

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAY 2 - 2007

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Norma C. Pangilinan Bayer Environmental Science 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Subject:

Efficacy Data Claim Support Merit FXT Tablet Insecticide EPA Reg. No. 432-1457

Your Submission date: January 2, 2007

Dear Ms. Pangilinan:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended is acceptable provided you make the following change are made:

- 1. Add in the descriptive use line located under the product name "For insect control in residential and commercial in forestry, nurseries, greenhouses ... as noted on the original label add.
- 2. Under the "Precautionary Statements" use the complete Agency's glove statement which should read as "chemical-resistant gloves made of any waterproof material such as, barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton".
- 3. The data submitted does not support a two year claim of high level control against various pests. Read enclosed review from Efficacy team.
- Within the Nursery and Greenhouse section of the level, revise the sentence "Merit FXT Tablet Insecticide will control or significantly reduce populations of insects ... to read "Merit FXT Table Insecticide will control or significantly reduce populations of insects that attack containerized, newly planted, and establishes trees for a full season" or delete altogether.
- Within the Landscape, Interiorscapes and Forested Areas section of the label, revise the sentence "Merit FXT Tablet Insecticide will control or significantly reduce populations of insects that attack containerized...to read "Merit FXT Table Insecticide will control or

significantly reduce populations of insects that attack containerized, newly-planted, and established trees for a full season" or delete altogether.

- Within the Forestry section of the label, revise the sentence "Merit FXT Tablet Insecticide will control or significantly reduce populations of insects that attack newly-planted seedlings..." to read "Merit FXT Tablet Insecticide will control or significantly reduce populations of insects that attack newly-planted seedlings and established seedling trees for a full season," or delete altogether.

A stamped copy is enclosed for your records. Submit two (2) copies of your final printed labeling before you release the product for shipment. If there are questions call me at 703 305-5409.

Sincerely,

Dani Daniel

Insecticide-Rodenticide Branch Registration Division 7505P

Enclosure:

Merit® FXT Tablet Insecticide In EPA Lottor Dated:

with COMMENTS

For use in forestry.	MAY 2 - 2007
For use in nurseries, greenhouses and interiorscapes.	Under the Federal Impariable
For use in forestry and landscapes.	Pengleide, and Reductions Act,
ACTIVE INGREDIENT:	regulatored under RPA Res. No.
*Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine	20%
OTHER INGREDIENTS:	<u>80%</u>
Fertilizer Analysis: X-X-X	100%
May be protected under U.S. Patent No. 5,783,203	
EPA Reg. No. 432-1457	EPA Est. No

STOP - Read the label before use. Keep out of reach of children.

CAUTION

For MEDICAL and TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-331-7577 For PRODUCT USE Information Call 1-800-331-2867

FIRST AID		
IF ON SKIN OR CLOTHING	 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 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 IN EYES	 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. 	
	by call toll free the Bayer Environmental Science Emergency Response Telephone No. 1-800-334-7577. Have or label with you when calling a poison control center or doctor, or going for treatmer t.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes, or clothing.

Personal Protective Equipment (PPE):

WPS USES: Applicators and Other Handlers who handle this product for any use covered by the Worker Protection Standard (40 CFR part 170) - in general, agricultural plant uses e.g., use in nursery, must wear:

- · Long-sleeved shirt and long pants
- · Chemical resistant gloves made of any waterproof material such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber. natural rubber, polyethylene, polyvinylchloride (PVC) or viton.
- Shoes plus socks

Non-WPS USES: Applicators and other handlers who handle this product for any use NOT covered by the Worker Protection Standard (40 CFR part 170) - in general, only agricultural plant uses are covered by the WPS, must wear:

- Shirt and pants
- · Shoes plus socks
- Gloves

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

User Safety Recommendations

User 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.
- 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.

ENVIRONMENTAL HAZARDS

This product is highly toxic to 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. Do not contaminate water when disposing of equipment washwaters.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds.

This chemical demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

Do not formulate this product into other end-use products.

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 requirement specific to your State or Tribe, consult the agency responsible for pesticide regulation.

MERIT FXT Tablet Insecticide can be used as directed on trees and shrubs in sites such as home lawns, business and office complexes, shopping complexes, multi-family residential complexes, golf courses, airports, cemeteries, parks, playgrounds, athletic fields, and municipal, city, state, national, and private wooded and forested areas.

Merit FXT Insecticide Tablet can be used as directed on trees in Forestry.

Ment FXT Insecticide Tablet can be used as directed in nurseries, greenhouses and interiorscapes.

