

11678-56

05/25/2000

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ai # 119200



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7501W) 401 M St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
11678-56

Date of Issuance:
MAY 25 2000

NOTICE OF PESTICIDE:
____ Registration
____ Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
TRICHODEX®

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Dr. Robert Everich
Makhteshim-Agan of North America Inc.
551 Fifth Ave., Suite 1100
New York, NY 10176

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you do the following:

1. Change the label by revising the EPA Registration Number to read, "EPA Reg. No. 11678-56".
2. Submit five copies of the revised final printed label for the record.

3a. Provide analyses of 5 batches at production and include data relevant to detection, identification, enumeration and rejection limits of potential human pathogens (bacterial and fungal) using the selective media proposed in the analysis of production batches. All batches containing human pathogens above regulatory levels must be destroyed. The production data will be a condition of registration and must be submitted within one year of the date of registration.

3b. Submit data demonstrating the efficacy of the PCR-RAPD protocol for strain identity within 90 days of receipt of this RED document and the conditional registration notice.

4. Provide additional information as a condition of registration to verify the integrity of the data submitted in support of Freshwater aquatic invertebrate toxicity/pathogenicity. The relationship between the 120 hour stability and 10 day range finding study must be explained to support the integrity of the data. The fact that the recovery percentages are identical at times 0 and 24 hours for 3 treatment

Signature of Approving Official:

JRH see next page

Date:

5/25/2000

levels is inconsistent with expected biological variability. The entire enumeration data for the 10 day range finding study must also be reported. Provided the requested information supports the integrity of the data, the submitted study may satisfy the stated objective of determining the acute toxicity of the microbial pesticide to *Daphnia magna*. Should this information not be sufficient to verify the integrity of the data, the registrant has agreed to submit a new 21 day *Daphnia* study.

5. Data to demonstrate no pathogenicity to plants must be submitted to the Agency. The label must not include sugarcane, pechay (bok choy), rice, tomatoes, mushrooms, kiwi, tobacco, wheat, barley, oats, soybean, cotton, corn, lemon, apples and chickpea until the reports regarding phytotoxicity and/or pathogenicity to these plants by *T. harzianum* are satisfactorily addressed.

6. The Agency requires a non-target insect pathogenicity study on the lady bird beetle to satisfy this data requirement. We suggest submitting a protocol for Agency review prior to initiating the study.

7. The honey bee studies are considered supplemental and upgradable to core of scientifically sound if you submit, as a condition of registration:

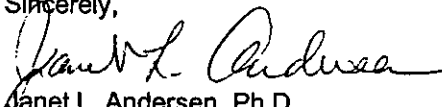
- (i) all recorded data, including individual brood size and hive weights by hive number;
- (ii) Trichodex weight in application trays and individual spore counts;
- (iii) the hive numbers and day of swarming for those hives that swarmed.

Also, please explain why five of the 15 hives were not used in the experiment.

Further data to demonstrate effects on freshwater fish will be required should you wish to register aquatic sites, or to apply the pesticide using aerial equipment. If EPA determines, at any time, that additional data are required to maintain in effect an existing conditional registration, the Agency will require submission of such data under Section 3(c)2(B) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,


Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division

cc: Encl.

ACCEPTED
with COMMENTS
In EPA Letter Dated
MAY 25 2000

TRICHODEX® WP

Biological Fungicide Wettable Powder

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

11678-56

ACTIVE INGREDIENT:

Viable propagules consisting of spores and mycelial fragments of
Trichoderma harzianum isolate T-39

Inert Ingredients

20%

80%

Total

100%

Contains:

0.5 x 10⁹ colony forming units (CFU)/g *Trichoderma harzianum* isolate T-39

Net Contents: 2.2 lbs. (1.0 kg.)

EPA Est. No.: 11678-IS-01

EPA Reg. No.: 11678-56

MAKHTESHIM CHEMICAL WORKS, LTD., C/O MAKHTESHIM-AGAN OF NORTH AMERICA INC.
551 FIFTH AVENUE, SUITE 1100, NEW YORK, NY 10176

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.)

FIRST AID:

IF SWALLOWED:

- 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 INHALED:

- 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.

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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.



PRECAUTIONARY STATEMENTS:**Hazards to Humans and Domestic Animals**

Do not breathe spray mist. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Harmful if absorbed through skin. Harmful if swallowed.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeve shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Protective eyewear or goggles
- Dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, R-95, P-95 or HE filter.

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.

User Safety Recommendations**Users are advised to:**

- 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 discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Do not apply directly to water or to areas when surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters.

Not tested for compatibility with insects released for biocontrol of plant pests. Do not apply this product while bees are actively visiting the treatment area.



