

264-1068

09-27-2010

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

SEP 27 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Melvin K. Tolliver
Product Registration
Bayer CropScience LP
P.O. Box 12014
2T.W Alexander Drive
Research Triangle Park, NC 27709

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request General Label Change/Add Various Pest Diseases Controlled
EPA Reg. No. 264-1068
Application Dated September 3, 2010

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 09/03/10 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. Tony Kish (PM-22) concurred with this action. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-5335 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in cursive script that reads "Rachel C. Halloran".

Paul J. Mastradone, Ph.D., Acting *for*
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-1068	2. EPA Product Manager Tony Kish	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Trilex ALConcentrate	PM# Team 22	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION

SEP 27 2010

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of adding a pest per PR Notice 98-10. See attached for explanation.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Melvin K. Tolliver	Title Registration Product Manager, Fungicides	Telephone No. (Include Area Code) (919) 549-2631	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) CCCC CCCC
2. Signature <i>Melvin K. Tolliver</i>	3. Title Registration Product Manager, Fungicides		
4. Typed Name Melvin K. Tolliver	5. Date September 3, 2010		

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Trilex AL Concentrate
EPA Reg. No. 264-1068

Section II - Continued

Trilex AL Concentrate is currently registered as a seed treatment for control of various diseases infecting a number of crops. With this application form, we are notifying the Agency that we are adding claims for control of the following additional diseases: *Alternaria* spp., *Aspergillus* spp., *Cladosporium* spp., and *Penicillium* spp.

As required by PR Notice 98-10 we are enclosing one copy of draft labeling, dated September 1, 2010, in which the disease *Alternaria* spp., *Aspergillus* spp., *Cladosporium* spp., and *Penicillium* spp are highlighted in yellow. In addition, we are also enclosing two copies of final printed labeling. There are no other changes in the currently registered label.

This notification is consistent with the provision of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA, and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

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TRILEX[®] AL Concentrate**ACTIVE INGREDIENTS (% by weight):**

Trifloxystrobin.....7.12%
Metalaxyl.....5.69%

OTHER INGREDIENTS:.....87.19%

TOTAL:.....100.00%

Contains 0.64 lbs. trifloxystrobin per gallon and 0.51 lbs. metalaxyl per gallon.

EPA Reg. No. 264-1068

EPA Est.

KEEP OUT OF REACH OF CHILDREN CAUTION

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

IF SWALLOWED	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Do not induce vomiting unless told to by a 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 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 treatment advice.
IF 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 treatment advice.
IF INHALED	<ul style="list-style-type: none">• 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.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.
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

CAUTION

Harmful if swallowed, absorbed through skin, or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, 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.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: Long-sleeved shirt and long pants, socks plus shoes, chemical-resistant gloves made of any waterproof material and protective eyewear.

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.

Engineering Controls: When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or 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 washwaters or rinsate. Cover or incorporate spilled treated seeds in accordance with local regulations.

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.

Groundwater Advisory: Metalaxyl is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

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 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store in a cool dry location.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited.

CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Rigid Non-refillable containers small enough to shake (capacities equal to or less than 5 gallons).

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Rigid non-refillable containers that are too large to shake (capacities greater than 5 gallons).

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Offer for recycling, if available. If not recycled, then puncture and dispose of in a sanitary landfill, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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) 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 24 hours. 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, chemical-resistant gloves made of any waterproof material, shoes plus socks and protective eyewear.

LABELING OF TREATED SEED

Seed commercially treated with Trilex AL Concentrate must be labeled in accordance with all applicable requirements of the Federal Seed Act. All bags containing treated seed must be labeled or tagged as follows:

- This seed has been treated with trifloxystrobin and metalaxyl at the rates recommended by the manufacturer.
- DO NOT USE FOR FOOD, FEED OR OIL PURPOSES.
- Store away from feeds and other foodstuffs.

GENERAL INFORMATION

Trilex AL Concentrate provides seed and seedling protection against seedborne fungi, *Alternaria* spp., *Aspergillus* spp., *Cladosporium* spp., and *Penicillium* spp. causing seed decay and soilborne pathogens, *Rhizoctonia solani*, *Fusarium* spp., and *Pythium* spp. that cause seed and seedling damping-off. Trilex AL Concentrate can be used for suppression of early-season *Phytophthora* seed and root rot. Trilex AL Concentrate is a concentrated formulation especially formulated for application using standard slurry or mist-type seed treatment equipment. Consult a seed treatment specialist for proper guidelines in using Trilex AL Concentrate to insure uniform coverage of seed, thus ensuring seed safety and best disease protection. For commercial and on-farm use.

USE PRECAUTIONS

When using formulations that do not contain dye, to comply with 40 CFR 153.155, all seed treated with an economic poison must be colored to distinguish it and prevent subsequent inadvertent use as a food for man or feed for animals.

USE RESTRICTION

Do not use treated seed for food, feed, or oil processing.

Corn:

Apply at a product rate of 0.5 fl. oz. of product per 100 lbs. of seed.

Cotton:

Apply at a product rate of 2.0 fl. oz. of product per 100 lbs. of seed.

Soybean, Adzuki Bean, Asparagus Bean, Broad Bean (Succulent or Dry), Catjang Bean, Chinese Longbean, Field Bean, Guar Bean, Jackbean, Kidney Bean, Lablab Bean, Lima Bean (Succulent or Dry), Moth Bean, (Succulent or Dry), Mung Bean, Navy Bean, Pinto Bean, Rice Bean, Runner Bean, Snap Bean, Sword Bean, Tepary Bean, Urd Bean, Wax Bean, Yardlong Bean, Blackeyed Pea (Succulent or Dry), Chickpea, Cowpea (Succulent or Dry), Crowder Pea, Dwarf Pea, Edible-Pod Pea, English Pea, Field Pea, Garden Pea, Green Pea, Pigeon Pea (Succulent or Dry), Snow Pea, Southern Pea (Succulent or Dry), Sugar Snap Pea, Grain Lupin, Sweet Lupin, White Lupin, White Sweet Lupin, Lentil:

Apply at a product rate of 1.0 fl. oz. of product per 100 lbs. of seed.

Rice:

Apply at a product rate of 1.0 – 2.0 fl. oz. of product per 100 lbs. of seed.

ROTATIONAL CROP RESTRICTION

Areas planted with treated seed may be replanted immediately with any crop for which a tolerance exists for trifloxystrobin. Do not plant any crop without trifloxystrobin tolerances until 30 days after planting trifloxystrobin treated seed.

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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.

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. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, 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:

Trilex is a registered trademark of Bayer

Produced for



Bayer CropScience

**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)**

TRILEX AL CONCENTRATE (MASTER) 06/12/08, Notification 04/01/09, Notification 09/01/10