Do not apply more than 450 tablets per acre per year (0.5 lb imidacloprid) to in-ground plants.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Par 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), 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 12 hours.

Exception: The Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

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 such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinylchloride (PVC) or viton
- Shoes plus socks

NON-AGRICULTURAL USE REQUIREMENTS

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep children and pets off treated area until dry.

NURSERY AND GREENHOUSE

MERIT FXT Tablet Insecticide will control or significantly reduce populations of insects that attack container zed, newly-planted, and established trees for a full season, and in some cases up to two years. The tablet also has been shown to improve survival and growth rates of newly-established seedlings, containerized trees and shrubs, and newly-planted and welf-established trees and shrubs.

Merit FXT Tablet Insecticide is formulated to provide consistent delivery of active ingredient over time. Release of active ingredient is dependent on presence of adequate soil moisture. For best results, irrigate the plant after treatment, and ensure that the plant receives regular irrigation for at least 2-3 months after treatment.

Treatment of containerized ornamental plants - For containerized, balled and burlapped, and pot-in-pot trees and shrubs, place the prescribed number of Merit FXT Tablet Insecticide 1-4" deep into the soil, and at least 2" from the outside edge of the container. Ensure that the tablet is completely covered with soil after application.

Treatment of bare root seedlings, whips, sticks, cuttings, etc., at planting – Place the prescribed number of Merit FXT Tablet Insecticide in each planting hole or slit, directly underneath to or next to the root system of the plant. Or, place the tablets 1-4" deep into the soil next to the plant (ca. within 2-5") after the plant has been planted and the root system covered with soil. Avoid applying tablets if the soil is saturated or if there is water present at the bottom of the planting hole or slit.

Treatment of containerized or balled and burlapped trees and shrubs at planting – While planting containerized trees and shrubs, place the prescribed number of Merit FXT Tablet Insecticide in each planting hole directly underneath the root ball, or 1-4" deep into the root ball after the plant has been placed in the hole and the hole filled with soil. Avoid applying tablets if the soil is saturated or if there is water present at the bottom of the planting hole.

Treatment of in-ground trees and shrubs – For best results on established trees and shrubs, Merit FXT Tablet Insecticide should be placed as close to the fine absorptive roots as possible. For most deciduous trees and shrubs, these and adequate number of these absorptive roots are located with 6-24" of the trunk, depending on tree size. Apply Merit FXT Tablet Insecticide 2-5" below the soil surface, next to the plant (ca. within 3-5" of newly planted trees or shrubs, or within 6-24" of well-established ornamentals). Ensure that the tablets are completely covered with soil after application.

For bushy coniferous trees and shrubs, numerous absorptive roots may be located near the drip-line. To apply Merit FXT Tablet Insecticide post-plant to plants with a definite drip-line, place tablets 2-5" below the soil surface, evenly spaced around the tree and along the drip-line. Ensure that the tablets are completely covered with soil after application.

Crop	Pest	Container size	Dose (# tablets per pot)
Trees and Shrubs (including non- bearing fruit and nut trees) in containers or in containers prior to planting, during or after planting into landscape environments	Adelgids Aphids Armored scales (suppression) Black vine weevil larvae Flatheaded borers Japanese beetle adults Lace bugs Leaf beetles Leafhoppers (including glassy- winged sharpshooter) Leafminers Mealybugs Pine tip moth larvae Psyllids Roundheaded borers Royal palm bugs Sawfly larvae Soft scales Thrips (foliage only) White grub larvae Whiteflies	< 1 gallon 1 gallon 3 gallon 5 gallon 7 gallon 10 gallon Large containers, or spaded, balled and burlaped, and pot-in-pot ornamentals	1 1-2 2-3 3-4 4-5 5-7 2-3 tablets per inch of trunk diameter or per foot of shrub height

Crop	Pest	Dose (# tablets)
Newly-planted whips or seedling ornamentals (including non- bearing fruit and nut trees), less than 1" dbh, or less than 1 ft of shrub height	Adelgids Aphids Armored scales (suppression) Japanese beetle adults Lace bugs Leaf beetles Leafhoppers (including glassy-winged sharpshooter) Mealybugs Psyllids Softis scales Thrips (foliage feeding) White grub larvae Whiteflies	1 tablets per plant
	Adelgids Aphids Armored scales (suppression) Black vine weevil larvae Flatheaded borers Japanese beetle adults Lace bugs Leaf beetles Leafhoppers (including glassy-winged sharpshooter) Leafminers Mealybugs Pine tip moth larvae Psyllids Roundheaded borers Royal palm bugs Sawfly larvae Soft scales Thrips (foliage feeding) White grub larvae Whiteflies	1-2 tablets per plant