STORAGE AND DISPOSAL

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

Pesticide Storage: Store in the original container in a safe, dry, well ventilated cool area. Keep container tightly closed when not in use. Keep refrigerated for longest shelf-life.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

Container Disposal: Do not reuse empty containers. Triple rinse or equivalent. Puncture and dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities. If burned, stay clear of smoke.

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 it 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 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 12 hours.

During the restricted entry interval (REI), the following PPE are required for early entry to treated areas or for handling anything that involves contact with treated plants, soil, or water:

- Long-sleeve shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Protective eyewear or goggles
- Dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, R-95, P-95 or HE filter.



GENERAL DIRECTIONS FOR USE:

Trichodex is a wettable powder fungicide to be used as a foliar spray for control of the plant disease Gray Mold (*Botrytis cinerea*). Trichodex may be applied only to crops listed on this label. Those listed include outdoor field crops, row crops, and, tree and vine crops, or, indoor crops grown in Greenhouses or shade houses.

NOTE:

For best results, read all directions for use thoroughly. Consult your local Trichodex agricultural specialist for the spray schedule best suited to your conditions.

Prepare solution concentrations in a clean, empty spray tank. Use clean coarse spray filters. Add water to the spray tank until agitation is maintained. Add the appropriate amount of Trichodex to the tank with the agitator running. Continue agitation until spraying is completed.

Discard any unused spray material at the end of each day.

Use only as directed. The label should be read thoroughly and understood before making applications. Product efficacy requires that all parts of the crop receive uniform spray coverage or else desired result may not occur. Consult your local Trichodex agricultural specialist for specific information on the best rates, timings, and spray volumes for your region.

General Information:

Trichodex is a biocontrol agent for control of the plant pathogenic fungus *Botrytis cinerea*. Trichodex may be applied alone or in rotation with chemical botryticides to give control of *Botrytis cinerea*. The active ingredient in Trichodex is the naturally-occurring T-39 strain of *Trichoderma harzianum*. The primary mode of action is by competition of *Trichoderma harzianum* with *Botrytis cinerea* for nutrients and space on the plant surfaces.

Crops on which Trichodex may be used:

Trichodex may be used on most crops since *Trichoderma harzianum* Strain T-39, the active ingredient, is exempt from residue tolerances when applied to growing crops. Consult with your local Trichodex agricultural specialist for specific information on the best rates, timings, and spray volumes for your crop use and region.

Trichodex is not to be used on certain crops until reports pertaining to phytotoxicity and/or pathogenicity to these plants by *T. harzianum* are addressed. These include the following: apples, barley, chickpea, corn, cotton, kiwi, lemon, mushrooms, oats, pechay, rice, soybean, sugarcane, tobacco, tomatoes, and, wheat.

VEGETABLES:

Brassica (cole) leafy vegetables: broccoli, broccoli raab, Brussels sprouts, cauliflower, Chinese broccoli, Chinese cabbage, Chinese gai lon, Chinese mustard, collards, kale,



kohlrabi, mustard greens, rape greens, rapini, turnip (for tops).

Bulb vegetables: garlic, leek, onion, shallot.

Cucurbit Vegetables: balsam pear, cantaloupe, casaba melons, chayote, Chinese waxgourd, citron melon, crenshaw melon, cucumber, gherkin, Golden pershaw, melon, gourds, honey balls, honeydew melon, mango melon, muskmelon hybrids/varieties, Persian melon, pineapple melon, pumpkin, snake melon, squash (summer/winter), watermelon, zucchini.

Foliage of legume vegetables: black-eyed peas, catjang, guar.

Fruiting vegetables (except cucurbits): eggplant, groundcherry, okra, pepinos, peppers (all varieties), tomatillo.

Herbs and spices: celery, chervil, cilantro, dock, fennel, horseradish, parsley, peppers, pimento(all varieties), tumeric.

Leafy Vegetables (except Brassica): arugula, celery, celtuce, chervil, chicory, Chinese spinach, chrysanthemum (edible), cilantro, cress, dandelion, dock, endive, escarole, lettuce, New Zealand spinach, orach, parsley, purslane, radicchio, rhubarb, spinach, Swiss chard.

Leaves of root and tuber vegetables: arracacha, artichoke (Jerusalem), beet, burdock, cassava, celeriac, chicory, chufa, dasheen, daikon, radish, radicchio, rutabaga, salsify, sugar beet, tanier, turnips, yam.

Legume Vegetables (succulent or dried): beans (all varieties except soybeans and chickpeas), bean (goa), black-eyed peas, catjang, Chinese longbeans, dock, edamame, guar, lentils, peas (all varieties).

