

264-749

7/30/2009

1 of 12



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

JUL 30 2009

SUBJECT: Application for Pesticide Notification – Changing NY Restrictions on Label
Elite® 45 DF Foliar Fungicide
EPA Reg. No. 264-749
Application June 1, 2009

Dear Mr. Tolliver:

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

If you have any questions, please call me directly at 703-305-6249 or Terri Stowe of my staff at 703-305-6117.

Sincerely,

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

30912

Bayer CropScience



Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
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One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

June 1, 2009

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
RTP, NC 27709
Phone: (919) 549-2000

Subject: Elite 45 DF Foliar Fungicide Fungicide, EPA Reg. No. 264-749
Notification of Other Revisions per PR Notice 98-10

Dear Sir or Madam:

In New York's Pesticide Product Registration Section May 18, 2009 letter (copy enclosed) Bayer CropScience is required to revise our Elite 45 DF Foliar Fungicide label by replacing statements such as "By ground application only in the state of New York" and "No aerial application is allowed on Long Island, New York" with "Aerial application is prohibited in New York State." In response to this letter, enclosed is a notification to make these label changes. There are no other changes in the labeling from that which is currently registered.

Since this is a notification, no fee is required under PRIA II.

If you have any questions or need additional information, please contact me by phone at (919) 549-2631 or by e-mail at mel.tolliver@bayercropscience.com.

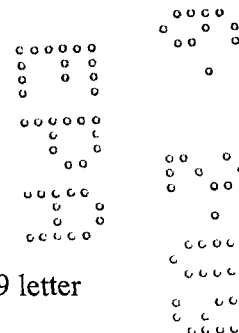
Sincerely,

Melvin K. Tolliver

Melvin K. Tolliver
Registration Product Manager, Fungicides

Enclosures:

1. EPA application form 8570-1
2. Draft labeling with changes highlighted in yellow and redlining
3. Final Printed labeling (two copies)
4. Copy of New York's Pesticide Product Registration Section May 18, 2009 letter



5012

NOTIFICATION

JUL 30 2009

GROUP 3 FUNGICIDE

Elite[®] 45 DF Foliar Fungicide

ACTIVE INGREDIENT: Tebuconazole, α -[2-(4-chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol 45%

OTHER INGREDIENTS: 55%

100%

EPA Reg. No. 264-749

EPA Est. No.

STOP - Read the label before use
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.
 (TO THE USER: If you do not understand the label, find someone to explain it to you in detail.)

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 in eyes	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15 to 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 swallowed	<ul style="list-style-type: none"> 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 clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.
 Have a product container or label with you when calling a poison control center or doctor, or going for treatment.

Note To Physician: No specific antidote. Treat symptomatically.

Symptoms of Poisoning: The compound does not cause any definite symptoms that would be diagnostic. Contact with the eyes may cause irritation.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

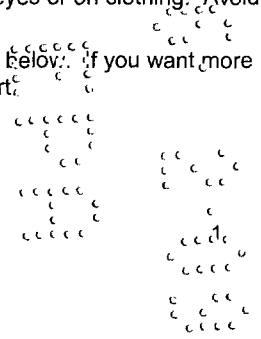
WARNING

Causes substantial but temporary eye injury. Harmful if swallowed, inhaled or absorbed through the skin. Prolonged or frequently repeated skin contact may cause allergic skin reactions in some individuals. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing dust or spray mist.

Personal Protective Equipment (PPE): Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for Category A on an EPA Chemical Resistant Category Selection Chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks



600F12

- Protective eyewear

Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

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

USER SAFETY RECOMMENDATIONS

Users should:

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

ENVIRONMENTAL HAZARDS

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

Ground Water Advisory: Tebuconazole is known to leach through soil into ground under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination.

Surface Water Advisory: This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted within 48 hours.

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.

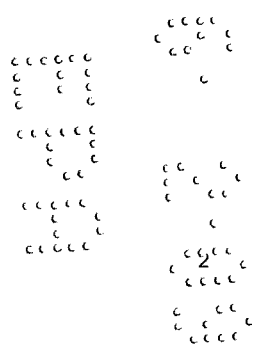
AGRICULTURAL USE REQUIREMENTS

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 agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), restricted-entry interval and notification to workers. 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). The REI for each crop is listed in the application directions associated with each crop.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material
- Shoes plus socks
- Protective eyewear



- * Adjust deflectors and aiming devices so that spray is only directed into the canopy;
- * Block off upward pointed nozzles when there is no overhanging canopy;
- * Use only enough air volume to penetrate the canopy and provide good coverage;
- * Do not allow the spray to go beyond the edge of the cultivated area (i.e., turn off sprayer when turning at end rows);
- * Only spray inward, toward the orchard or vineyard, for applications to the outside rows.

