

82996-1

5/24/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BioForest Technologies, Inc.
c/o Olav Messerschmidt
OMC Ag Consulting
828 Tanglewood Lane
East Lansing, MI 48823

MAY 24 2012

Subject: Registration Amendment to add two (2) year efficacy claim, create master label with two sublabels, add additional optional marketing claims, edit directions for use, add elm leaf beetle pest, and make other minor label edits.
TreeAzin Systemic Insecticide
EPA Reg. No.: 82996-1
Your submission dated February 6, 2012
Decision Number: 460911, PRIA Category B680

Dear Mr. Messerschmidt:

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5), is acceptable provided that you:

- 1) Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) Submit two (2) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Should you have any questions, you may contact Mr. Colin Walsh directly at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda A. Hollis, Chief

CONCURRENCES
Biochemical Pesticides Branch

Biopesticides and Pollution
Prevention Division (7511P)

SYMBOL	7611P						
SURNAME	Walsh						
DATE	5/24/12						

TreeAzin™ Systemic Insecticide (EPA Reg. No. 82996 – 1)
MASTER LABEL
Sublabel A is for Commercial Use
Sublabel B is for Residential Use

TreeAzin™ Systemic Insecticide

A solution containing azadirachtin for tree injections for use with tree injection devices to manage specific insect pests of forests, trees and landscape ornamentals in woodlot, urban and residential environments.

ACTIVE INGREDIENT:

Azadirachtin A + Azadirachtin B*	5%
OTHER INGREDIENTS	95%
TOTAL	100%

* Contains 0.42 lbs. of Azadirachtin A + B per gallon (50 gms. per liter)

KEEP OUT OF REACH OF CHILDREN
WARNING

FIRST AID	
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. Call a poison control center or doctor for treatment advice.
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 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 by a poison control center or doctor. Do not give anything to an unconscious person.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call your poison control center at 1-800-222-1222. For information on product, usage, etc., call 1-888-236-7378, Monday through Friday, 9 a.m. to 5 p.m. (Eastern time).</p>	

Net Contents: 20 ml, 1 liter (1.06 quart), or 2 liter (2.12 quarts)

EPA Reg. No. 82996 – 1
EPA Est. XXXX-Y

[Batch Number]

Manufactured by:
BioForest Technologies Inc.
105 Bruce Street
Sault Ste. Marie, ON P6A 2X6 Canada

ACCEPTED


MAY 24 2012

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 82996-1

TreeAzin™ Systemic Insecticide (EPA Reg. No. 82996 – 1)
Sublabel A: Commercial Use

TreeAzin™ Systemic Insecticide
For Commercial Use

A solution containing azadirachtin for tree injections for use with tree injection devices to manage specific insect pests of forests, trees and landscape ornamentals in woodlot, urban and residential environments.

 FOR ORGANIC PRODUCTION

[add OMRI logo]

ACTIVE INGREDIENT:

Azadirachtin A + Azadirachtin B* 5%
OTHER INGREDIENTS.....95%
TOTAL.....100%

* Contains 0.42 lbs. of Azadirachtin A + B per gallon (50 gms. per liter)

KEEP OUT OF REACH OF CHILDREN
WARNING

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Manufactured by:
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[Optional marketing claims, may be used on any panel]

- *Pictures illustrating how to determine a trees circumference at breast height and performing the injection (i.e. drilling the hole at the proper angle, depth of drill hole and nozzle and canister placement in the tree etc.) may be added.*
- *Provides two (2) years protection against emerald ash borer.*
- *Injected directly into the tree for minimal personal, animal and environmental exposure..*
- *Rapid uptake and translocation of TreeAzin Systemic Insecticide after being injected into trees.*
- *Effective control of insect pests that consume tree leaves (e.g. gypsy moth, tent caterpillars, leaf miners), needles (budworms, sawflies), cambial tissue (e.g. Emerald ash borer) and sucking and piercing insects (e.g. Hemlock woolly adelgid).*
- *Trees saving trees*

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Warning: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE): Applicators and other handlers must wear:

- Long sleeved shirt and pants
- Shoes plus socks
- Protective eyewear
- Chemical resistant gloves

Follow manufacturer's instructions for cleaning and 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

User should:

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

PHYSICAL AND CHEMICAL HAZARDS

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees Fahrenheit may cause bursting.

ENVIRONMENTAL HAZARDS

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 washwater or rinsate.

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 out of the treated area until sprays have dried.

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. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

IMPORTANT: Before using TreeAzin, read this label carefully, as well as the instructions for the tree injection device used to inject TreeAzin. Failure to follow label directions and instructions may lead to unnecessary exposure to the applicator, bystanders and the environment.

This formulation is for use with tree injection devices that meet the label and dosage requirements. Follow the manufacturer's directions for use. The Smart-Shot Refillable Tree Injector is a tree injection device that is recommended for use with TreeAzin.