Adelgids	2-3 tablets per inch of trunk diameter or per foot of
Aphids	shrub height
Armored scales (suppression)	-
Black vine weevil larvae	
Flatheaded borers	
Japanese beetle adults	
Lace bugs	
Leaf beetles	
Leafhoppers (including glassy-winged	
sharpshooter)	
Leafminers	
Mealybugs	
Pine tip moth larvae	
Psyllids	
Roundheaded borers	
Royal palm bugs	
Sawfly larvae	
Soft scales	
Thrips (foliage only)	
White grub larvae	
Whiteflies	
	Armored scales (suppression) Black vine weevil larvae Flatheaded borers Japanese beetle adults Lace bugs Leaf beetles Leafhoppers (including glassy-winged sharpshooter) Leafminers Mealybugs Pine tip moth larvae Psyllids Roundheaded borers Royal palm bugs Sawfty larvae Soft scales Thrips (foliage only) White grub larvae

LANDSCAPE, INTERIORSCAPES AND FORESTED AREAS

MERIT FXT Tablet Insecticide will control or significantly reduce populations of insects that attack container zed, newly-planted, and established trees for a full season, and in some cases up to two years. The tablet also has been shown to improve survival and growth rates of newly established seedlings, containerized trees and shrubs, and newly-planted and well-established ornamental plants.

MERIT FXT Tablet Insecticide is formulated to provide consistent delivery of active ingredient over time. Release of active ingredient is dependent on presence of adequate soil moisture. For best results, irrigate the plant after treatment, and ensure that the plant receives regular irrigation for at least 2-3 months after treatment.

Treatment of containerized ornamentals - For containerized, balled and burlapped, or pot-in-pot ornamentals, place the prescribed number of MERIT FXT Tablet Insecticide 1-4" deep into the soil, and at least 2" from the outside edge of the container. Ensure that the tablet is completely covered with soil after application.

Treatment of containerized or balled and burlapped ornamentals at planting – While planting containerized ornamentals, place the prescribed number of MERIT FXT Tablet Insecticide in each planting hole directly underneath the root ball, or 1-4" deep into the root ball after the plant has been placed in the hole and the hole filled with soil. Do not apply tablets if the soil is saturated or if there is water present at the bottom of the planting hole.

Treatment of in-ground ornamentals – For best results on established ornamentals, MERIT FXT Tablet Insecticide should be placed as close to the fine absorptive roots as possible. For most deciduous trees and shrubs, an adequate number of these absorptive roots are located with 6-24" of the trunk, depending on tree size. Apply MERIT FXT Tablet Insecticide 2-5" below the soil surface, next to the plant (ca. within 3-5" of newly planted trees or shrubs, or within 6-24" of well-established ornamentals). Ensure that the tablets are completely covered with soil after application.

For bushy coniferous trees and shrubs, numerous absorptive roots may be located near the drip-line. To apply MERIT FXT Tablet Insecticide post-plant to plants with a definite drip-line, place tablets 2-5" below the soil surface, evenly spaced around the tree and along the drip-line. Ensure that the tablets are completely covered with soil after application.

Crop	Pest	Container size	Dose (# tablets per pot)
Trees, shrubs and ornamental plants in containers prior to, planting, during or after planting into landscapes and interior plantscapes Established or newly-planted trees and shrubs	Adelgids Aphids Armored scales (suppression) Black vine weevil larvae Flatheaded borers Japanese beetle adults Lace bugs Leaf beetles Leafhoppers (including glassy- winged sharpshooter) Leafminers Mealybugs Pine tip moth larvae Psyllids Roundheaded borers Royal palm bugs Sawfly larvae Soft scales Thrips (foliage only) White grub larvae Whiteflies	< 1 gallon 1 gallon 3 gallon 5 gallon 7 gallon 10 gallon Large containers (spaded, balled and burlapped, and pot-in-pot)	1 1-2 2-3 3-4 4-5 5-7 2-3 tablets per inch of trunk diameter or per foot of shrub height

Стор	Pest	Dose (# tablets)
Established or newly-	Adelgids	2-3 tablets per inch of trunk diameter or
planted Trees and	Aphids	per foot of shrub height
Shrubs	Armored scales (suppression)	
	Black vine weevil larvae	
	Flatheaded borers	
	Japanese beetle adults	
	Lace bugs	
	Leaf beetles	
	Leafhoppers (including glassy-winged sharpshooter)	
	Leafminers	
	Mealybugs	
	Pine tip moth larvae	
	Psyllids	
:	Roundheaded borers	
	Royal palm bugs	
	Sawfly larvae	
	Soft scales	
	Thnps (foliage only)	
	White grub larvae	
	Whiteflies	

FORESTRY

MERIT FXT Tablet Insecticide will control or significantly reduce populations of insects that attack newly-planted seedlings and established seedling trees for a full season, and in some cases up to two years. The tablet also has been shown to improve survival and growth rates of newly established seedlings and newly planted trees.