Root and Tuber Vegetables: arracacha, arrowroot, artichoke(Chinese and Jerusalem), bean (goa), beet, burdock, cassava, celeriac, chayote, chicory, chufa, dasheen, daikon, ginger, horseradish, loren, parsnip, potato, radish, radicchio, rutabaga, salsify, sugar beet, sweet potato, tanier, tumeric, turnips, yam.

Stalk and Stem Vegetables: artichoke(Globe), asparagus, bamboo shoots.

Tropical and Subtropical Vegetables (edible peel): acerola, carambols.

Tropical and Subtropical Vegetables (inedible peel): atemoya, rambutan.

FRUITS AND BERRIES:

Berries: blackberry, blueberry, boysenberry, currant, dewberry, elderberry, gooseberry, huckleberry, loganberry, marionberry, ollalieberry , raspberry, youngberry.

Citrus fruits: chironja, citrus citron, citrus hybrids, grapefruit, kumquat, mandarin, orange, pummelo, tangerine.



Citrus hybrids: calamondin, tangelo.

Oil seed: olives (all varieties).

Pome fruits: crabapple, loquat, Oriental pear, pear, quince.

Small fruits: cranberry, grape (table, raisin, wine), strawberry.

Stone fruits: apricots nectarine, peach, plum, prune, sour cherry, sweet cherry.

Tropical and subtropical fruits (edible peel): carob, dates, figs, guava, olives (all varieties), persimmon.

Tropical and subtropical fruits (inedible peel): avocado, bananas, cherimoya, durian, feijoa, lychee, mango, papaya, passion fruit, pineapple, pomegranate.

Tropical and subtropical fruits with edible seed for beverages and sweets: coffee.

TREE NUTS:

Tree nuts: almonds, beechnut, Brazil nut, butternut, cashew, chestnut, chinquapin, filbert, hickory nut, macadamia nut, pecan, pistachios, walnut.

Tropical and subtropical fruits (edible peel): cashew.

AGRONOMIC CROPS:

Foliage of legume vegetables: peanuts.

Nongrass animal feed: alfalfa.

Oil seed: sunflower.

Oil seed: Legume vegetables (succulent or dried): peanuts.

Root and tuber vegetables: potato.

Tropical and subtropical trees with edible seed for beverages and sweets: coffee.

Specific Use Directions for Wine Grapes, Table Grapes, Strawberry:

Use 2 - 4 lb. of Trichodex per acre per application from pre-bloom to harvest.

Application Instructions: ***APPLY VIA GROUND APPLICATION ONLY***

Apply Trichodex by calibrated ground spray equipment in at least 50 gallons of water per acre. Choose a volume of water per acre that will ensure thorough and uniform coverage of the plants, but avoids excessive wash-off of the product.

Trichodex may be applied at 7 to 14 day intervals up to 6 times per season.



Special Considerations:

Apply Trichodex in the late afternoon, early evening, or early in the morning when drying conditions are slower in order to favor germination and development of the *Trichoderma* organism on the plant surfaces. Consult your local Trichodex agricultural specialist for information about tank mixing Trichodex with agrochemical products registered for use on the treated crop.

NOTICE TO USER:

WARRANTY STATEMENT

MAKHTESHIM-AGAN OF NORTH AMERICA warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with directions under normal use conditions. It is impossible to eliminate all risks inherently associated with 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 MAKHTESHIM-AGAN OF NORTH AMERICA. In no case shall MAKHTESHIM-AGAN OF NORTH AMERICA be liable for consequential, special or indirect damages resulting from the use, or handling of this product. All such risks shall be assumed by the Buyer. In addition to the foregoing, no purchaser of this product (other than an end user) shall be entitled to any reimbursement for any loss suffered as a result of any suspension or cancellation of the registration for this product by the U.S. Environmental Protection Agency. Except as expressly provided herein, MAKHTESHIM-AGAN OF NORTH AMERICA makes no warranties, guarantees, or representations of any kind, either expressed or implied, or by usage of trade, statutory or otherwise, with regard to the product sold, including, but not limited to merchantability, fitness for a particular purpose, use or eligibility of the product for any particular trade usage. The exclusive remedy of any buyer or user of this product for any and all losses, injuries, or damages resulting from or in any way arising from the use, handling, or application of this product, whether in contract, warranty, tort, negligence, strict liability, or otherwise, shall be damages not exceeding the purchase price paid for this product or, at MAKHTESHIM-AGAN OF NORTH AMERICA's election, the replacement of this product.

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c/o Makhteshim-Agan of North America Inc.
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New York, NY 10176

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