

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

OFFICE OF PREVENTION, PESTICIDES AND FOXIC SUBSTANCES

Mrs. Danielle A. Larochelle Registration Product Manager Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, N.C. 27709

NOV. 9 2007

Re: Notification of Labeling Amendment

EPA Reg No.: 264-1057

Date of Submission: October 9, 2007

Dear Mrs. Larochelle:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated October 9, 2007, for the AERS™ Seed-Applied Insecticide/Nematicide. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. 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 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

Linda Arrington Notifications & Minor Formulations Team Leader Registration Division (7505P) Office of Pesticide Programs

United States .

Registration

OPP Identifier Number

\$EPA	Washington DC 20460				Amenda Other	nent				
	Арр	lication fe	or Pestic	de - Sect	tion	ĺ		· · · · · · · · · · · · · · · · · · ·		
1. Company/Product Number 264-1057			2. EPA Product Manager Thomas Harris			3. Proposed Classification				
4. Company/Product (Name) AERIS(TM) Seed-Applied Insecticide/Nematicide			PM# Team 7				None		betricted	
5. Name and Address of Ap Bayer CropScience P.O. Box 12014; 2 T.W Research Triangle Par	-	6. Expedited Reveiw. In accordance with FIFRA Section (b)(i), my product is similar or identical in composition at to: EPA Reg. No.					and lat			
Check if thi		Product Name								
		S	ection -	11		-				
Amendment - Explain below. Resubmission in response to Agency letter dated				Final printed labels in repsonse to NOTIFICATION Agency letter dated "Me Too" Application. NOV - 9 2007						N
X Notification - Explain	below.			Other - Expl	ain be	low.				
made to the labeling or the con EPA. I further understand that subject to enforcement action a	This notification is consistent wifidential statement of formula of the fifth this notification is not consistent and penalties under sections 12 at Larochelle; Phone #: 919-549-27	nis product. I ur t with the terms nd 14 of FIFRA. 718; e-mail: Da	nderstand that i of PR Notice 9 nielle.Larochell	t is a violation of 3-10 and 40 CFF e@bayercropsc	f 18 U.S R 152.4	S.C. Sec. 1001 16, this product	to willfull	y make any fals	se staten	nent to
			ection -	E						
1. Material This Product Will Be Packaged In: Child-Resistant Packaging Yes No ** Certification must be submitted Unit Packaging If "Yes" Unit Packaging wgt. No. per Container		per If	Water Soluble Packaging Yes No If "Yes" No. per Package wgt Container			2. Type of Container Metal Plastic Glass Paper Other (Specify)				
3. Location of Net Contents	Information 4. Siz	re(s) Retail Co	ntainer		5. Loc	cetion of Leb	el Direct	ions		
6. Manner in Which Label is		Lithograph Paper glued Stenciled		Other						
		S	ection - I	V						
1. Contact Point (Complete	items directly below for idea	ntification of i	ndividual to b	e contected, i	if nece	essary, to pro	cess thi	s application.	,	
Name Danielle A. Larochelle							hone No. (Include Area Code) //549-2분취용으로			
	ments I have made on this for ny knowlingliy false or mislea							6. Date Ap Receive	j imped	
2. Signature Dan 1 Yhull			3. Title Registration Product Manager						ι	
4. Typed Name Danielle A. Larochelle			5. Date October 9, 2007						ć.	
Darnono A, Larvonono		I	3, 2001					1		

RESTRICTED USE PESTICIDE

Due to Avian, Aquatic and Small Mammal Toxicity

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered

by the Certified Applicator's Certification.

AERIS Seed-Applied Insecticide/Nematicide

For Use Only in Commercial Seed Treatment Equipment

Contains 2.5 pounds active thiodicarb per U.S. gallon

EPA Reg. No. 264-1057

EPA Est. No. 264-MO-02

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 PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

Thiodicarb is an N-methyl carbamate.

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 ON SKIN OR	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:	Move person to fresh air.					
If person is not breathing, call 911 or an ambulance, then give artificial respiration, pref 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.					
	Call a poison control center or doctor for treatment advice.					

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

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

SIGNS AND SYMPTOMS OF OVEREXPOSURE

Salivation, Muscle tremors, Nausea, Watery eyes, Difficult breathing, Vomiting, Pinpoint eye pupils, Excessive swearing, Diarrhea Blurred vision, Abdominal cramps, Weakness, Headache.

IN SEVERE CASES, CONVULSIONS, UNCONSCIOUSNESS, AND RESPIRATORY FAILURE MAY OCCUR.

ANTIDOTE STATEMENT: ATROPINE SULFATE IS HIGHLY EFFECTIVE AS AN ANTIDOTE. See NOTE TO PHYSICIAN.

GENERAL

Contact a physician immediately in all cases of suspected poisoning. If breathing stops, establish an airway, start artificial respiration, and provide oxygen. Make certain to remove all sources of continuing contamination. Remove clothing and wash skin and hair immediately with large amounts of water. Transport the patient to a physician or hospital immediately and SHOW A COPY OF THIS LABEL TO THE PHYSICIAN. If poisoning is suspected in animals, contact a veterinarian.