MERIT FXT Tablet Insecticide is formulated to provide consistent delivery of active ingredient over time. Release of active ingredient is dependent on presence of adequate soil moisture. For best results, ensure that the plant receives adequate soil moisture for at least 2-3 months after treatment.

Treatment of containerized seedlings prior to planting - For containerized plants, place the prescribed number of MERIT FXT Tablet Insecticide 1-4" deep into the soil Ensure that the tablet is completely covered with soil after application.

Treatment of bare-root seedlings, rooted and unrooted cuttings, or small trees at planting – During planting, to maximize uptake by roots place the prescribed number of MERIT FXT Tablet Insecticide in each planting hole directly underneath the tree, or next to the tree (i.e., within 1-3") ca. 1-3" deep into soil. Do not apply tablets if the soll is saturated or if there is water present at the bottom of the planting hole.

Treatment of previously planted trees – For best results on newly-planted and established trees, MERIT FXT Tablet Insecticide should be placed as close to the fine absorptive roots as possible. For decicuous and most confererous trees, an adequate number of these absorptive roots are located with 6-24" of the trunk, depending on tree size. Apply MERIT FXT Tablet Insecticide 2-5" below the soil surface, next to the plant (ca. within 3-5" of newly-planted trees, or within 6-24" of well-established trees). Ensure that the tablets are completely covered with soil after application.

For some coniferous trees, the many of the absorptive roots may be located near the drip-line. To apply MERIT FXT Tablet Insecticide post-plant to bushy plants with a definite drip-line, place tablets 2-5" below the soil surface, evenly spaced around the tree and along the drip-line. Ensure that the tablets are completely covered with soil after application.

Crop	Pest	Dose	Applications
Poplar and cottonwood plantations	Cottonwood leaf beetle Aphids	1 tablet per tree	Place tablet directly into the planting hole of seedlings, cuttings, or containerized stock at the time of establishment, or next to each plant (ca. within 3" of the seedling) at the time of establishment or as soon as possible after planting.

Crop	Pest	Dose	Applications
Conifer plantations	Nantucket pine tip moth Aphids Soft and armored scales	1-2 tablets per tree	Place either one or two tablets cirectly into the planting hole of either bare-root seedlings or containerized stock at the time of establishment, or the same number of tablets next to each bare-root seedlings or containerized seedling at the time of establishment (ca. within 3" of the seedling) or as soon as possible after planting.

STORAGE AND DISPOSAL

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

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: If empty: Do not reuse this container. Offer for recycling if available or dispose of in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material Absorb spilled material with absorbing type compounds and dispose of as directed for pesticides above. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer Environmental Science Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer Environmental Science Emergency Response Telephone No. is 1-800-334-7577 or contact Chemtrec at 800-424-9300.

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.

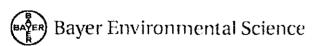
CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury or ineffectiveness or other unintended consequences may result because of such factors as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

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTANT WITH APPLICABLE LAW, BAYER ENVIRONMENTAL SCIENCE 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 Environmental Science is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTANT WITH APPLICABLE LAW, BAYER ENVIRONMENTAL SCIENCE 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 CONSISTANT 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 ENVIRONMENTAL SCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

This Product is specially formulated and sold under license from Bayer only for the uses set forth on this label. The active ingredient of this product, formulations containing this active ingredient, and/or methods of making or using this active ingredient or its formulations many be the subject of one or more Bayer patents, including but not limited to U.S. Patent No. 5,783,203. The purchase and/or use of this product constitutes acceptance of a limited license to use this product only in strict accordance with the instructions set forth on this label. Any use of this product other than as expressly set forth on this label is prohibited and is not licensed through the purchase and/or use of this product and may result in the infringement of one or more Bayer patents and/or other intellectual property rights.

PRODUCED FOR



A Business Group of Bayer CropScience LP 2 T. W. Alexander Drive Research Triangle Park, NC 27709

Merit FXT Insecticide (PENDING) Submitted 02/01/07