Runoff Management: Do not cultivate within 10 feet of the aquatic areas to allow growth of a vegetative filter strip. When used on erodible soils, best management practices for minimizing runoff should be employed. Consult your local Soil Conservation Service for recommendations in your use area.

ROTATIONAL CROPS

Any crop not specified on this label may be planted into treated areas 120 days after last application.

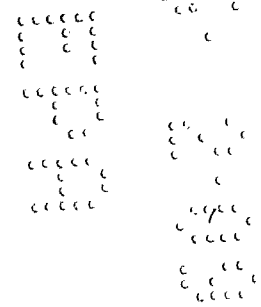
APPLICATION DIRECTIONS		
CROP	DISEASE	RATE OF ELITE 45 DF FOLIAR FUNGICIDE
Grape	Black rot (<i>Guignardia bidwellii</i>) Powdery mildew (<i>Uncinula necator</i>)	4 oz./A
<p>Powdery Mildew Apply in a preventive spray schedule. Make the first application of ELITE 45 DF FOLIAR FUNGICIDE before bloom and continue applications using spray intervals of up to 21 days in low to moderate disease pressure. Use a 14-day schedule when disease pressure is severe.</p> <p>Black Rot <u>Preventive Schedule:</u> Make the first application at 1 to 3 inches of new shoot growth and continue at 7- to 14-day intervals through 5° Brix stage or until veraison (berry coloring) is complete. Apply at 1 inch new shoot growth and at 7- to 10-day intervals on highly susceptible varieties or under severe disease conditions. <u>Post-Infection Schedule:</u> A post-infection schedule may be followed from 1-inch new shoot growth through 5° Brix stage. Apply within 72 hours after the beginning of an infection period. ELITE 45 DF FOLIAR FUNGICIDE applications should not be closer than 7 days apart. Continue ELITE 45 DF FOLIAR FUNGICIDE applications using the preventive schedule if the post-infection schedule is discontinued.</p> <p>Botrytis ELITE 45 DF FOLIAR FUNGICIDE, applied in a powdery mildew spray schedule, will enhance the activity of registered fungicides used for control of Botrytis bunch rot. Applications must be made on a 14-day schedule for suppression of Botrytis.</p> <p>GENERAL REMARKS: ELITE 45 DF FOLIAR FUNGICIDE may be applied up to 14 days before harvest. A maximum of 2 pounds of ELITE 45 DF FOLIAR FUNGICIDE may be applied per acre per crop season. The minimum interval between applications is 7 days.</p> <p>Apply product in sufficient water for thorough coverage of vines and fruit. Increase spray volume as vine growth increases. Restricted-entry interval (REI) = 12 hours.</p> <p>RESISTANCE MANAGEMENT STRATEGY: ELITE 45 DF FOLIAR FUNGICIDE is a sterol demethylation inhibitor (DMI) fungicide. It may be applied in a tank-mix or alternated (every other spray application) with a non-DMI fungicide as a resistance management strategy. Tank-mixing ELITE 45 DF FOLIAR FUNGICIDE with other DMI fungicides is not recommended.</p>		

APPLICATION DIRECTIONS		
CROP	DISEASE	RATE OF ELITE 45 DF FOLIAR FUNGICIDE
Banana Plantain	Black Leaf Streak (<i>Mycosphaerella fijiensis</i>) Yellow Sigatoka (<i>Mycosphaerella musicola</i>)	3.2 oz./A
<p>Apply specified dosage as a foliar spray in a minimum of 20 gallons or more of water per acre to assure thorough coverage of the plants. A spray oil recommended for use on banana or plantain should be utilized at 4.3 pints per acre in tank-mix with ELITE 45 DF FOLIAR FUNGICIDE. Thoroughly mix ELITE 45 DF FOLIAR FUNGICIDE in the spray solution prior to the addition of spray oil. Make the first application before disease becomes established and repeat applications at 14-day intervals if necessary to maintain disease control.</p> <p>Do not apply ELITE 45 DF FOLIAR FUNGICIDE to non-bagged bananas. A maximum of 16 ounces of ELITE 45 DF FOLIAR FUNGICIDE may be applied per acre per harvest cycle. ELITE 45 DF FOLIAR FUNGICIDE may be applied up to the day of harvest.</p> <p>Restricted-entry interval (REI) = 12 hours.</p>		

