



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Larry R. Hodges
Bayer CropScience LP
2 T.W. Alexander Drive,
Research Triangle Park, NC 27709

AUG 07 2009

SUBJECT: Label Notification(s) for Pesticide Registration Notice PRN 2007-4
Request Storage and disposal changes
EPA Reg. No. 264-943
Application Dated June 24, 2009

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated 6/24/2009 for the product **RTU-Vitavax-Thiram Seed Protectant Fungicide**. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-4 and finds that the action(s) requested does not clearly fall within the scope of PRN 2007-4 and will require additional administrative review of the related files. A summary of our findings include:

The statements for rigid non-refillable containers larger than 5 gallons and the refillable statements are not exact as in the PR Notice. Modified statements must be reviewed as an amendment.

Therefore, the RD has determined that this action is denied and will be further processed as an amendment and our records have been updated accordingly. The label submitted with the application is considered proposed drafts and has been forwarded to Tony Kish (PM 22) for further processing.

If you have any questions, please call me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269

Sincerely,
Rachel C. Holloman
Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-943	2. EPA Product Manager NOTIF	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) RTU-Vitavax-Thiram Seed Protectant Fungicide	PM# 22	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience LP 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. NOTIFICATION Product Name AUG 07 2009	

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.

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

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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."

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input checked="" type="checkbox"/> Paper
				Other (Specify) fiber drum	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gal. bottle and 50 gal. fiber drum		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued 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 Larry R. Hodges	Title Registration Manager - Insecticides	Telephone No. (Include Area Code) 919-549-2870
2. Signature 		6. Date Application Received (Stamped)
3. Title Registration Manager - Insecticides		
4. Typed Name Larry R. Hodges		
5. Date June 24, 2009		

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.

3/8

NOTIFICATION

AUG 07 2009

RTU[®]-VITAVAX[®]-THIRAM

Seed Protectant Fungicide

For sale to and use by professional applicators only. Not for sale or use by homeowners/consumers. Contains petroleum distillate.

ACTIVE INGREDIENTS:

Carboxin: (5,6-Dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide).....	10.0%
Thiram (Tetramethylthiuram disulfide)	10.0%

INERT INGREDIENTS:	80.0%
TOTAL 100.00%	

EPA Reg. No. 264-943

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"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person.
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 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 INHALED:	<ul style="list-style-type: none"> • 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.

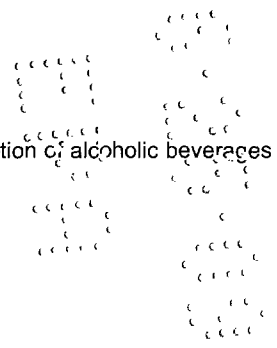
NOTE TO PHYSICIAN: Contains petroleum distillate – vomiting may cause aspiration pneumonia.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.
Have a 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. Avoid contact with skin and clothing. Do not use or store near food or feed. Consumption of alcoholic beverages increases the toxic effects of thiram.



PERSONAL PROTECTIVE EQUIPMENT (PPE)

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

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

Long-sleeved shirt and long pants

Shoes and socks

Chemical-resistant gloves

Chemical-resistant apron when loading, cleaning up spills, or cleaning equipment.

NOTE: Persons involved in bagging treated seed, sewing or moving bags of treated seed, or cleaning up bagging areas or seed treatment equipment are pesticide handlers and must wear the PPE required for this label for pesticide handlers.

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.

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 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. 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

This chemical is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate.

Treated seed are hazardous to fish, birds and mammals. Do not plant treated seeds 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 planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.

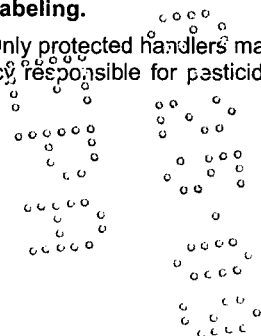
ENDANGERED SPECIES

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.

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.



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 agriculture 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. 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 subsurface.

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, or treated seed, is: coveralls, shoes plus socks and chemical-resistant gloves made of any waterproof material.

SEED LABELING (Commercial Seed)

Seed that are treated with this product and are then packaged or bagged for future use must contain the following 13 statements on the outside of the seed package or bag.

1. This seed treated with Carboxin and Thiram. Do not use treated seed for food, feed, or oil purposes. Add appropriate information for any other chemical treatments.
2. Store away from feeds and foodstuffs.
3. When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.
4. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds.
5. 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.
6. After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 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 seeds.
7. Planting Note: Seed treated with this product does not flow as freely as untreated seed. The drill should therefore be adjusted to compensate for this restricted seed flow to prevent lower than desired seeding rates.
8. Augers used for handling treated seed should not be used to move grain for food, feed or oil processing.
9. Do not reuse bags from treated seed to handle food or feed products.
10. Do not graze or feed livestock on vines grown from treated seed. Dry Beans: Do not allow livestock to graze or feed on bean forage until 60 days after treated seed is planted.
11. Treated seeds are hazardous to fish, birds and mammals. Do not plant treated seeds 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 planter during planting, additional incorporation may be required to thoroughly cover exposed seeds.
12. 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 or by disposal of wastes.
13. Plant cotton, wheat, barley and oat seed a minimum of 1 inch deep.

DIRECTIONS FOR USE

RTU-VITAVAX-THIRAM Seed Protectant Fungicide is a ready-to-use seed treatment. Apply as a commercial seed treatment or as a pour-on hopper-box application. This product does not require the addition of water for application.

