

73049-43

7/18/2014

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



JUL 18 2014

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Mr. Thomas Bade, Ph. D.
Regulatory Manager
Valent Biosciences Corps.
870 Technology Way
Libertyville, Illinois 60048

Re: DiTera ES Biological Nematicide
EPA Reg. No. 73049-43
Submission dated June 19, 2014

Dear Dr. Bade:

The Agency has reviewed your request to amend the subject product registration. Changes to the product's label include:

- Restricting chemigation applications to low pressure drip irrigation;
- Removal of furrow and border forms of irrigation; and
- Additional language that would require application of more than one bag of product per acre.

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

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

If these conditions are not complied with, then the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the label and A-79 are enclosed for your records. If you have questions, please contact Michael Glikes by phone at (703) 305-6231 or by email at glikes.michael@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly Nesci".

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division

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DiTera ES

BIOLOGICAL NEMATICIDE EMULSIFIABLE SUSPENSION

ACTIVE INGREDIENT ⁽¹⁾:

Myrothecium verrucaria*strain AARC-0255 fermentation solids and solubles.....	27.5% w/w
INERT INGREDIENTS.....	72.5% w/w
TOTAL.....	100.0% w/w

Contains 2.34 lbs. active ingredient per gallon

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

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

POTENCY: 18,200 RKU (Root-knot Units) per gram of product.

Potency units should not be used to adjust use rates.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA Reg. No. 73049-43
EPA Est. No. 33762-IA-1

Lot No.:

Registrant:
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

ACCEPTED

JUL 18 2014

Net Contents

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 73049-43

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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.	

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

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

Personal Protective Equipment

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

ACCEPTED

Applicators and other handlers must wear:

- * Long-sleeved shirt and long pants.
- * Chemical-resistant gloves, such as barrier laminate, or nitrile rubber, or neoprene rubber or viton.
- * 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/PPE 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

For terrestrial uses:

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.

This pesticide is toxic to fish and aquatic invertebrates.

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 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
- *Chemical-resistant gloves, such as barrier laminate, or nitrile rubber, or neoprene rubber or viton.
- *Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until soil surface has dried

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and 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 must be disposed of on site or at an approved waste disposal facility. Do not contaminate water when disposing of equipment washwater.

Container Handling: Non refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL INFORMATION

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

INSTRUCTIONS

Apply DiTera ES 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) mixed with water and the mixed suspension applied as a soil applied spray or through drip irrigation systems. Best results will be obtained from Pre-plant applications close to the actual planting times. Unless otherwise specified, DiTera ES must be incorporated into the soil for optimum results. Incorporation may be accomplished by irrigation or mechanical equipment.

The optimal application time must be determined based on the cultural practices and the nematode population dynamics. For perennial crops, apply DiTera ES 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 ES must be applied using ground sprays and incorporated into the soil, or using approved irrigation systems (Refer to Chemigation Use Directions), with quantities of water sufficient to provide incorporation into 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, weather, soil moisture conditions, level of nematode infestation, etc. Use a minimum dilution of 1 part DiTera ES and 2 parts water.

Do not apply directly to foliage.

Do not apply by mist sprayer or aerial spray equipment.

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.

MIXING RECOMMENDATIONS

Important - Do not add DiTera ES to the mix tank before filling with 1/2 to 3/4 the desired quantity of water. Start the mechanical or hydraulic agitation to provide moderate circulation before adding DiTera ES. Add the desired amount of DiTera ES and the remaining volume of water to the mix tank and continue circulation. Include rinse water from the container. Do not mix more DiTera ES 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.

DO NOT add an agricultural surfactant to the DiTera ES tank mix.

APPLICATION INSTRUCTIONS

Apply DiTera ES as a soil applied spray suspended in water, applied using ground equipment with subsequent soil incorporation into the root zone, or using listed irrigation systems. DiTera ES may be injected undiluted (neat) or diluted with water into irrigation systems. The undiluted

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product and the thoroughly mixed 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 ES 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 the root zone, DiTera ES 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.

Undiluted Applications

For undiluted injection for chemigation make sure tank and injection system are free of all residual water. Flush and clean nurse tanks, lines, screen canister, and pump with diesel fuel or a non-emulsifiable oil until they are water-free before and after application. Recirculate product in container. Charge the irrigation system. Inject DiTera ES into the irrigation system using a high-volume positive displacement pump. To avoid excessive leaching of product, flush irrigation lines for the minimum time period at the end of the application.

