

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

33657-10

EPA Reg.

Number:

Date of Issuance:

SEP 1 7 2004

NOTICE OF PESTICIDE:

x Registration

Reregistration (under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Dinotefuran Technical

Name and Address of Registrant (include ZIP Code):

Mitsui Chemicals, Inc. 3-2-5 Kasumigaseki Chiyoda-ku, Tokyo 100-6070, Japan

Authorized U. S. Agent: Landis International P.O. Box 5126 Valdosta, GA 31603-5126

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered 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:

- 1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.
 - 2. Make the following label changes before you release the product for shipment:
 - a. Add the phrase "EPA Registration Number 33657-10".

(continued on page 2)

Signature of Approving Official:

Rita Kumar

Date:

SEP 1 7 2004

- b. Under Directions for Use, change the first paragraph as follows: "Dinotefuran Technical is intended for use only in the formulation of insecticide products used in the control of sucking, biting and chewing insects infesting leafy vegetables (except Brassica), turf and ornamentals, domestic outdoors, (lawns, perimeter, and ornamentals), and certain public health pests." Delete the second paragraph.
- c. Under Storage and Disposal, add the following restriction under Pesticide Storage: "Do not store in metal containers." This restriction will be reconsidered after submission and review of the study testing stability to metals and metal ions. Should the study demonstrate Dinotefuran Technical to be reactive to metals and metal ions, you will be required to add this storage restriction to the end-use products formulated from this technical.
- 3. Submit the following data. These data requirements must be fulfilled in accordance with applicable provisions of the Good Laboratory Practice, as laid out in the Code of Federal Regulation (CFR) Volume 40, Part 160, and submitted in the format described in Pesticide Registration (PR) Notice 86-5:

Product Chemistry

Stability to metals and metal ions (Guideline 830.6316).

Residue Chemistry

- a. Submit the dates of sample extraction and analysis. If samples from the confined rotational crop study were stored >6 months from harvest to final analysis, storage stability data may be required to support the sample storage intervals. This information must be submitted within 90-days from the date of registration.
- b. If you wish to support any plantback interval less than 120 days, then a new confined rotational crop study, reflecting a 1x application rate, will be required.

Toxicology

- a. A confirmatory dermal absorption study in the rat is required. This study must be submitted within one year from the date of registration.
- b. A developmental neurotoxicity study in the rat is required. This study must be submitted within two years from the date of registration.
- c. A developmental immunotoxicity study in the rat with comparative measures between pups and the parents is required. The protocol for this testing should be developed following discussion with Agency scientists. This study must be submitted within two years from the date of registration.

Environmental Fate:

- a. Photodegradation in Soil: This confirmatory study needs to be repeated to better evaluate photolysis/photodegradation as a major degradation pathway. This study must be submitted within one year from the date of registration.
- b. Aerobic Soil Metabolism: You submitted two studies (MRID#s 45640111 and #45640112), both of which were found to be supplemental. The two studies combined provide sufficient data to determine the rate of degradation of dinotefuran, but neither study provides information about the fate of the major transformation products of dinotefuran. The second study (MRID#45640112) can be upgraded if you address the characterization of the major degradates at various sampling intervals. Otherwise, a new study is required to fully address the data requirement. This data gap must be fulfilled within one year from the date of registration.
- c. Anaerobic Aquatic/Soil Metabolism: This anaerobic aquatic metabolism study, conducted along with the anaerobic soil metabolism study, was found to be supplemental. This study will need to be repeated if a use with direct application to water is proposed.
- d. Aerobic Aquatic Metabolism: This study provides supplemental information about a system that was partially aerobic (water) and partially anaerobic (sediment). To assess any future aquatic uses for this chemical a new study may be needed.

Ecological Effects:

- a. Fish Early Life Stage Toxicity Test: This chronic study with rainbow trout was classified as invalid and must be repeated within one year from the date of registration..
- b. Avian Acute Oral Test: An acute oral LD₅₀ test using bobwhite quail or mallard duck must be submitted within one year from the date of registration.
- c. Aquatic Invertebrate Life Cycle Test: This study will be needed to assess any future aquatic uses for dinotefuran.
- 4. Submit production information (gallons produced) for this product for the fiscal year in which this use is conditionally registered, in accordance with FIFRA section 29. The fiscal year begins October 1, and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year. This information should be submitted to:

Registration Support Branch Registration Division (7505C) U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington D.C. 20460-0001 Notice of Registration (Continued); EPA Registration Number 33657-10

5. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(a). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Sincerely,

Rita Kumar

Senior Regulatory Specialist Insecticide Rodenticide Branch Registration Division (7505C)

Rita Kumar

Enclosure

DINOTEFURAN TECHNICAL

FOR FORMULATION INTO INSECTICIDE PRODUCTS

Active Ingredient:	
Dinotefuran, (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine	99.0%
Other Ingredients	
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN **CAUTION**

See side panels for additional precautionary statements

FIRST AID				
In 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 further treatment advice. 			
If Swallowed	 Call poison control center or doctor for treatment advice. Do not induce vomiting unless told to do so by the poison control center or doctor. Have person sip a glass of water if able to swallow. 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 moutl to-mouth, if possible. Call poison control center or doctor for 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 further treatment advice. 			
	HOT LINE NUMBER			
	label with you when calling a polson control center or doctor or going for treatment. You may also EMTREC (800) 424-9300 (24 hours) for emergency medical treatment information.			
	See side/back panels for additional precautionary statements			

EPA Reg No. 33657-RN			EPA Establishment No.
		Net Contents:	

With TOMARNOON
WERA LISTED BOARD

SEP 1 7 2004

Manufactured By: MITSUI CHEMICALS, INC.

3-2-5 Kasumigaseki Chiyoda-ku, Tokyo 100-6070 **JAPAN**

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to shrimp. Do not discharge effluent containing this product into lakes, steams, 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.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Do not use, pour, spill or store near heat or open flame.

DIRECTIONS FOR USE

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

Dinotefuran technical is intended for use in the formulation of insecticide products used in the control of sucking, biting and chewing insects infesting leafy vegetables, turf and ornamentals and also certain Public Health and nuisance insects.

Dinetefuran technical is for use only in the formulation of insecticides for use on agricultural crops, non-crop sites, turf and ornamental plants, domestic indoor (household) and domestic outdoor (lawns, perimeter and ornamentals), animal treatments (including livestock and pets and their living quarters), industrial/commercial/institutional uses, terrestrial food/feed and non food, greenhouse uses and certain Public Health and nuisance pests.

Products formulated from this technical material will require registration with the U.S. Environmental Protection Agency (EPA).

STORAGE AND DISPOSAL

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

De not stone in metal containers.

Pesticide Storage: Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool dry place. Do not store diluted spray. For help with any spill, leak, fire or exposure involving this material, call-day or night 1-800-CLEANUP.

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:

Triple rinse (or equivalent). Do not reuse container. Offer for recycling or reconditioning, 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 smcke.

DINOTEFURAN TECHNICAL -3-

CONDITIONS OF SALE

MITSUI CHEMICALS, INC., warrants that this product in its unopened package conforms to the chemical description on the label and is reasonably fit for the purposes set forth on the label when used according to directions under normal use conditions to the crops specified. There are no other warranties, expressed or implied, concerning the use of this product other than indicated on the label. This warranty does not extend to the handling or use of this product contrary to label instructions or under abnormal conditions or conditions not reasonably foreseeable to seller, and buyer assumes all risk of any such use.

9 August 2004