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

12/17/2012

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 EXP3 Seed-Applied Nematicide/Insecticide EPA Reg. No. 264-1048

Dear Dr. Hodges:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated <u>November 29, 2012</u> for the product <u>Aeris Seed-Applied</u> <u>Nematicide/Insecticide</u>. 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.

fer Sained Sincerely.

Jennifer Gaines Wildlife Biologist Insecticide-Rodenticide Branch Registration Division (7505P) Office of Pesticide Programs

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Please read instructions on r	everse before compl	j form			Form A	pproved	AB No.	2070-006	0. Approval expires 2-28-95
United States Environmental Protectio Washington, DC 204						Registration Amendme ✓ Other		OPP Identifier Number	
Application for Pesticide - Section I									
1. Company/Product Number 264-1048			2. EPA Product Manager John Hebert			3. Pr	oposed Classification		
4. Company/Product (Name) EXP3 Seed Applied Nematicide/Insecticide				PM# []					
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience LP 2 T. W. Alexander Drive Research Triangle Park, NC 27709			6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No						
			Sec	tion - I					
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section			Final printed labels in repsonse to Agency letter dated "Me Too" Application. Other - Explain below.						
Notification, per PR Notice 98 contains a chemical known to regulations at 40 CFR 152.46 it is a violation of 18 U.S.C. S of PR Notice 98-10 and 40 Cl and 14 of FIFRA.	-10: As required by C the state of California , and no other change ec. 1001 to willfully ma	alifornia Propositi to cause cancer. s have been mad ike any false state	ion 65 th " This n le to the ement to ion of FI	e following otification is labeling or EPA. I fur FRA and I r	consisten the confide ther unders nay be sub	t with the ntial stat stand the	e provisions of tement of for at if this notifi	of PR Notic mula of this cation is no	e 98-10 and EPA product. I understand that t consistent with the terms
			Sec	tion - II]				·
1. Material This Product Will	Be Packaged In:						T		
Child-Resistant Packaging Yes ✓ No * Certification must be submitted	Unit Packaging Yes Vos If "Yes" Unit Packaging wgt. Vo. per container		↓ If "Yes	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 I	3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions						ons		
✓ Label C	ontainer	30 gal drum	s & 260) gal bulk d	ontainer	-			
6. Manner in Which Label is ,	Affixed to Product	Lithogra Paper g Stencile	iph lued id		Oth	er			
			Sect	tion - IV	1				
1. Contact Point <i>(Complete)</i>	items directly below i	for identification	of indiv	idual to be	contacted	l, if nec	essery, to p	rocess this	application.)
Name Larry R. Hodges			Title Registration Manager			Telephon 919-549-	e No. (Include Area Code) 2686		
i certify that the staten i acknowledge that any both under applicable i	/ knowlinglly false or		ll attach						6. Date Application Received (Stamped)
2. Signature LyR. Hodges			3. Title Registration Manager						
4. Typed Name			5. Date					1	
Larry R. Hodges			November 29, 2012						
EPA Form 8570-1 (Rev. 3-94)	Previous editions ar	e obsolete.			W	hite - Ef	A File Copy	(original)	Yellow - Applicant Copy



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

Bayer CropScience

Re: EXP3 Seed Applied Nematicide/Insecticide (EPA Reg. No. 264-1048): 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 EXP3 Seed Applied Nematicide/Insecticide (EPA Reg. No. 264-1048). 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,

Ray R. Hodges

Larry R. Hodges, Ph.D. Registration Manager

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.

EXP3 Seed Applied Nematicide/Insecticide

NOTIFICATION

DEC 1 7 2012

For Use Only in Commercial Seed Treatment Equipment

EPA Reg. No. 264-1048

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN WARNING AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

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:	 Immediately call a poison control center or doctor for treatment advice. 						
	 Do not induce vomiting unless told to do so 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:	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.						
IF ON SKIN OR CLOTHING:	Take off contaminated clothing.						
	Rinse skin immediately with plenty of water for 15-20 minutes.						
<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 an ambulance, then give artificial respiration, preferably mouth-to- mouth if possible.						
· · · · · · · · · · · · · · · · · · ·	Call a poison control center or doctor for further treatment advice.						
	For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.						
Have the prod	uct 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. EXP3 Seed Applied Nematicide/Insecticide 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