NOTE TO PHYSICIAN

All treatments should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred.

This product contains an N-methyl carbamate insecticide, which is a cholinesterase inhibitor. Overexposure to this substance may cause toxic signs and symptoms due to stimulation of the cholinergic nervous system. These effects of overexposure are spontaneously and rapidly reversible. Gastric lavage may be used if this product has been swallowed. AERISTM Seed-Applied Insecticide/Nematicide poisoning may occur rapidly after ingestion and prompt removal of stomach contents is indicated.

Specific treatment consists of parenteral atropine sulfate. Caution should be maintained to prevent over atropinization. Mild cases may be given 1 to 2 mg intramuscularly every 10 minutes until full atropinization has been achieved and repeated thereafter whenever symptoms reappear. Severe cases should be given 2 to 4 mg intravenously every 10 minutes until fully atropinized, then intramuscularly every 30 to 60 minutes as needed to maintain the effect for at least 12 hours. Dosages for children should be appropriately reduced. Complete recovery from overexposure is to be expected within 24 hours.

Narcotics and other sedatives should not be used. Further, drugs like 2-PAM (pyridine-2-aldoxime methiodide) are <u>NOT</u> recommended unless organophosphate intoxication is also suggested.

To aid in confirmation of a diagnosis, urine samples should be obtained within 24 hours of exposure and immediately frozen. Analyses will be arranged by Bayer CropScience.

Consultation on therapy can be obtained at all hours by calling the Bayer CropScience emergency number: 1-800-334-7577.

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. Avoid breathing fumes. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Workers involved with treating the seed (e.g. connecting and disconnecting hoses and transfer pumps, mixing, equipment calibration, etc.) and others exposed to the concentrate, and cleaners/repairers of seed treatment equipment must wear a long-sleeve shirt and long pants, shoes plus socks, chemical resistant gloves made out of any waterproof material, and a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any R, P, or HE filter.

Baggers and bag sewers must wear a long-sleeve shirt and long pants, shoes plus socks, chemical resistant gloves made out of any waterproof material, and a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any R, P, or HE filter.

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.
- 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.
- Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate.
 Do not reuse them.
- 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.

ENVIRONMENTAL HAZARDS

This product is highly toxic to birds and aquatic invertebrates and toxic to fish and mammals. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

RESTRICTED USE PESTICIDE

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

GENERAL DIRECTIONS

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other farmer-applied applications.

Read the entire label and observe all label directions and precautions before use. Do not use this product except as directed on this label or on other Bayer CropScience supplemental labeling for this product.

COMPATIBILITY

It is essential that before using AERISTM Seed-Applied Insecticide/Nematicide in any tank mixture the compatibility of the mixture be established. Add AERISTM Seed-Applied Insecticide/Nematicide at the recommended label rate to a clean quart jar containing approximately one-half the amount of water intended for a final slurry application rate. Next, follow with all other tank mix components that will be used in the total slurry application. Add last the remaining balance of water. The total amount of volume is determined by the seed size and how much is necessary to ensure complete and uniform coverage and distribution on the seed, as well as the type of commercial seed treating application equipment that will be used

DO NOT USE MIXTURES THAT CURDLE, PRECIPITATE, OR GEL. FOR BEST RESULTS, TANK MIXTURES SHOULD BE USED IMMEDIATELY AFTER MIXING WITH ADEQUATE AGITATION.

NOTE: Thiodicarb is hydrolytically sensitive to degradation of active ingredient by strong acids AND strong bases. DO NOT ADD AERISTM SEED-APPLIED INSECTICIDE/NEMATICIDE TO WATER WITH pH VALUES BELOW 3.0 OR ABOVE 8.5. If necessary, water should be buffered within this range before adding AERISTM Seed-Applied Insecticide/Nematicide. Degradation can cause reduced effectiveness, plant phytotoxicity and increased handling hazards.

DIRECTIONS FOR SEED TREATMENT

All seed treated with this product must be colored with an EPA-approved dye or colorant that imparts an unnatural color to the seed to help prevent the inadvertent use of treated seed for food, feed or oil purposes.

COTTON (Delinted Seed Only)

For Early Season Protection Against Certain Sucking and Lepidopteran Insects and Certain Nematodes:

AERIS Seed-Applied Insecticide will provide protection of cotton seedlings against injury by early season thrips, aphids, lygus, fleahoppers, cutworms and reniform and root knot nematodes. Where the specific application rate is desired on an individual seed basis apply 0.375 mg. imidacloprid and 0.375 mg. thiodicarb per seed prior to planting as a slurry treatment so as to ensure thorough coverage. Otherwise apply 25.6 fluid ounces product per hundred pounds of seed. Do not apply more than 25.6 fluid ounces per hundredweight of seed.

Do not exceed a total of 5.4 pounds thiodicarb per acre per season for seed treatment and foliar applications combined. In Arizona and California, do not exceed a total of 1.8 pounds thiodicarb per acre per season for seed treatment and foliar applications combined.