RTU-VITAVAX-THIRAM Fungicide combines the systemic action of carboxin with the surface action of thiram to control various seed and seedling diseases. It is particularly effective against *Rhizoctonia solani* and shows good activity against various *Helminthosporium*, *Fusarium* and *Pythium* species. This often results in increased and more uniform stands of seedlings with higher yield potential. Use the higher rate under conditions of expected heavy disease pressure.

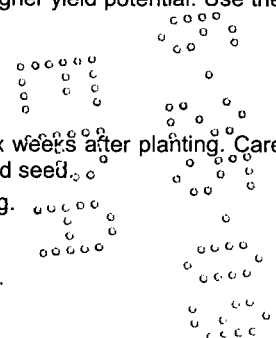
USE RESTRICTIONS

Do not use treated seed for food or feed purposes. Do not graze or feed livestock on treated areas for six weeks after planting. Care must be exercised in the handling of treated seed. Do not graze or feed livestock on vines grown from treated seed.

Barley, Wheat, Oats and Triticale: Do not graze or feed livestock on treated areas for six weeks after planting.

Soybeans: Do not graze or feed livestock on forage and hay on treated areas.

Dry Beans: Do not allow livestock to graze or feed on bean forage until 60 days after treated seed is planted.



COMPATIBILITY

RTU-VITAVAX-THIRAM Fungicide should not be tank mixed with any pesticide unless adequate physical compatibility and phytotoxicity tests have been completed and proved to be satisfactory.

DIRECTIONS FOR USE AS A HOPPER-BOX SEED TREATMENT

Mix well before use: Apply RTU-VITAVAX-THIRAM Fungicide directly to seed in hopper box. Partially fill hopper box with a premeasured amount of seed. Apply the proper amount of RTU-VITAVAX-THIRAM Fungicide evenly over the surface of the seed. Mix with a stick or paddle until a uniform color is imparted to all seed. Repeat procedure until hopper box is filled.

Barley, Wheat, Oats and Triticale:

In addition, loose smut (*Ustilago nuda*), covered smut (*Ustilago hordei*), and flag smut (*Urocystis agropyri*) are controlled on barley and loose smut (*Ustilago tritici*), common bunt (*Tilletia caries*), and flag smut (*Urocystis agropyri*) are controlled on wheat by RTU-VITAVAX-THIRAM Fungicide.

Use 5 to 6.8 fl oz of RTU-VITAVAX-THIRAM Fungicide per 100 lbs of seed. The higher rate is recommended where smuts and bunt are severe.

Do not graze or feed livestock on treated areas for six weeks after planting.

Dry Beans, Soybeans:

RTU-VITAVAX-THIRAM provides suppression of seedborne *Sclerotinia* and *Phomopsis* seed decay, seed and seedling disease caused by *Fusarium* and *Pythium* and protection against damping-off caused by *Rhizoctonia solani*.

Use 4.0 fl oz of RTU-VITAVAX-THIRAM Fungicide per bushel of seed or 6.8 fl oz per 100 lbs of seed.

On soybeans, do not graze or feed livestock on forage and hay on treated areas. On dry beans, do not allow livestock to graze or feed on bean forage until 60 days after treated seed is planted.

Cotton:

RTU-VITAVAX-THIRAM Fungicide provides systemic control of seed and seedling diseases of cotton. Seed rot, damping-off and sore-shin due to *Rhizoctonia solani* are reduced. RTU-VITAVAX-THIRAM Fungicide can be used on both machine and acid-delinted cottonseed at the rate of 6.8 fl oz 11 to 13.5 fl oz per 100 lbs of seed.

Rice:

Use 5.0 to 6.8 fl oz of RTU-VITAVAX-THIRAM Fungicide per 100 lbs of seed. The higher rate is recommended for control of *Helminthosporium oryzae*.

DIRECTIONS FOR USE AS A COMMERCIAL SEED TREATMENT

Application should be made using standard mechanical, slurry or mist-type seed treatment equipment. Uniform application is necessary to insure seed safety and best disease control. Seed should be sound and well cured prior to treatment



STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not store near heat or open flame.

PESTICIDE DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, 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

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

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

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 ¼ 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.

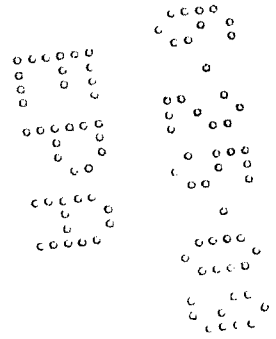
Once container is rinsed, offer for recycling if available, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons).

Non-refillable container. Do not reuse or refill this container. After emptying product from container, contact Bayer CropScience Customer Service Center (1-800-527-4781) with return authorization for container return instructions. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Once container is rinsed, offer for recycling if available 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.

Refillable container.

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, contact Bayer CropScience Customer Service Center (1-800-527-4781) with return authorization for container return instructions. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Once container is rinsed, offer for recycling if available 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.



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:

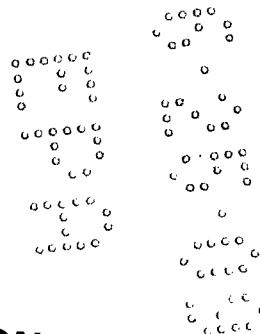
RTU is a registered trademark of Bayer
VITAVAX is a registered trademark of Chemtura Inc.

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)**



NOTIFICATION

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