WARNING

May be fatal if swallowed. Harmful if 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, chemical resistant footwear plus socks, chemical resistant gloves made out of any waterproof material, chemical-resistant apron 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 pesticide is toxic to fish, aquatic invertebrates 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 EXP3 Seed Applied Nematicide/Insecticide in any tank mixture the compatibility of the mixture be established. Add EXP3 Seed Applied Nematicide/Insecticide 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 Insecticide is hydrolytically sensitive to degradation of active ingredient by strong acids AND strong bases. DO NOT ADD EXP3 SEED APPLIED NEMATICIDE/INSECTICIDE TO WATER WITH pH VALUES BELOW 3.0 OR ABOVE 8.5. If necessary, water should be buffered within this range before adding EXP3 Seed Applied Nematicide/Insecticide. 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.

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.

SEED TREATMENT USE FOR COTTON (Delinted Seed Only)

For Early Season Suppression of Certain Nematodes and Protection Against Certain Early Season Insects EXP3 Seed Applied Nematicide/Insecticide provides early season suppression of damage to cotton seeds and seedlings by Reniform and root knot nematodes and will aid in the protection of seedlings against injury by certain early season insects.

		DC	DSAGE		
SITE	PEST	mg a.i. per Seed	Fluid oz. per Hundredweight	SPECIFIC DIRECTIONS	USE RESTRICTIONS
COTTON (Delinted Seed)	Reniform and root knot nematodes (suppression)	0.375 to 0.563	20 to 30	Where the specific application rate is desired on an individual seed basis, apply 0.375 to 0.563 mg a.i. per seed prior to planting as a slurry treatment so as to ensure thorough coverage. Otherwise, apply at 20 to 30 fluid ounces per hundredweight of seed.	Do not apply more than 30 fluid ounces per hundredweight of seed. Do not exceed a total of 5.4 pounds 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 active ingredient per acre per season for seed treatment and foliar applications combined.

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SEED TREATMENT USE FOR SOYBEAN

For Early Season Suppression of Nematodes Attacking Soybean:

EXP3 Seed Applied Nematicide/Insecticide will suppress early season injury to seedlings by nematodes attacking soybean, such as soybean cyst nematode and root knot nematode.

To provide early season protection of seedlings against injury by nematodes attacking soybean, apply at 2.5 to 5.0 fluid ounces 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 nematode pressure.

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

Do not feed forage, hay, or straw 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 Insecticide.
- 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 EXP3 Seed Applied Nematicide/Insecticide:

- 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.
- 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 wildlife. Cover or collect treated seeds that are spilled during loading and in areas such as row ends.
- For cotton, 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.
- For soybean, growers must not exceed a total of 3.0 pounds thiodicarb per acre per season for seed treatment and foliar
 applications combined. Do not feed forage, hay, or straw to livestock.
- Dispose of all excess treated seed by burying seed away from bodies of water.
- Do not contaminate bodies of water when disposing of planting equipment wash water.
- Dispose of seed packaging in accordance with local requirements.
- Plant EXP3 Seed Applied Nematicide/Insecticide treated seed based upon local production and Best Management Practices as
 recommended by your state's Crop Specialist, IPM Coordinator or Extension Nematologist. For cotton seed only: In soils with a
 history of high nematode populations, an at-plant application of TEMIK[®] brand 15G Aldicarb Pesticide is recommended.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not store in or around the home. Store unused product in a cool, ventilated, dry, locked area. Do not allow prolonged storage in areas where temperatures frequently exceed 115°F (46°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 by 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 EXP3 Seed Applied Nematicide/Insecticide. 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 EXP3 Seed Applied Nematicide/Insecticide TELEPHONE (24 HOURS A DAY) IN THE U.S.A. 1-800-334-7577.

In case of minor spills or leaks follow all precautions indicated above and cleanup immediately. Soak up with sand, earth or other suitable material. Before clean-up, put on long-sleeved shirt and long pants, chemical resistant gloves made out of any waterproof material, shoes plus socks, and chemical-resistant headgear for overhead exposure.

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.

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)

EXP3 Seed Applied Nematicide/Insecticide (PENDING) 12/28/07, Notification 11/29/12