

432-1447

12/23/2013

117

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



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 23, 2013

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

Subject: Label notification to add restrictions for the state of Oregon, per PRN 98-10

Dear Dr. Pangilinan:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10, dated December 10, 2013 for "Merit Tree Injection" EPA Registration No. 432-1447.

The Registration Division (RD) has conducted a review of the request for applicability under PRN 98-10 and finds that the changes 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 contact me directly at 703-308-8735 or email me at chao.julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Julie A. Chao".

Julie A. Chao
Insecticide-Rodenticide Branch
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 432-1447	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Merit Tree Injection Insecticide	PM# 1	
5. Name and Address of Applicant (Include ZIP Code) Bayer Environmental Science 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. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION DEC 23 2013
<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.)

To revise label to add the pollinator protection statement restricting use on linden trees that is being required by the Oregon Department of Agriculture

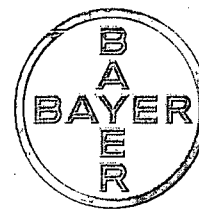
Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Direction <input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> 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 Norma C. Pangilinan, Ph.D.		Title Registrations Manager		Telephone No. (Include Area Code) 919-549-2428	
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.					6. Date Application Received (Stamped)
2. Signature 		3. Title Registrations Manager			
4. Typed Name Norma C. Pangilinan, Ph.D.		5. Date December 10, 2013			

Bayer CropScience



Document Processing Desk (NOTIF)
EPA - Office of Pesticide Programs (7504P)
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

NOTIFICATION

DEC 23 2013

Attn: Venus Eagle,
Product Manager Team 1
Registration Division, Insecticide-Rodenticide

**Subject: Label Notification with Oregon Dept of Agriculture Requirement
- Merit Tree Injection Insecticide (EPA Reg. No. 432-1447)**

December 10, 2013

Dear Ms. Eagle

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

The enclosed Notification is being submitted to add the pollinator protection statement restricting use on linden trees that is being required by the Oregon Department of Agriculture.

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.

The following documents are enclosed in support of this application:

1. Completed EPA Form 8570-1
2. ~~Five~~ ^{two} copies of the revised product label plus one highlighted copy tracking revision to label.

Please do not hesitate to call (919-549-2428) or e-mail (norma.pangilinan@bayer.com), if you have any questions.

Sincerely,

BAYER ENVIRONMENTAL SCIENCE
A DIVISION OF BAYER CROPSCIENCE

Norma C. Pangilinan
NORMA C. PANGILINAN, Ph.D,
Registrations Manager

GROUP	4A	INSECTICIDE
-------	----	-------------

Merit[®] Tree Injection

Insecticide

For injection into trees in and around industrial and commercial buildings and in residential areas.

For injection into trees in private, municipal, state, and national forested areas under the supervision of Federal, State, or Local Agencies.

ACTIVE INGREDIENT:

*Imidacloprid, 1-[(6-Chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine 17.1%

OTHER INGREDIENTS: 82.9%
100.0%

EPA Reg. No. 432-1447

EPA Est. No.432-TX-1

STOP - Read the label before use.

Keep out of reach of children.

CAUTION

FIRST AID	
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 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 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.
In case of emergency call toll free the Bayer Environmental Science 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 is available. Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:

Harmful if absorbed through skin. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves.

Personal Protective Equipment (PPE):

Applicators and Other Handlers who handle this product must wear:

- Shirt and pants
- Chemical resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber or natural rubber
- Shoes plus socks

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.

NOTIFICATION

DEC 23 2013

User Safety Recommendations

User should:

- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.
- Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-334-7577 for emergency medical treatment information.

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 trees and shrubs.

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

Resistance Management Recommendations

Some insects are known to develop resistance to insecticides after repeated use. As with any insecticide, the use of this product should conform to resistance management strategies established for the use area.

MERIT Tree Injection Insecticide contains a Group 4A insecticide. Insect biotypes with acquired or inherent resistance to Group 4A insecticides may eventually dominate the insect population if Group 4A insecticides are used repeatedly as the predominant method of control for targeted species.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent 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. If container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. 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 below. 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.

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: Nonrefillable container. Do not reuse or refill this container. Triple 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. Offer for recycling, if available, or reconditioning, 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.

APPLICATION TO TREES

Merit Tree Injection Insecticide can be used as directed on ornamental trees in residential areas, business and office complexes, shopping complexes, multi-family residential complexes, golf courses, airports, cemeteries, parks, playgrounds, and athletic fields. Merit Tree Injection Insecticide can also be used on ornamental trees in private, municipal, state, and national forested areas under the supervision of Federal, State, or Local Agencies.

Application of Merit Tree Injection Insecticide in residential areas may be made by commercially licensed applicators only.

Merit Tree Injection can be used to control a variety of insect pests of ornamental or forest trees. Pests controlled include aphids, whiteflies, soft scales, adelgids, leafhoppers, lace bugs, mealybugs, psyllids, leaf-feeding beetles, sawflies, borers, and leafmining flies, beetles, and wasps. Merit Tree Injection also can be used for suppression of thrips and armored scales.