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APPLICATION DIRECTIONS		
CROP	DISEASE	RATE OF ELITE 45 DF FOLIAR FUNGICIDE
Tree Nuts: Almond (see specific use directions) Beechnut Brazil nut Butternut Cashew Chestnut Chinquapin Filbert (see specific use directions) Hickory nut Macadamia nut Pistachios (see specific use directions) Walnut	Brown rot blossom blight (<i>Monilinia laxa</i> , <i>M. fructicola</i>) Botryosphaeria panicle and shoot blight (<i>Botryosphaeria dothidea</i>) Eastern filbert blight (<i>Anisogramma anomala</i>)	8 oz/A
<p>Begin applications when conditions are favorable for disease but before infection. Apply on a 7- to 14-day spray schedule.</p> <p>A maximum of 32 ounces of product may be applied per acre per crop season. Do not cut cover crops in treated areas for feed, or allow livestock to graze treated areas. ELITE 45 DF FOLIAR FUNGICIDE may be applied up to 35 days before harvest.</p> <p>Restricted-entry interval (REI) = 12 hours.</p> <p>RESISTANCE MANAGEMENT STRATEGY: ELITE 45 DF FOLIAR FUNGICIDE is a demethylation inhibitor (DMI) fungicide. It may be applied in a tank mix or alternated (every other spray application) with a non-DMI fungicide as a resistance management strategy. Tankmixing ELITE 45 DF FOLIAR FUNGICIDE with other DMI fungicides is not recommended.</p>		
Almond	Brown rot blossom blight (<i>Monilinia laxa</i> , <i>M. fructicola</i>)	8 oz/A
<p>Blossom blight: Begin application at pink bud. If the bloom period is extended, and/or severe disease conditions exist, make a second application at full bloom. If conditions remain favorable for disease, make another application at petal fall.</p> <p>GENERAL REMARKS: Apply ELITE 45 DF FOLIAR FUNGICIDE in a minimum spray volume of 15 gallons per acre by air or 50 gallons per acre by ground. Reduce the application interval for varieties that are highly susceptible to the indicated diseases or when severe disease conditions exist. The use of ground application after petal fall is preferred because of difficulty in penetrating the canopy and obtaining thorough coverage of the foliage and fruit by air.</p> <p>A maximum of 32 ounces of product may be applied per acre per crop season. Do not cut cover crops in treated areas for feed, or allow livestock to graze treated areas. ELITE 45 DF FOLIAR FUNGICIDE may be applied up to 35 days before harvest.</p> <p>Restricted-entry interval (REI) = 12 hours.</p> <p>RESISTANCE MANAGEMENT STRATEGY: ELITE 45 DF FOLIAR FUNGICIDE is a demethylation inhibitor (DMI) fungicide. It may be applied in a tank mix or alternated (every other spray application) with a non-DMI fungicide as a resistance management strategy. Tankmixing ELITE 45 DF FOLIAR FUNGICIDE with other DMI fungicides is not recommended.</p>		
Pistachio	Botryosphaeria panicle and shoot blight (<i>Botryosphaeria dothidea</i>)	8 oz/A
<p>Botryosphaeria: Begin application at 25 to 50% bloom and repeat again 10 to 14 days later to protect young flower clusters and fruit. Make two additional applications of ELITE 45 DF FOLIAR FUNGICIDE 14 days apart beginning 49 days before harvest.*</p> <p>GENERAL REMARKS: Apply ELITE 45 DF FOLIAR FUNGICIDE in a minimum spray volume of 15 gallons per acre by air or 50 gallons per acre by ground. Reduce the application interval for varieties that are highly susceptible to the indicated diseases or when severe disease conditions exist. The use of ground application after flowering is preferred because of difficulty in penetrating the canopy and obtaining thorough coverage of the foliage and fruit by air.</p> <p>A maximum of 32 ounces of product may be applied per acre per crop season. Do not cut cover crops in treated areas for feed, or allow livestock to graze treated areas. ELITE 45 DF FOLIAR FUNGICIDE may be applied up to 35 days before harvest.</p> <p>Control of insect vectors and a thorough pruning program to remove plant tissue infected by <i>Botryosphaeria</i> are critical for optimum control of this disease.</p> <p>Restricted-entry interval (REI) = 12 hours.</p> <p>RESISTANCE MANAGEMENT STRATEGY: ELITE 45 DF FOLIAR FUNGICIDE is a demethylation inhibitor (DMI) fungicide. It may be applied in a tank mix or alternated (every other spray application) with a non-DMI fungicide as a resistance management strategy. Tankmixing ELITE 45 DF FOLIAR FUNGICIDE with other DMI fungicides is not recommended.</p>		

