

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

DEC 1 7 2012

Dr. Larry Hodges
Bayer CropScience
2 T.W. Alexander Dr
P.O. Box 12014
Research Triangle Park, NC 27709

Subject:

Notification to add CA Proposition 65 statement to the label

Aeris Seed-Applied Insecticide/Nematicide

EPA Reg. No. 264-1057

Dear Dr. Hodges:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated November 29, 2012 for the product Aeris 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 action(s) 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 703-305-5967 or e-mail me at gaines.jennifer@epa.gov.

Sincerely,

Jennifer Gaines

Wildlife Biologist

Insecticide-Rodenticide Branch Registration Division (7505P)

Office of Pesticide Programs

2/9

			,
M			before comp
78858 7880	Instructions	<i>on reverse</i>	netore comi
TOTAL TOTAL	1110110000110	0/1 / 0 / 0/ 0	DOIDIO COMP

M IOIII

/MB No. 2070-0060. Approvel expires 2-28-9

\$EPA ■	nvironmenta	United States I Protection Ington, DC 204	_	ncy		✓	Registra Amenda Other		OPP Identifier Number
		Application	n for P	esticid	e - Sect	ion	l		
1. Company/Product Number				2. EPA P	oduct Mana	ger		3. Pr	posed Classification
264-1057				John He	ebert				None Restricted
4. Company/Product (Name) Aeris Seed-Applied Insec	ticide/Nematicid	e		PM# 7					
5. Name and Address of Applic	ant (Include ZIP Co	ode)							FIFRA Section 3(c)(3)
Bayer CropScience LP				(b)(i), my	product is	s simi	ilar or iden	icalia So	mposition and labeling
2 T. W. Alexander Drive					eg. No				
Research Triangle Park							D	EC 17	2012
Check if this is	a new address				t Name _				
			Sect	ion - II	·			····	
Amendment - Explain be	se to Agency letter	dated		- 📋	Final printed Agency lette "Me Too" A Other - Expl	er date pplica	ition.	e to	
Explanation: Use additional									
Notification, per PR Notice 98-10 contains a chemical known to th regulations at 40 CFR 152.46, a it is a violation of 18 U.S.C. Sec. of PR Notice 98-10 and 40 CFR and 14 of FIFRA.	e state of California nd no other change: . 1001 to willfully ma	to cause cance s have been ma ke any false sta	r." This no ide to the la itement to E	tification is abeling or t EPA. I furtl	consistent w he confidenti her understa	ith the al stat nd tha	e provisions of ement of for t if this notific	of PR Notice mula of this cation is no	e 98-10 and EPA product. I understand that consistent with the terms
			Secti	on - III					
1. Material This Product Will Be	Packaged In:								
Child-Resistant Packaging U	nit Packaging		Water S	ioluble Pac	ckaging		2. Type of	Container	
Yes	Yes			Yes			1	Metal Plastic	
✓ No	✓ No		V	No				Glass	
* (OFFITICATION MILET)	"Yes" nit Packaging wgt.	No. per container	If "Yes" Package		No. per container			Paper Other (S	pecify)
3. Location of Net Contents Info	ormation	4. Size(s) Ret	ail Contain	 er		5. Loc	ation of Lal	oel Directio	ns
	tainer	30 gal drui			ontainer	[1			
6. Manner in Which Label is Aff		Lithog Paper Stenci	raph	<u> </u>	Other				
		Stenci		on - IV					
1. Contact Point (Complete iter	disaathi balayy	las idantifiantia			contracted i	f noor	occur to a	acces this	opplication I
	ms directly below i	or Identificatio		iuai (o be	contacted, i	i nece	ssary, to pr		
Name Larry R. Hodges			Title Registrat	ion Mana	ger			919-549-	No. (Include Area Code) 2686
. I certify that the statemen I acknowledge that any k both under applicable law	nowlinglly false or		all attachn		hable by fin			t or	6. Date Application Received (Stamped)
2. Signature Lyk	2. Hodges		3. Title Registration	on Manage	((((((((((((((((((((((((((((((((((((((((()	
4. Typed Name			5. Date	-	<u> </u>	((
Larry R. Hodges			November 29: 2012						

Bayer CropScience

BAYER E R

Bayer CropScience 2 T.W. Alexander Drive P. O. Box 12014 Research Triangle Park, NC 27709 Tel: 919 549-2000

November 29, 2012

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

Re: Aeris Seed-Applied Insecticide/Nematicide (EPA Reg. No. 264-1057): Amendment by Notification (per PR Notice 98-10) to Add the Required California Proposition 65 Statement to the Label.