Diluted Applications

Pre-mix product in a mix tank. Fill tank $\frac{1}{2}$ - $\frac{3}{4}$ with the desired amount of water and start hydraulic or mechanical agitation. Add DiTera ES to water at ratio of 1 part product and 1.5 - 2.0 parts water and mix thoroughly. Charge irrigation system. Inject mixture into system using a high-volume positive displacement pump while maintaining agitation in the mix tank. To avoid excessive leaching of product, flush irrigation lines for the minimum time period at the end of the application.

COMPATIBILITY

The DiTera ES application directions refer to the use of the product alone. Data concerning the compatibility of DiTera ES 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 ES with other agricultural products including fertilizers.

CHEMIGATION USE DIRECTIONS

Apply this product only through low pressure drip irrigation (including drip/trickle, drip tape, strip tubing).

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-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

CHEMIGATION SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS

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.

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.

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 contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

DRIP IRRIGATION

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.
- * 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.

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TABLE 1: DITERA ES <u>CROP GROUPS</u>	NEMATODE	BROADCAST APPLICATION RATE
<p><u>BERRIES</u> such as grape, Kiwifruit, blackberry*, raspberry*, blueberry*, strawberry*, cranberry*</p> <p><u>CITRUS FRUITS</u> such as sweet orange, lemon, grapefruit</p> <p><u>CUCURBIT VEGETABLES</u> such as cucumber*, melon*, squash*</p> <p><u>FLOWERING, BEDDING PLANTS, ORNAMENTALS</u> such as fern and hosta</p> <p><u>FRUITING VEGETABLES</u> such as eggplant*, pepper*, tomato*</p> <p><u>HERBS AND SPICES</u> such as basil*, black pepper*, chive*, celery*, dill*</p> <p><u>LEAFY VEGETABLES AND COLE CROPS</u> such as celery, head & leaf lettuce, spinach, broccoli, cabbage</p> <p><u>LEGUME VEGETABLES</u> such as bean*, pea*, soybean*, peanut*</p> <p><u>POME FRUITS</u> such as apple, pear</p> <p><u>ROOT AND TUBER VEGETABLES</u> such as carrot*, potato*, radish*, ginseng* sugar beet*</p> <p><u>STONE FRUITS</u> such as peach, plum</p> <p><u>TREE NUTS</u> such as almond, pecan, walnut</p> <p><u>MISCELLANEOUS CROPS:</u> pineapple, kiwi fruit, asparagus*, avocado*, banana*, cacao bean*, coconut*, coffee*, cotton*, date*, fig*, globe artichoke*, hops*, mango*, mushroom*, okra*, papaya*, pawpaw*, persimmon*, plantain*, sugarcane*, tobacco*, turf*, water chestnut*</p>	<p>Burrowing Citrus Cyst Dagger Lance Lesion Needle Pin Reniform Ring Spiral Root-knot Sting Stubby-root Stunt and other plant parasitic nematodes</p>	<p>0.31 lbs / 1000 sq ft (5 oz / 1000 sq ft 142 gm/1000 sq ft to 2.4 lbs / 1000 sq ft (38.4 oz / 1000 sq ft 1.09 kgm / 100 sq ft)</p> <p>(See Table 2 for rates for 1000 linear feet of row of various bandwidths)</p> <p>Broadcast rates can be made at 13 lbs per acre to 100 lbs per acre (which would require 1.3 to 10 bags of product per acre for these rates.)</p>
<p>* Crops Not Registered for Use in California</p>		
<p>NOTE: For application rates based on linear feet of banded application, one package will treat from 32,000 feet of 12 inch wide row at the low use rate, to 1000 feet of 48 inch wide row at the high use rate. See Table 2 for various bandwidth rates per 1000 linear feet.</p> <p>At the maximum label 'Broadcast Rate' one package of this product will treat 1/10 acre. At the minimum label 'Broadcast Rate' one package will treat 3/4 acre.</p>		

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TABLE 2: DITERA ES - APPLICATION RATE

Row Band Width (Inches)	Pounds of DiTera per 1,000 linear Feet of Row (Row band-width in inches -- to the left)			
	0.31 lbs/1000 sq ft	0.6 lbs/1000 sq ft	1.2 lbs/1000 sq ft	2.4 lbs/1000 sq ft
12	0.31	0.60	1.2	2.4
18	0.47	0.91	1.8	3.6
24	0.63	1.20	2.4	4.8
30	0.79	1.51	3.0	6.0
36	0.94	1.82	3.6	7.2
48	1.26	2.40	4.8	9.6
60	1.58	3.00	6.0	---

NOTICE TO USER

To the fullest extent permitted by law, the 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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