APPLICATION DIRECTIONS			
CROP	DISEASE	RATE OF ELITE 45 DF FOLIAR FUNGICIDE	
Stone Fruits: Apricot Cherry Nectarine Peach Plum Plumcot Prune (fresh)	Brown rot (blossom blight, fruit rot) (<i>Monilinia laxa</i> , <i>M. fructicola</i>) Cherry Leaf Spot (<i>Blumeriella jaapii</i>) Powdery mildew (<i>Podosphaera</i> spp., <i>Sphaerotheca pannosa</i>)	4 to 8 oz./acre*	2 oz./100 gal.**
Plum Plumcot Prune (fresh) Peach	Rust (<i>Tranzschelia discolor</i>)	5 to 8 oz./acre*	
<p>Blossom blight: Begin application at white bud on cherry, pink bud on peach and nectarine, and green tip on plums and prunes. Apply again at 50% bloom and at petal fall if conditions continue to be favorable for disease development.</p> <p>Fruit rot: Begin application at two to three weeks before harvest and continue at 7-day intervals through the day of harvest. The blossom and fruit stages must be protected for optimum control of brown rot. If ELITE 45 DF FOLIAR FUNGICIDE is applied during only one of these stages, another registered fungicide should be applied to the other stage to provide optimum protection. Additional cover sprays during the early post-bloom period are also important for preventing quiescent fruit infections on sweet cherry and peach.</p> <p>Leaf spot: Begin application at petal fall or when first leaves unfold and continue applications at 7- to 14-day intervals. Applications should be made at 7-day intervals early in the growing season when terminal growth is rapid and/or under severe disease conditions. A post-harvest application may be made to maintain control and reduce overwintering inoculum.</p> <p>Powdery mildew: Follow leaf spot schedule until terminal growth ceases.</p> <p>Rust: Begin applications after canker emergence and continue applications at 14-day intervals under severe disease conditions.</p> <p>GENERAL REMARKS: ELITE 45 DF FOLIAR FUNGICIDE may be applied up to and including the day of harvest (0-day PHI). Do not apply more than 3 lb. of product per acre per crop season. * The amount of ELITE 45 DF FOLIAR FUNGICIDE required per acre will depend on tree size and volume of foliage present. The rate per acre is based on a standard of 400 gallons of dilute spray solution per acre for large trees. For smaller trees, multiply 2 ounces times the number of 100 gallons of spray solution required to thoroughly wet, to the point of runoff, one acre of the trees being treated. For concentrate sprays, apply the same amount of product per acre as would be applied in a dilute spray based on tree size and foliage volume, but not less than 4 ounces of ELITE 45 DF FOLIAR FUNGICIDE per acre. Apply 6 to 8 ounces per acre of ELITE 45 DF FOLIAR FUNGICIDE when severe disease conditions exist. ** When using the 2 oz./100 gal. rate, use at least 4 ounces of ELITE 45 DF FOLIAR FUNGICIDE per acre.</p> <p>Restricted-entry interval (REI) = 5 days.</p> <p>RESISTANCE MANAGEMENT STRATEGY: ELITE 45 DF FOLIAR FUNGICIDE is a demethylation inhibitor (DMI) fungicide. It may be applied in a tank-mix or alternated (every other spray application) with a non-DMI fungicide as a resistance management strategy. Do not mix ELITE 45 DF FOLIAR FUNGICIDE with other DMI fungicides.</p>			
Plums (Post-Harvest) Including Chickasaw, Damson, Japanese, Plumcot, Prune (Fresh)	Brown rot (<i>Monilinia</i> spp.) Grey Mold (<i>Botrytis cinerea</i>) Rhizopus rot (<i>Rhizopus</i> spp.)	8.0 oz. per 200,000 lb. of fruit	
<p>Mix specified rate of ELITE 45 DF FOLIAR FUNGICIDE in 100 gallons of water, with or without wax. Maintain ELITE 45 DF FOLIAR FUNGICIDE suspension by direct or by-pass agitation sufficient to prevent settling of product in spray mixture. Apply as spray to fruit as they travel along packing line. After sizing, sorting or washing, ELITE 45 DF FOLIAR FUNGICIDE application may be incorporated into a waxing system using conventional equipment that provides for even and complete coverage of fruit. Do not apply more than once prior to boxing and do not rise.</p>			



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IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO 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:

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)

Elite 45 DF Foliar Fungicide (MASTER) Approved 07/31/08, Notification 05/11/09, Notification 05/29/09

NOTIFICATION

JUL 30 2009

