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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 2 4 2008

Jamin Huang, Ph.D Bayer Environmental Science 2 T.W. Alexander Dr. Research Triangle Park, NC 27709

SUBJECT: Reregistration Label Amendment Per Carboxin and Thiram RED

for Titan FL

EPA Reg. No. 264-984

Your Submission Dated September 18, 2007

Dear Dr. Huang:

EPA determined that you fulfilled the requirements of the Metalaxyl, Carboxin and Thiram RED for the subject product. However, we are unable to reregister the product under FIFRA 4(g)(2)(c) at this time, because it also contains the active ingredient Clothianidin, which has outstanding conditional data. When this data is satisfied, this product can be reregistered.

Within thirty (30) days from the date of this letter, you must submit a revised master label which adds the following changes. If these conditions are not complied, with the registration will be subject to cancellation in accordance with FIFRA section 6(e).

- 1. On the label's front panel, under the product name "TITAN" or another prominent location, insert "For sale to and use by professional applicators only. Not for sale to or use by homeowners/consumers."
- 2. From the 'PPE' section, revise the bullet, referring to 'chemical resistant gloves,' by deleting: "except when...seeds," because it is inconsistent with the product's usage.
- 3. Delete "Directions for Use," on page 2, then, add "General Information."
- 4. Revise the 'Storage and Disposal' box, on page 2, by deleting 'PROHIBITIONS, Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment. Do not reuse empty container. Open dumping is prohibited" then, add "Do not contaminate water, food, or feed by storage and disposal."
 - A. To this section, append "Pesticide" to "Storage," so that it reads "Pesticide Storage."
 - B. Submit a separate label notification or amendment, which complies with the container disposal statement PR 2007-4.

- 5. Above the 'User Safety Recommendations' section, on page 2, add "NOTE: Persons involved in bagging treated seed, sewing or moving bags of seed, or cleaning up bagging areas or seed treatment equipment are pesticide handlers and must wear the PPE required on this label for pesticide handlers."
- 6. From the 'Endangered Species' section, on page 2, delete the first sentence "This bag contains...with carboxin."
- 7. Immediately after 'Container Disposal' heading, on page 2, add, "Do not reuse empty container."
- 8. After deleting the current text from the 'Environmental Hazards' section, on page 2, insert the following: "This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do no apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate."

Treated seeds are fish, birds, and mammals. Do not plant treated seed by broadcasting to the soil surface. Ensure that all seeds are thoroughly covered with soil, especially in turn areas. If seeds are not thoroughly incorporated by the planer during planting, additional incorporation may be required to thoroughly cover exposed seeds.

This product contains metalaxyl that is known to leach though soil into ground water under certain conditions as a result of agricultural use. Use of this product in area where soils are permeable, particularly where the water table is shallow, may results in ground water contamination.

- 9. The section 'Labeling of Treated Seed', on page 2, must be revised, accordingly.
 - A. To the seventh bullet, of this section, change the REI from '12 hours' to '24 hours', which is consistent with such restrictions for the active ingredient thiram.
 - B. At the third bullet, delete the first sentence, "This bag...carboxin."

Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions. One copy of the label stamped "Accepted with comments" is enclosed for your records. If you have any questions regarding this correspondence, contact Bryant Crowe of my staff by phone at 703-305-0025 or via email at crowe.bryant@epa.gov or myself at 703-308-9443 or via email at kish.tony@epa.gov.

Sincerely.

Enclosure

Tony Kish V Product Manager (22) Fungicide Branch

Registration Division (7505P)

TITAN™

Flowable Insecticide and Fungicide Seed Treatment

TITAN FL contains the following amount of active ingredient per gallon:		
1 lb. clothianidin; 1 lb. thiram; 0.47 lb. carboxin; 0.033 lb. metalaxyl.		
ACTIVE INGREDIENTS:		
Clothianidin: [(C(E)]-N-(2-chloro-5-thiazolyl)methyl]-N'-methyl-N"-nitroguanidine	9.49%	
Thiram: tetramethylthiuram disulfide		
Carboxin: 5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide		
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester		
OTHER INGREDIENTS:		
	TOTAL 100.000/	

EPA Reg. No. 264-984

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

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

FIRST AID

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. 	
<u> </u>	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 ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.	
	Call a poison control center or doctor for further 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.	

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if inhaled or absorbed through the skin. Avoid breathing vapor or spray mist. Avoid contact with eyes or skin.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are barrier laminate, nitrile rubber, neoprene rubber. If you want more options, follow the instructions for category C and E on an EPA chemical-resistance category selection chart.

