

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR 23 2005

Mr. Ronald Landis, Ph.D.
Landis International
P.O. Box 5126
Valdosta, GA 31603-5126

Authorized agent for Mitsui Chemicals

Dear Mr. Landis:

Subject: Label amendment; add new uses (fruiting vegetables, cucurbits, head and stem
brassica, grapes, potatoes, and cotton)
Dinotefuran Technical
EPA File Symbol 33657-10
Your submissions dated February 14, February 22, and March 10, 2005

The amendment referred to above is acceptable in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(B), subject to the comments listed below:

1. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data.
2. Registration of these new uses is conditional upon successful laboratory validation of the proposed livestock enforcement method, which is being currently reviewed by the Agency.
3. Make the following label changes:
 - a. Change the chemical name in the label ingredient statement as follows: Dinotefuran [N-methyl-N'-nitro-N'-((tetrahydro-3-furanyl)methyl)guanidine].
 - b. Add the following to the Environmental Hazard statement:

“Dinotefuran and its degradate, MNG have the properties and characteristics associated with chemicals detected in ground water. The high water solubility of dinotefuran, and its degradate, MNG, coupled with its very high mobility, and resistance to biodegradation indicates that this compound has a strong potential to leach to the subsurface 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. Periodic monitoring of shallow groundwater in the use area is recommended.”

4. Submit the following data:

a. Submit information pertaining to storage intervals of samples from the plant metabolism studies (rape, potato, rice, apple, and lettuce). If samples were stored >6 months from harvest to final analysis, storage stability data may be required. This information should be submitted within 3 months from the date of this letter.

b. Submit additional storage stability data for up to five months for metabolites DN and UF in cotton seed for 5 months and for dinotefuran, and metabolites DN and UF in cotton processed commodities. This information should be submitted within 12 months from the date of this letter.

c. Additional information pertaining to the storage conditions and intervals of milk (whole and skim) and cream samples from the ruminant feeding study is required. If samples were stored frozen for less than 30 days prior to analysis, then no storage stability data are required. However, if samples were stored for more than 30 days, then data depicting the frozen storage stability of residues of dinotefuran and its metabolites DN and UF in milk will be required. Submit this information within 3 months from the date of this letter.

d. Submit a honeybee study (guideline 141-5) to properly assess the risk to honey bees. This study should evaluate the effects of dinotefuran to the hive over time from a typical dinotefuran use pattern. The use pattern chosen should be one that will result in bee exposure from residues in the nectar or pollen. This study should include but not necessarily be limited to the following: a) an evaluation of two complete life cycles (~130 days) including egg, larvae, adult stages, and mortality of the honeybee colony; b) an evaluation of the exposure and effects to the queen during these life cycles; c) complete analysis of the dinotefuran residues in the stored nectar, honey, and pollen at the beginning of the study, at periodic intervals during the study and at the end of the study; and d) the study must include replicated data with statistical comparison to controls.

You must file a protocol for the honeybee study following the guideline (141-5) within 60 days, and the completed study within 18 months from the date of this letter.

5. This amendment is subject to the time frames for submission of generic data for the active ingredient, as indicated in the Notice of Registration issued on September 17, 2004.

6. Submit production information (gallons produced) for this product for the fiscal year in which these uses are 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

7. 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).

A stamped copy of the label is enclosed for your records. If you have any questions, please do not hesitate to write or call me at (703) 308-8291.

Sincerely,



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

Enclosure

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DINOTEFURAN TECHNICAL

FOR FORMULATION INTO INSECTICIDE PRODUCTS

Active Ingredient:

Dinotefuran, (RS)-1-methyl-2-nitro-3-(tetrahydro-3-furylmethyl)guanidine	99.0%
Other Ingredients	1.0%
Total:	100.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION
See side panels for additional precautionary statements

FIRST AID	
In On Skin Or Clothing	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<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 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 15-20 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	
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact CHEMTREC (800) 424-9300 (24 hours) for emergency medical treatment information.</p>	
<i>See side/back panels for additional precautionary statements</i>	

EPA Reg No. 33657-10 RN

Net Contents:

EPA Establishment No. 33657-JP-2

Manufactured By:
mitsui chemicals, inc.
 Shiodome City Center
 1-5-2 Higashi-Shimbashi
 Minato-ku, Tokyo 105-7117
 JAPAN

ACCEPTED

MAR 23 2005

33657-10

5 8 6

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, 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.

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.

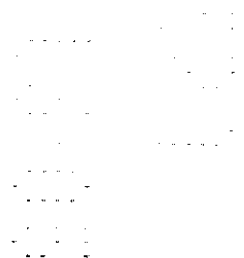
DIRECTIONS FOR USE

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

Dinotefuran technical is intended for use only in the formulation of insecticide products used in the control of sucking, biting and chewing insects infesting cotton, leafy vegetables, fruiting vegetables, cucurbits, potatoes, grapes, head and stem brassica, turf and ornamentals, domestic outdoors (lawns, perimeters, and ornamentals), and certain public health pests. ~~and also certain Public Health and nuisance insects.~~

~~Dinotefuran 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.

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 smoke.

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.

