

264-723

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Sherry Movassaghi, Ph.D.
Bayer CropScience
P.O. Box 12014
Research Triangle Park, NC 27709

JAN 15 2008

Dear Dr. Movassaghi:

Subject: Amendment - revise per North Carolina Pesticide Section request
D-Syston 15%
EPA Reg. No. 264-723
Your submission dated October 22, 2007

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

1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. In the Restricted Use block, expand the reason for restricted use, i.e., "Due to acute oral, dermal, inhalation, eye, and skin toxicity."
 - b. In the Hazards to Humans and Domestic Animals, after "Do not breathe dust." add "Wear the personal protective equipment (PPE) specified below."
 - c. Revise the heading "**Personal Protective Equipment**" to read "**Personal Protective Equipment (PPE)**".
 - d. Replace the heading "Handlers and applicators must wear:" and the associated six bullets with the following:

Handlers using engineering controls must wear:

- long-sleeved shirt and long pants
- shoes plus socks

In addition to the above, loaders must wear:

- Chemical-resistant gloves

Handlers engaged in those activities for which use of engineering control is not possible must wear:

- Coveralls over long-sleeved shirt and long pants
 - Chemical-resistant gloves
 - Chemical-resistant footwear plus socks
 - Chemical-resistant headgear (if overhead exposure)
 - Protective eyewear (goggles, face shield, or safety glasses)
 - A dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH-approved respirator with any N, R, P, or HE filter
- e. In the User Safety Recommendations, revise the second bullet to read "Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- f. In the new second sentence under the heading Engineering controls, delete "to Christmas trees", since this limitation applies to both Christmas tree and coffee tree applications.
- g. Do not delete "level" from the sentences in the Environmental Hazards (third paragraph, you identified it as second) and Directions for Use (first paragraph). The exemption for the North Carolina growers in mountainous areas will appear as a "Note" in the Christmas Trees "Remarks" section, see item "k" below.
- h. In the **Application Restrictions**, delete "Do not enter or allow people or pets to enter until after product is soil incorporated or watered in." The REI appears in the Agricultural Use Requirements block.
- i. In the paragraph beginning "As a preplant treatment for trees...", revise the third sentence to read "Work the granules uniformly into top soil or water thoroughly."
- j. In the Recommended Applications table, delete **TREES** from the DOSAGE column and from the REMARKS column.
- k. In the REMARKS column for Christmas Trees, at the end of the first paragraph add "Do not make more than one application per year.". Also, after the sentence ending "...48 hours of application", add "If rainfall is to be used to water-in the granules, then application may be made when rainfall is anticipated between 36 and 48 hours after application.". Beneath "Not for use in bare-ground plantations." add "Note: Because Fir trees (especially Fraser Firs) are grown in mountainous terrain, the 25 foot buffer strip is not required to be level."

Please submit 3 copies of amended labeling bearing the above revisions prior to release for shipment.

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

Sincerely,

George LaRocca.
Product Manager 13
Insecticide Branch
Registration Division (7505P)

RESTRICTED USE PESTICIDE

Due to acute toxicity

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Di-Syston® 15% Granular Systemic Insecticide

For effective systemic protection of coffee trees in Puerto Rico, and fir grown for Christmas trees.

ACTIVE INGREDIENT:

Disulfoton, O,O-Diethyl S-[2-(ethylthio)ethyl]phosphorodithioate 15%

INERT INGREDIENTS: 85%

100%

EPA Reg. No. 264-723

EPA Est. No.



**STOP – Read the label before use.
KEEP OUT OF REACH OF CHILDREN
DANGER POISON
PELIGRO**



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.)

For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577
For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

Contains an organophosphate that inhibits cholinesterase.

If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
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 mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7377. Have a product container or label with you when calling a poison control center or doctor.

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JAN 15 2008

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
264-723**

Note To Physician: ANTIDOTE - Administer atropine sulfate in large therapeutic doses. Repeat as necessary to the point of tolerance. 2-PAM is also antidotal and may be administered, but only in conjunction with atropine.

Compound inhibits cholinesterase resulting in stimulation of the central nervous system, the parasympathetic nervous system, and the somatic motor nerves. Do not give morphine. Watch for pulmonary edema, which may develop in serious cases of poisoning even after 12 hours. At first sign of pulmonary edema, the patient should be placed in an oxygen tent and treated symptomatically. Probable mucosal damage may contraindicate the use of gastric lavage.

SYMPTOMS OF POISONING: A sense of "tightness" in the chest. Sweating. Contracted pupils. Stomach pains. Vomiting and diarrhea.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Fatal if swallowed, inhaled, or absorbed through skin. Corrosive. Causes irreversible eye damage. Causes skin burns. Do not get in eyes, on skin, or on clothing. Do not breathe dust. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment: Some materials that are chemical-resistant to this product are (natural rubber, nitril rubber, butyl rubber, and neoprene rubber). If you want more options, follow the instructions for category F on an EPA chemical-resistance category selection chart.