All mixers, loaders, applicators and other handlers must wear:

- -long-sleeved shirt and long pants
- -socks plus shoes
- -chemical resistant gloves, except when bagging or sewing bags of treated seeds,
- -chemical resistant aprons when mixing, loading, or participating in dip treatments.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

ACCEPTED
with COMMENTS
In EPA Letter Dated
SEP 2 4 2000

Under the Federal Insecticide, Fundicide, and Redenticide Act as amended, for the pesticide registered under EPA Reg. No. Page 1 of 4

264-984

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should 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

When handlers use closed systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people and the system is functioning properly and is used and maintained in accordance with the manufacturer's written operating instructions, the handlers need not wear the chemical-resistant apron. However, the chemical-resistant gloves must be immediately available for use in an emergency, such as a spill or equipment breakdown.

ENVIRONMENTAL HAZARDS

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 water when disposing of equipment washwater or rinsate by disposal of wastes. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds.

Endangered Species

This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product.

DIRECTIONS FOR USE

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

For use by commercial treaters only. Not for use on agricultural establishments in hopper-box, slurry-box, or other seed treatment applications at, or immediately before, planting. Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

STORAGE AND DISPOSAL

PROHIBITIONS

Do not contaminate water, food or feed by storage, disposal, or by cleaning of equipment. Do not reuse empty container. Open dumping is prohibited.

STORAGE

Storage at low temperatures is not recommended. Do not store above 95°F. Do not store in direct sunlight.

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

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then 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.

LABELING OF TREATED SEED

Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:

- This seed has been treated with clothianidin, trifloxystrobin, carboxin, and metalaxyl.
- Dispose of seed packaging in accordance with local requirements.
- This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species with out authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product.
- Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds.
- When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.

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- Treated Seed- Do Not Use for Food, Feed, or Oil Purposes.
- After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface.
- Rapeseed greens and seed grown or harvested from TITAN FL -treated seed must not be used for feed or human
 consumption. Rapeseed grown and harvested from TITAN FL -treated seed is only for industrial uses and cannot be used for
 edible oil or any other human/feed consumption.
- Areas planted with treated seed may be replanted immediately with canola, rapeseed and corn. These areas may also be
 replanted after 30 days with cereal grains, grasses, non-grass animal feeds, soybeans, and dried beans. Do not plant any
 other crop in the treated area for at least four months after treated seeds are planted.

GENERAL INFORMATION

TITAN FL is a systemic insecticide and fungicide seed treatment for use on canola and rapeseed for control of certain insect pests and for control of seed rot, damping off, seedling blight and early season root rot caused by Pythium, Rhizoctonia, Fusarium and Alternaria. Also controls seedborne Blackleg. For protection of seeds and emerging seedlings only.

For use in commercially available equipment designed for seed treatment only. Not for use in hopper-box, slurry-box, or similar seed treatment applications used at planting. This product is to be used in liquid or slurry treaters. Mix thoroughly before use or use entire container at one time. All tank mixes should be pre-tested to determine physical compatibility between formulations. Observe all cautions and limitations on labeling of all products used in mixtures.

All seed treated with this product must be conspicuously colored at the time of treatment. If this product contains no colorant, an appropriate colorant must be added to distinguish seed and to prevent subsequent inadvertent use as a food for man or a feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

DIRECTIONS FOR USE

Prior to and during application, TITAN FL must be thoroughly agitated to ensure uniform mixing.

Canola and Rapeseed: Apply 19.2 to 25.6 fl.oz. of TITAN FL to 100 lbs. of seed using commercial seed treatment equipment. For longer season control of flea beetles, and for areas where flea beetle populations are often high TITAN FL can be tank mixed with Poncho™ 600 according to the directions in the table below. Do not apply more than a total of 6.4 oz. of clothianidin active ingredient per 100 pounds (400 g. a.i./100 kg.) of canola or rapeseed.

TITAN™ FL Application Rate	Poncho™ 600 Application Rate
19.2 fl.oz / 100 lbs. of seed	Up to 6.4 fl.oz. / 100 lbs of seed
25.6 fl.oz. / 100 lbs. of seed	Up to 5.12 fl.oz. / 100 lbs. of seed



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.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

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 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.

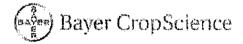
NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

NET CONTENTS: 1 gal, 2.5 gal, 30 gal, 200 gal, 400 gal

TITAN and PONCHO are registered trademarks of Bayer

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)

TITAN Flowable Insecticide and Fungicide Seed Treatment (PENDING) SUBMITTED TO EPA 09/24/07