any type of irrigation system unless labeling on chemigation is followed.

Pre-mix product in a mix tank having both mechanical and by-pass agitation. Fill tank with 1/2 to 3/4 of the desired amount of water. Start mechanical and hydraulic systems to provide maximum agitation. Add an agricultural wetting agent prior to adding DiTera WP. Add 1/3 to 1/2 of DiTera WP and allow to mix until thoroughly suspended. Add the remaining material slowly while bringing water to the desired volume. Continue agitation. If a concentration greater than 1 lb. DiTera WP per 2 gallons of water is

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desired, the material should be added in smaller increments with sufficient agitation following each addition. To avoid excessive leaching of product, flush irrigation lines for the minimum time period at the end of the application.

CHEMIGATION USE DIRECTIONS

Apply this product only through the following types of irrigation systems: sprinkler, including center pivot, lateral move, end tow, side (wheel) roll, traveler, solid set, or hand move; flood (basin); furrow; border; or low pressure (including drip/trickle, minisprinklers, drip tape, strip tubing and jets).

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 local state extension personnel, equipment manufacturers or other experts.

Do not connect irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label 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.

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 backflow if water flow stops.

Systems utilizing sprinkler chemigation, a pressurized water and pesticide injection system, or drip/trickle chemigation, 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 backflow.
- * 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 controls to automatically shut off the pesticide injection pump when the water pump motor stops.

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- * 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.
- * For sprinkler chemigation, do not apply when wind speed favors drift beyond the area intended for treatment.

Due to the nature of the active ingredient and the distribution of nematodes in agricultural soils, in-row or band application is generally suitable for adequate nematode control. The rates provided are for broadcast applications. If banding or side-dressing, corresponding rates need to be calculated based on the actual area of soil to be treated (see Table 2 for rate conversions). Higher rates and/or multiple applications may be required in coarse (light) soils with less than 1% organic matter. Maximum benefits may not be realized in agricultural fields containing non-decomposed plant materials including infected roots from a previous crop or in fields with very high nematode infestations.

NOTICE TO USER

Seller makes no warranty, express or implied, of the merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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TABLE 1.		
CROP GROUPS/REPRESENTATIVE COMMODITIES	NEMATODE	BROADCAST*RATE (pounds/acre/appl)
<u>BERRIES</u> such as blackberry, raspberry, blueberry	Burrowing	25-100
<u>CITRUS FRUITS</u> such as sweet orange, lemon, grapefruit	Citrus	
<u>CUCURBIT VEGETABLES</u> such as cucumber, melon, squash	Cyst	
<u>FLOWERING, BEDDING PLANTS, ORNAMENTALS</u> , such as fern and hosta	Dagger	
<u>FRUITING VEGETABLES</u> such as eggplant, pepper, tomato	Lance	
<u>HERBS AND SPICES</u> such as basil, black pepper, chive, celery seed, dill seed	Lesion	
<u>LEAFY VEGETABLES AND COLE CROPS</u> such as celery, head & leaf lettuce, spinach, broccoli, cabbage	Needle	
<u>LEGUME VEGETABLES</u> such as bean, pea, soybean	Pin	
<u>POME FRUITS</u> such as apple, pear	Reniform	
<u>ROOT AND TUBER VEGETABLES</u> such as carrot, potato, radish, sugar beet, ginseng	Ring	
<u>STONE FRUITS</u> , such as peach, plum, prune	Spiral	
<u>TREE NUTS</u> such as almond, pecan, walnut	Root-knot	
<u>MISCELLANEOUS CROPS</u> : asparagus, avocado, banana, cacao bean, coconut, coffee, cotton, cranberry, date, fig, globe artichoke, grape, hops, kiwi fruit, mango, mushroom, okra, papaya, pawpaw, peanut, persimmon, pineapple, plantain, strawberry, sugarcane, tobacco, turf, water chestnut	Sting	
	Stubby-root	
	Stunt	

*Refer to accompanying table for band application rates.

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DiTera WP

TABLE 2. CONVERSION TABLE FOR BAND APPLICATIONS

Band Width Inches	Pounds of DiTera per 1000 Feet of Row at Equivalent Broadcast Rate of Indicated Pounds of Product Per Acre.		
	25 lbs/A	50 lbs/A	100 lbs/A
12	0.6	1.2	2.3
18	0.9	1.7	3.4
24	1.2	2.3	4.6
30	1.4	2.9	5.7
36	1.7	3.4	6.9
48	2.3	4.6	9.2
60	2.9	5.8	11.5