To Whom It May Concern:

As allowed by PR Notice 98-10, we are notifying the Agency of a minor labeling amendment for Aeris Seed-Applied Insecticide/Nematicide (EPA Reg. No. 264-1057). As required by California Proposition 65, the following statement has been added to the label, "This product contains a chemical known to the state of California to cause cancer."

"This notification is consistent with the provisions 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."

In support of this action, you will find the following:

- EPA Form 8570-1. Application for Pesticide Amendment, dated November 29, 2012.
- The amended label, dated November 29, 2012.
- The amended label, dated November 29, 2012, with the change highlighted in yellow.

Please email me at <u>larry.hodges1@bayer.com</u> or phone me at (919) 549-2686 if you have any questions regarding this submission.

Sincerely,

Larry R. Hodges, Ph.D. Registration Manager

Lan R. Hodges

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.

AERISTM Seed-Applied Insecticide/Nematicide For Use Only in Commercial Seed Treatment Equipment

ACTIVE INGREDIENTS	•
THIODICARB: Dimethyl N, N' [thiobis[(methylimino)carbonyloxy]]bis[ethanimidothioate]	24% by wt.
IMIDACLOPRID: 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine]	. 24% by wt.
INERT INGREDIENTS	52% by wt.
TOTAL:	100.00%

Contains 2.5 pounds active imidacloprid per U.S. gallon Contains 2.5 pounds active thiodicarb per U.S. gallon

EPA Reg. No. 264-1057

EPA Est. No.

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

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.
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, preferably mouth-to-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.

or 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 sweating, 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 a.i. (active ingredient) and 0.375 mg. thiodicarb a.i. 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 a.i. 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 a.i. per acre per season for seed treatment and foliar applications combined.

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

SOYBEAN

For Early Season Protection from Certain Nematodes and Certain Insects Attacking Soybean:

AERIS Seed Applied Insecticide/Nematicide will provide protection from early season injury to seeds and seedlings by nematodes attacking soybean, such as soybean cyst nematode and root knot nematode, and from damage caused by seed corn maggot, soybean aphids and over-wintering bean leaf beetles, and will help suppress the spread of certain viruses. Apply 3.2 – 6.4 fl. oz. of product per hundredweight of seed prior to planting as a slurry treatment so as to ensure thorough coverage. Use higher rates to provide increased length of protection and for heavy insect pressure.

Do not exceed a total of 3.0 pounds thiodicarb a.i. (active ingredient) per acre per season for seed treatment and foliar applications combined.

Do not exceed a total of 0.38 pound imidacloprid a.i. per acre per season for seed treatment, soil and foliar applications combined.

Do not allow grazing or feed soybean forage or hay to livestock.

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 seed treated with AERISTM Seed-Applied Insecticide/Nematicide:

- Store away from food and feedstuffs.
- Do not allow children, pets, or livestock 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.
- For cotton, growers must not exceed a total of 5.4 pounds thiodicarb a.i. (active ingredient) 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 a.i. per acre per season for seed treatment and foliar applications combined. Growers must not exceed a total of 0.5 pounds imidacloprid a.i. per acre per season for seed treatment, soil, and foliar applications combined.
- For soybean, growers must not exceed a total of 3.0 pounds thiodicarb a.i. per acre per season for seed treatment and foliar applications combined. Do not exceed a total of 0.38 pound imidacloprid a.i. per acre per season for seed treatment, soil and foliar applications combined. Do not allow grazing or feed soybean forage or hay to livestock.
- 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 AERISTM Seed-Applied Insecticide/Nematicide treated seed based upon local production and Best Management Practices as recommended by your state's Crop Specialist, IPM Coordinator or Extension Nematologist. For control only, in soils with a history of high nematode populations, an at-plant application of TEMIK® brand 15G Aidicard Pesticide is recommended.
- Always calibrate planters prior to planting to ensure the desired seeding ra(e.

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

Non-refillable container. Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. - Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inch on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.- Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

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.

This product contains a chemical known to the state of California to cause cancer.

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)

AERIS SEED™ Seed-Applied Insecticide/Nematicide (MASTER) 02/18/10, Notification 11/29/12