Handlers and applicators must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves
- Protective eyewear (goggles, face shield or safety glasses)
- Shoes plus socks
- A NIOSH-approved dust mist filtering respirator with any N, R, P or HE filter.

User Safety Requirements

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.

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

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.

Engineering controls

This product is packaged to be used in a closed application system (such as select-A-Feed). When applying this product to Christmas trees, a closed application system must be used. All loaders/applicators must use and maintain this system in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition, loaders/applicators must:

- wear long-sleeved shirt and long pants, chemical-resistant gloves, footwear plus socks;
- be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown the following PPE:
- Coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear (if overhead exposure), and a NIOSH-approved dust-mist filtering respirator with any N, R, P, or HE filter.

Applicators using motorized ground-equipment (except for motorcycles) must use and maintain an enclosed cab for dermal protection in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR 170.240(d)(4)]. In addition, applicators using an enclosed cab must:

- Wear long-sleeved shirt and long pants, shoes, and socks; and Either wear a NIOSH-approved dust-mist filtering respirator with any N, R, P, or HE filter or use an enclosed cab that is declared in writing by the manufacturer or by a government agency to provide at least as much respiratory protection as the type of respirator specified in the PPE section of this labeling.
- Be provided and have immediately available for use in case of an emergency when they must exit the cab, the following PPE:
- Coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear (if overhead exposure), and a NIOSH-approved dust-mist respirator with any N, R, P, or HE filter.
- Applicators re-entering the enclosed cab after spending time in the treated area must:
- Take off any PPE that was worn in the treated area before reentering the cab, and Store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to birds, mammals, fish and aquatic invertebrates. Collect any granules spilled during loading or application. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in neighboring areas.

This product has a high potential for runoff for several months. Poorly draining soils and soils with shallow water tables are more prone to product runoff that contains this product.

A well maintained 25 foot vegetative buffer strip between areas to which this product is applied to permanent surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Refer to the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for additional guidance. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

Disulfoton is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

RESTRICTIONS

Not for residential use. Use only according to label directions. Application at rates above those shown may result in illegal crop residues. Do not use in greenhouses. Do not apply in any manner not specified on the label. Do not apply by air.

DIRECTIONS FOR USE Restricted Use Pesticide

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

A well maintained 25 foot vegetative buffer strip between areas to which this product is applied and permanent surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Refer the the March 2000 USDA Natural Resources Conservation Service document: *Conservation Buffers to Reduce Pesticide Losses* for additional guidance. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

Application Restrictions

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.

Do not enter or allow people or pets to enter until after product is soil incorporated or watered in.

Product must be either soil incorporated, watered in or applied to areas with permanent ground cover.

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), notification to workers, 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 workers to enter into treated areas during the restricted entry interval (REI) of 48 hours.

The REI is 72 hours in outdoor areas where average rainfall is less than 25 inches a year.

Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated areas without restriction if there will be no contact with anything that has been treated.

The following 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 worn over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Chemical-resistant footwear plus socks, and
- Chemical-resistant headgear (if overhead exposure)
- Protective eyewear

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle in a manner as to prevent spillage. If container is leaking invert to prevent leakage. If the container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer CropScience Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer CropScience Emergency Response Telephone No. is 1-800-334-7577.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, 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: Completely empty container then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

DI-SYSTON 15% Granular systemic insecticide enters the plant through the root system. The insecticide when placed near the roots, is picked up and moves in the sap stream to all parts of the plant where it kills insects as they feed on the plant.

As a preplant treatment for trees apply granules evenly to seed bed and mix into soil; seeds or transplants are then placed in the normal manner. Established plants may be treated by distributing granules uniformly under foliage canopy. Work the granules uniformly into top soil and water thoroughly. The active ingredient will move into the root zone and be taken up by the root system.

Do not contaminate feed or food.

RESTRICTIONS

Use only according to label directions. Application at rates above those shown may result in illegal crop residues. Do not use in greenhouses.

RECOMMENDED APPLICATIONS			
CROP	INSECT	DOSAGE DI-SYSTON 15% G	REMARKS
Christmas trees (For use on Firs only)	Aphids Mites, including Spruce spider mite Nantucket Pine Tip Moth Scales	TREES 20-30 lb/A	TREES For use on Firs only. Product must be either soil incorporated, watered in, or applied to areas with permanent groundcover. Broadcast: Spread granules in the root zone of the trees at the dripline and work into soil and water thoroughly within 48 hours of application. Not for use in bare-ground plantations.
Coffee Trees (For use in Puerto Rico only)	Leaf miner	2 to 4 grams/ft of tree height	Distribute granules uniformly under the tree canopy. Do not apply more than twice per year. Make no more than one pre-harvest and one post-harvest application. Do not make the pre-harvest application within 90 days of harvest.

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IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

NET WEIGHT:

Produced for



**Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)**

Di-Syston 15% Granular Systemic Insecticide (PENDING) 10/22/07