Do not exceed a total of 0.5 pounds imidacloprid per acre per season for seed treatment, soil, and foliar applications combined.

SEED BAG LABEL REQUIREMENTS

The Federal Seed Act requires that bags containing treated seeds shall be labeled with the following statements:

- This seed has been treated with thiodicarb and imidacloprid.
- Do not use for food, feed or oil purposes.

In addition, the U.S. Environmental Protection Agency requires the following statements on bags containing cottonseed treated with AERISTM Seed-Applied Insecticide/Nematicide:

- · Store away from food and feedstuffs.
- Do not allow children, pets, or livestocks to have access to treated seeds.
- Wear long-sleeved shirt, long pants, and chemical resistant gloves made out of any waterproof material when handling treated seed
- Growers must not exceed a total of 5.4 pounds thiodicarb per acre per season for seed treatment and foliar applications combined.
 In Arizona and California, do not exceed a total of 1.8 pounds thiodicarb per acre per season for seed treatment and foliar applications combined.
- Growers must not exceed a total of 0.5 pounds imidacloprid per acre per season for seed treatment, soil, and foliar applications combined.
- Treated seed must be planted into the soil at a depth greater than 1 inch. Treated seeds exposed on soil surface may be hazardous to birds or other wildlife. Cover or collect treated seeds that are spilled during loading and in areas such as row ends.
- Dispose of all excess treated seed by burial away from bodies of water.
- · Dispose of seed packaging in accordance with local requirements.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- Plant AERIS[™] Seed-Applied Insecticide/Nematicide treated cotton seed based upon local production and Best Management Practices as recommended by your state's Cotton Specialist, IPM Coordinator and Extension Nematologist. In soils with a history of high nematode populations, an at-plant application of TEMIK® brand 15G Aldicarb Pesticide is recommended.
- · Always calibrate planters prior to planting to ensure the desired seeding rate.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Store unused product in a cool, ventilated, dry area. Do not allow prolonged storage in areas where temperatures frequently exceed 115°F (46°C) or go below 35° F (2°C). NEVER TRANSFER THIS PRODUCT TO ANOTHER CONTAINER FOR STORAGE.

PESTICIDE DISPOSAL

Improper disposal of excess pesticides or rinsate is a violation of federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER DISPOSAL

NEVER REUSE EMPTY CONTAINERS. 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 container is burned, stay out of smoke.

RETURNABLE -- REFILLABLE CONTAINERS

After use, return the container to the point of purchase or designated locations. This container must only be refilled with AERISTM Seed-Applied Insecticide/Nematicide. DO NOT REUSE THE CONTAINER FOR ANY OTHER PURPOSE. Prior to refilling, inspect thoroughly for damage such as cracks, punctures, abrasions and damaged or worn out threads on closure devices. Do not refill or transport damaged or leaking containers. Check for leaks after refilling and before transportation. If the container is not being refilled, return it to the point of purchase.

ACCIDENTS: In case of a major spill of AERIS[™] Seed-Applied Insecticide/Nematicide TELEPHONE (24 HOURS A DAY) IN THE U.S.A. 1-800-334-7577.

WARRANTY STATEMENT

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.

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.

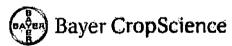
DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized 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.

NET CONTENTS:

* TEMIK is a registered trademark 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)

AERISTM Seed-Applied Insecticide/Nematicide (MASTER) EPA Approved 07/09/07, Notification 10/09/07

Bayer CropScience



October 9, 2007

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

(Team 7 - Mr. Tom Harris)

Dear Reviewer,

Re: AERISTM Seed-Applied Insecticide/Nematicide - EPA Reg. No. 264-1057 Notification of Labeling Amendment per PR Notice 98-10

In accordance with PR Notice 98-10, we are notifying the Agency of a minor labeling amendment for the subject product, EPA Reg. No. 264-1057. A claim against 2 pests, lygus and fleahoppers, was added to the use directions for cotton (delinted seed only) on the approved label. Also, the claim against reniform and root knot nematodes was modified. No changes were made in the dosage, concentration, or method of application of the product.

The following documents are enclosed in support of this action:

- A completed Application for Registration (EPA Form 8570-1) which includes the Certification Statement required by PR Notice 98-10.
- Two (2) copies of the label including one with the revised language highlighted in yellow.
- A CD including electronic copies of the label (one with changes highlighted) and a Certification with Respect to Label Integrity.

Please call me at 919/549-2718 if you need any additional information.

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Sincerely,

Danielle A. Larochelle

Registration Product Manager

Corr. # daL069-07

B syer CropScience RTP P. O. Box 12014 RTP, NC 27709 Tel. 919 549-2000

Certification with Respect to Label Integrity

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL								
EPA Registration#	Date Submitted to EPA	Electronic file name						
264-1057	10/09/07	000264-01057.20071009.AERISSeedApplie dInsecticideNematicide.pdf						

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

10/09/2007 Date Anna B. Wilkins Name (typed) Label Development Specialist Title