The active ingredient in Merit Tree Injection has sufficient residual activity so that applications can be made preceding the attack of the trees by target pests. Merit Tree Injection also controls existing infestations of most labeled pests; control of existing infestations of borers and other difficult-to-control pests can be achieved if the level of infestation is not excessively severe at the time of application. If the level of infestation is severe, the high label rate for the targeted pest is recommended.

Systemic activity occurs only after the active ingredient is translocated upwards in the tree. In some cases, translocation can take 10 days or longer, depending on the transpiration rate of the treated plant.

The need for an application can be based on historical monitoring of the site, previous records or experiences, current season adult trapping or other methods. For best results (i.e., to ensure uptake), make application when the tree is actively transpiring.

Application Equipment

Merit Tree Injection can be applied with a variety of trunk injection devices. Devices must be chemically-resistant. For all injector systems, read carefully and follow all manufacturer's directions for use.

Drilling the hole

With most injector systems, it is necessary to predrill holes prior to insertion of the applicator device. Drill holes deep enough to permit transport of Merit Tree Injection upwards in the vascular tissue.

DOSING: For microinjection, set and dispense into the injector the required dosage, and pressurize the injector as directed.

For high-volume injection, FIRST add the required amount of water to the reservoir of the injector, and then dispense the prescribed amount of Merit Tree Injection into the reservoir.

For high-volume injection, add no more than 7 ml of Merit Tree Injection per liter of water. While injecting, ensure that the active ingredient remains in solution. The solubility of the product in the water can depend upon the temperature, pH, and the mineral content of the water. Dilute a small amount of Merit Tree Injection in water, and the mixture carefully observed. If the mixture appears cloudy or if solid particles form within 5-10 minutes, prepare a more dilute injection solution.

APPLICATION INSTRUCTIONS	
Trees and shrubs (greater than 2" diameter and chest height)	
Pest	Dosage
Adelgids Aphids Japanese beetles Lace bugs Leaf beetles (including elm and viburnum leaf beetles) Leafhoppers (including glassy-winged sharpshooter) Leafmining flies and wasps Mealybugs Psyllids Soft scales Whiteflies	0.75 – 1.5 mL (0.025-0.05 fl. oz.) Merit Tree Injection per inch of cumulative trunk diameter at chest height (54" from ground). Space injection holes approx. 6" apart, around the circumference of the tree.
Armored scales (suppression) Roundheaded borers (incl. Eucalyptus longhorned borer) Flatheaded borers (including bronze birch borer, alder borer, and emerald ash borer) Leafmining beetles and moths Pine tip moth larvae Royal palm bug Sawfly larvae Thrips (suppression)	1.5 – 3 mL (0.05-0.1 fl. oz.) Merit Tree Injection per inch of cumulative trunk diameter at chest height (54" from ground). Space injection holes approx. 6" apart, around the circumference of the tree.

For trees greater than 12" diameter, or if trees are already infested, use the highest label rate specified for control of targeted pests. For trees larger than 24" diameter, always use the highest label rate for the targeted pest.

Restriction:

- Do not use on trees where the fruit and/or nuts are consumed
- Do not apply more than once per year per tree.
- Do not apply this product, by any application method, to linden, basswood, or other Tilia species.

7/7

U.S.D.A. RATE SPECIFICATIONS FOR ASIAN AND CITRUS LONGHORNED BEETLE PROGRAMS. FOR USE ONLY UNDER U.S.D.A. SUPERVISION. FOR USE WITH U.S.D.A. APPROVED INJECTION DEVICES.

Read and follow the manufacturers' written documentation on the proper use and maintenance of the injector you are using. Use the following rates as a function of tree diameter at breast height (DBH).

2 to 23 inches DBH – 1 mL per diameter inch
24 inches DBH and above use 2 mL per diameter inch

APPLICATION DIRECTIONS: To determine the initial number of needed injection holes, measure the tree at breast height using a standard forestry tape measure. a) If measuring the circumference, divide this number by six (6) to determine the number of holes needed. b) If measuring the diameter, divide this number by two (2) to determine the number of injection holes needed. c) Initial injector sites should be in the active sapwood, evenly spaced around the tree at the root buttress region and avoiding the root valleys. d) If a single hole cannot accept its full dose, that dose may be divided among the other initial injection holes. e) If additional injection holes are needed they may be spaced horizontally or vertically from the initial holes.

The minimum horizontal spacing for injection sites is 3 inches. The minimum vertical spacing for injection sites is 6 inches. Preferably vertical spacing should be staggered and not aligned.

RESTRICTIONS:

- Do not use on fruit or nut trees intended for food uses.
- Do not apply more than once per calendar year.
- Do not apply this product, by any application method, to linden, basswood, or other Tilia species.

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, because of manner of use and other factors beyond Bayer CropScience LP's control it is impossible for Bayer CropScience LP to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP 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. Bayer CropScience LP 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 LP ELECTION, THE REPLACEMENT OF PRODUCT.

Net Contents:

PRODUCED FOR



Bayer Environmental Science

A Division of Bayer CropScience LP
2 T. W. Alexander Drive
Research Triangle Park, NC 27709
1-800-331-2867

Merit Tree Injection (Pending) 12-05-2013