

71512-5

5-5-2005

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAY - 5 2005

Myron Bliss, Ph.D.
ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, Ohio 44077

Dear Mr. Bliss:

Subject: Label amendment
Nemathorin 500EC
EPA Registration Number 71512-5
Your submission dated February 7, 2005

The labeling referred to above, submitted in connection with reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below:

On the front panel, please indicate use site tomatoes, and provide EPA Establishment Number.

Five copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

Sincerely yours,

Rita Kumar

Rita Kumar
Senior Regulatory Specialist
Insecticide-Rodenticide Branch
Registration Division (7505C)
E-mail: kumar.rita@epa.gov

Enclosure

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Group	1B	Nematicide
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Nemathorin® 500EC

Broad Spectrum Contact Nematicide

Active Ingredient:

Fosthiazate [(RS)-O-ethyl S-(1-methylpropyl) (2-oxo-3-thiazolidinyl)
phosphonothioate] 47.2%

Other Ingredients: 52.8%

Total: 100.0%

Product contains 4.17 pounds active ingredient per gallon (500 g a.i./liter).

Contains petroleum distillate.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See side panel for first aid and additional precautionary statements.

Read entire label carefully and use only as directed.

EPA Reg. No. 71512-5

EPA Est.

ACCEPTED
WITH COMMENTS
IN EPA LETTER DATED
MAY - 5 2005

Net Contents: 5 Gallons

71512-5

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FIRST AID Nemathorin 500EC contains fosthiazate, an organophosphate nematicide.	
If swallowed	• Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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 soap and water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	• 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. • Call a poison control center or doctor for further treatment advice.
NOTE TO PHYSICIAN Contains an organophosphate (fosthiazate) that inhibits cholinesterase. Contains petroleum distillate – vomiting may cause aspiration pneumonia. Symptoms of cholinesterase inhibition may include salivation, sweating, headache, nausea, muscle twitching, tremors, poor coordination, blurred vision, tears, abdominal cramps, diarrhea, chest discomfort, and pinpoint pupils. Treat patient's symptoms immediately. Immediately decontaminate skin and hair with soap and water. Persons attending to the victim should avoid direct contact with heavily contaminated clothing and vomitus, and wear rubber gloves while washing exposed or contaminated areas. Immediately administer oxygen, assist in respiration, suction secretions, and maintain airway. Consider taking venous blood for determination of blood cholinesterase activity (use heparin tube). Administer atropine sulfate, intravenously, dependant on severity of poisoning. If indicated, specific oximes such as Pralidoxime (2-PAM) may also be therapeutic when used in conjunction with atropine sulfate. Avoid the use of opiates and phenothiazine. Carefully monitor patient because continued absorption of the poison may occur resulting in fatal relapse after initial improvement.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal)
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)
Call
1-888-484-7546

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if inhaled or absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse. Do not take internally.

Personal Protective Equipment (PPE)

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

Applicators and other handlers must wear:

- Long-sleeved coveralls over short-sleeved shirt and short pants
- Chemical-resistant gloves - Category G (e.g., barrier laminate, and viton $\geq$ 14mils).
- Chemical-resistant footwear plus socks
- Protective eyewear (goggles or face shield)
- Chemical-resistant apron when cleaning equipment, mixing or loading

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. Do not allow contact of contaminated clothing with unprotected skin.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. 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.

Engineering Control Statements

When handlers use closed systems, in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

Closed Systems are required for mixing and loading Nemathorin 500EC.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down. Do not allow contact between contaminated equipment parts and unprotected skin.

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if product 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

This product is toxic to birds, mammals, freshwater and estuarine invertebrates. 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 waters when disposing of equipment washwaters or rinsate.

Physical or Chemical Hazards

Flammable. Keep away from heat and open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of ISK BIOSCIENCES CORPORATION (ISK), or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold ISK and Seller harmless for any claims relating to such factors.

ISK warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or ISK, and Buyer and User assume the risk of any such use. **ISK MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

In no event shall ISK or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF ISK AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF ISK OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

ISK and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of ISK.

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 7 days. Exception: If the product is applied via drip irrigation, under plastic, 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 the 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 coveralls over short-sleeved shirt and short long pants
- Chemical-resistant gloves - Category G (e.g., barrier laminate, and viton $\geq$ 14mils).
- Chemical-resistant footwear plus socks
- Protective eyewear (goggles or face shield)

FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN CROP INJURY, POOR PEST CONTROL, AND/OR ILLEGAL RESIDUES.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

Pesticide Storage

Store unused product in original container in a cool, dry secure area, preferably in a locked storage area. Store in such a manner as to prevent cross contamination with other pesticides, fertilizers, food or feed. Do not store near a heat source or open flame. Do not store below 32°F. Do not store adjacent to, or near, foodstuffs, drugs, feed or any other material intended for consumption by humans or animals.

Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Do not reuse empty container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

GENERAL INFORMATION

Nemathorin 500EC is an excellent nematicide when used in accordance with label directions for control of a broad spectrum of nematode species that attack tomatoes.

Nemathorin 500EC must be applied to tomatoes through drip (trickle) irrigation systems placed under a plastic mulch.

Do not combine Nemathorin 500EC in the mix tank with pesticides, surfactants or fertilizers, unless your prior use has shown the combination physically compatible, effective and non-injurious under your conditions of use.

Do not apply with aircraft. Apply only to areas specified on the label.

INTEGRATED PEST MANAGEMENT

Nemathorin 500EC is recommended for use as part of an Integrated Pest Management (IPM) program, which may include the use of pest resistant crop varieties, cultural practices, biological control agents, pest scouting and pest forecasting systems aimed at preventing economic pest damage. Practices known to reduce pest development

should be followed. Consult your state cooperative extension service or local agricultural authorities for additional IPM strategies established in your area. Nemathorin 500EC may be used in State Agricultural Extension advisory (forecasting) programs which recommend application timing based on environmental factors which favor pest development.

RESISTANCE MANAGEMENT

Some plant pests are known to develop resistance to products used repeatedly for pest control. Nemathorin 500EC is effective for strategic use in programs that attempt to minimize pest resistance. Nemathorin 500EC is a **Group 1B** nematicide and may be tank mixed or rotated with nematicides from different groups. A nematode management program that includes alternation and/or tank mixes between Nemathorin 500EC and other labeled nematicides that have a different mode of action and/or control nematodes not controlled by Nemathorin 500EC is essential to prevent disease resistant nematode populations from developing. Consult with your Federal or State Cooperative Extension Service representatives for guidance on the proper use of Nemathorin 500EC in programs that seek to minimize the occurrence of pest resistance. No known resistance has developed to Nemathorin 500EC.

MIXING INSTRUCTIONS

Nemathorin 500EC mixes readily with water and can be injected directly into the drip irrigation lines as explained below. If dilution prior to injection is necessary, no special premixing should be required if used in an injector mix tank equipped with agitation.

If Nemathorin 500EC is diluted with water in a mix tank prior to injection, do not store the solution in mix tank overnight. Clean application equipment thoroughly after use by flushing with water.

APPLICATION AND CALIBRATION TECHNIQUES FOR DRIP IRRIGATION SYSTEMS

Nemathorin 500EC must be applied to tomatoes using drip (trickle) irrigation systems under a plastic mulch. Apply Nemathorin 500EC only through drip (trickle) irrigation systems. 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 State Extension Service specialists, equipment manufacturers or other experts.

Do not apply Nemathorin 500EC through irrigation systems connected to a public water system. '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 per year.

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.

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 back flow.

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 chemical supply tank when the irrigation system is either automatically or manually turned off.

The system must contain functional inter-locking 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, of either diaphragm or piston type, effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

For instructions on setting the emitter spacing and line pressure to give the best bed coverage and reduce the loss of chemigated products through leaching, contact your local extension service or drip tape manufacturer. Thoroughly mix recommended amount of Nemathorin 500EC for the acreage to be covered into the same amount of water used during calibration in a chemical supply tank and inject into system continuously for one run. Spray mixture in the chemical supply tank must be agitated at all times, otherwise settling and uneven application may occur. Shut off injection equipment after one run, but continue to operate irrigation system until this product has been cleared from the system.

Nemathorin 500EC should be injected at the beginning of the irrigation cycle or as a separate application. Stop injection equipment after treatment is completed and continue to operate irrigation system until this product has been cleared from the system. A total amount of 1/2 to 1 inch of irrigation water per acre should be applied to

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obtain adequate efficacy, but not cause runoff or excessive leaching. The system should provide uniform waterflow and should have no leaks.

Always inject Nemathorin 500EC into irrigation water after it discharges from the irrigation pump and after it passes through the check valve. Never inject pesticides into the intake line on the suction side of the pump.

Posting: This posting is in addition to any sign posted to comply with the Worker Protection Standard. Posting of areas to be chemigated is required when 1) any part of a treated area is within 300 ft. of sensitive areas such as residential areas, labor camps, businesses, day care centers, hospitals, in-patient clinics, nursing homes or in public areas such as schools, parks, playgrounds, or other public facilities not including public roads, or 2) when the chemigated area is open to the public such as golf courses or retail greenhouses.

Posting must conform to the following requirements. Treated areas shall be posted with signs at all usual points of entry and along likely routes of approach from the listed sensitive area. When there are no usual points of entry, signs must be posted in the corners of the treated areas and in any other locations affording maximum visibility to sensitive areas. The printed side of the sign should face away from the treated area towards the sensitive area. The signs shall be printed in English. Signs must be posted prior to application and must remain posted until foliage has dried and soil surface water has disappeared. Signs may remain in place indefinitely as long as they are composed of materials to prevent deterioration and maintain legibility for the duration of the posting period.

All words shall consist of letters at least 2 1/2 inches tall, and all letters and the symbol shall be a color which sharply contrasts with their immediate background. At the top of the sign shall be the words KEEP OUT, followed by an octagonal stop sign symbol at least 8 inches in diameter containing the word STOP. Below the symbol shall be the words PESTICIDES IN IRRIGATION WATER.

APPLICATION RATES & RESTRICTIONS

Crop	Nematodes Controlled	Rate/Planted Acre*
Tomato	Root-knot nematode (<i>Meloidogyne incognita</i>)	1.91 – 2.88 pts./A (1.0 – 1.5 lbs. a.i./A)
	Root lesion nematode (<i>Pratylenchus penetrans</i>)	Apply through drip irrigation systems to beds with a 28 to 40 inch bed base width with
	Spiral nematode (<i>Helicotylenchus</i> spp.)	54 to 84 inch row center spacing between rows.
	Stunt nematode (<i>Tylenchorhynchus</i> spp.)	
	Stubby nematode (<i>Trichodorus</i> spp.)	
	Sting nematode (<i>Belonalamus</i> spp.)	

* Use the higher rate in fine textured soils with high root-knot nematode populations or when planting varieties that are not resistant to root-knot nematode. The lower rate may be used on coarse textured

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soils, with low nematode populations or when planting root-knot resistant tomato varieties in soils.

Rate Conversion Chart

		Spacing Between Rows of Tomatoes for 1.0 lbs. a.i. or 1.91 pts./Planted Acre Application Rate of Nemathorin 500EC					
		54-inch ctr	60-inch ctr	66-inch ctr	72-inch ctr	78-inch ctr	84-inch ctr
Bed top width	Bed base width	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft
24 inch bed	28 inch	3.16	3.51	3.85	4.21	4.56	4.91
28 inch bed	32 inch	DNU	3.51	3.85	4.21	4.56	4.91
30 inch bed	34 inch	DNU	DNU	3.85	4.21	4.56	4.91
32 inch bed	36 inch	DNU	DNU	DNU	4.21	4.56	4.91
36 inch bed	40 inch	DNU	DNU	DNU	DNU	4.56	4.91

		Spacing Between Rows of Tomatoes for 1.5 lbs. a.i. or 2.88 pts./Planted Acre Application Rate of Nemathorin 500EC					
		54-inch ctr	60-inch ctr	66-inch ctr	72-inch ctr	78-inch ctr	84-inch ctr
Bed top width	Bed base width	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft	Fl. Oz/ 1000 lin ft
24 inch bed	28 inch	4.76	5.29	5.81	6.35	6.88	7.40
28 inch bed	32 inch	DNU	5.29	5.81	6.35	6.88	7.40
30 inch bed	34 inch	DNU	DNU	5.81	6.35	6.88	7.40
32 inch bed	36 inch	DNU	DNU	DNU	6.35	6.88	7.40
36 inch bed	40 inch	DNU	DNU	DNU	DNU	6.88	7.40

DNU = Do not use this combination of row spacing and bed width for Nemathorin 500EC application at 1.0 and 1.5 pounds a.i./planted acre because the dilution will result in an application rate that may not be effective in controlling nematodes.

Drip Irrigation Method: Nemathorin 500EC must be applied through a drip (trickle) irrigation system placed under polyethylene plastic mulch, before seeding or transplanting. The system should provide uniform waterflow and should have no leaks. For instructions on setting the emitter spacing and line pressure to give the best bed coverage and reduce the loss of chemigated products through leaching, contact your

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local extension service or drip tape manufacturer. To minimize the potential for phytotoxicity, do not transplant into beds within 3 days in porous soils or 7 days in heavier soils after application of Nemathorin 500EC.

Nemathorin 500EC should be injected at the beginning of the irrigation cycle or as a separate application. Use sufficient water to allow thorough incorporation throughout the bed to achieve efficacy, but not cause runoff or excessive leaching. In most soils, 1/2 to 1 inch of irrigation water/A is required for incorporation of the product when applied through a drip irrigation system.

USE RESTRICTIONS

Do not exceed 1.5 lbs. a.i. or 2.88 pts. per planted acre in any one calendar year.

Do not treat more than 25 acres per day per applicator.

Do not apply immediately before a torrential rainfall is forecasted.

Hand transplanting of tomatoes through plastic mulch is allowed if chemical resistant gloves and boots are worn.

ROTATIONAL CROP RESTRICTIONS

90-day Plantback Restriction: Do not plant root and tuber vegetables, fruiting vegetables, or cucurbits within 90 days of application. Rotation to other crops not listed is prohibited for 1 year after application of Nemathorin 500EC.

INSECTS SUPPRESSED

Application rates in this range will suppress sweet potato whitefly, tomato pinworm and beet armyworm for 21-30 days after seeding or transplanting.

Nemathorin® is a trademark of Ishihara Sangyo Kaisha, Ltd.

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NEM 500EC - 122904