Apply TreeAzin undiluted. TreeAzin is a systemic insecticide. Therefore, to ensure optimum efficacy, it is necessary to inject TreeAzin into the active sapwood. Injection times will vary by tree species, weather conditions, time of year and time of day, but injection times are improved when trees are maintained and watered.

TreeAzin is not to be applied to trees that will produce food.

Determining Dose

- Using a diameter tape or calipers, determine the tree's diameter in inches at breast height (dbh) (4.5 ft. above ground).
- Multiply the tree's diameter in inches at breast height (dbh) by appropriate dosage (see Application Rates in Trees and Ornamentals chart) to calculate the total dose of TreeAzin for the tree.

Example: Preventative Treatment for Emerald Ash Borer

1. The tree diameter (dbh) is 16 in.
2. Multiply: 16 in. x 5 ml/in. = 80 ml of TreeAzin required

The Injection Hole

- Using a power drill and a 5/32 in. drill bit for the Smart-Shot Refillable Tree Injector (for other injection devices, refer to user instructions for drill bit size), drill a hole at a 20 to 45 degree downward angle into the tree approximately 6-12 in. above ground (Brad point bits are recommended).
- The hole should extend through the bark and be approximately 1/2 -1 in. deep into the sapwood of the tree.

Application Rates in Trees and Ornamentals

Pests Controlled	Dosage																								
<p>Emerald Ash Borer</p>	<div style="text-align: center;">•</div> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td rowspan="4" style="width: 30%; padding: 5px;"> <p>Within a quarantined county, a state quarantine generally-infested area or less than 15 mi. from a known EAB infestation</p> </td> <td rowspan="2" style="width: 15%; padding: 5px;"> <p>EAB infested</p> </td> <td style="width: 20%; padding: 5px;"> <p>≥ 30% canopy thinning and/or dieback</p> </td> <td style="width: 35%; padding: 5px;"> <p>Treatment not recommended</p> </td> </tr> <tr> <td style="padding: 5px;"> <p>< 30% canopy thinning and/or dieback</p> </td> <td style="padding: 5px;"> <p>12.5 ml/in. dbh</p> </td> </tr> <tr> <td rowspan="2" style="padding: 5px;"> <p>Suspicious EAB symptoms or No EAB symptoms</p> </td> <td style="padding: 5px;"> <p>≥ 30% canopy thinning and/or dieback</p> </td> <td style="padding: 5px;"> <p>12.5 ml/in. dbh *</p> </td> </tr> <tr> <td style="padding: 5px;"> <p>< 30% canopy thinning and/or dieback</p> </td> <td style="padding: 5px;"> <p>12.5 ml/in. dbh</p> </td> </tr> </table> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td rowspan="5" style="width: 30%; padding: 5px;"> <p>In a county where EAB has not been detected and greater than 15 mi. from a known EAB infestation</p> </td> <td rowspan="2" style="width: 15%; padding: 5px;"> <p>Suspicious EAB symptoms</p> </td> <td style="width: 20%; padding: 5px;"> <p>≥ 30% canopy thinning and/or dieback</p> </td> <td style="width: 35%; padding: 5px;"> <p>12.5 ml/in. dbh *</p> </td> </tr> <tr> <td style="padding: 5px;"> <p>< 30% canopy thinning and/or dieback</p> </td> <td style="padding: 5px;"> <p>12.5 ml/in. dbh</p> </td> </tr> <tr> <td rowspan="3" style="padding: 5px;"> <p>No EAB symptoms</p> </td> <td style="padding: 5px;"> <p>> 16 in. dbh</p> </td> <td style="padding: 5px;"> <p>10 ml/in. dbh</p> </td> </tr> <tr> <td style="padding: 5px;"> <p>8 - 16 in. dbh</p> </td> <td style="padding: 5px;"> <p>8 ml/in. dbh</p> </td> </tr> <tr> <td style="padding: 5px;"> <p>< 8 in. dbh</p> </td> <td style="padding: 5px;"> <p>5 ml/in. dbh</p> </td> </tr> </table> <div style="text-align: center; margin-top: 10px;">○ * Tree condition may compromise treatment effectiveness</div>	<p>Within a quarantined county, a state quarantine generally-infested area or less than 15 mi. from a known EAB infestation</p>	<p>EAB infested</p>	<p>≥ 30% canopy thinning and/or dieback</p>	<p>Treatment not recommended</p>	<p>< 30% canopy thinning and/or dieback</p>	<p>12.5 ml/in. dbh</p>	<p>Suspicious EAB symptoms or No EAB symptoms</p>	<p>≥ 30% canopy thinning and/or dieback</p>	<p>12.5 ml/in. dbh *</p>	<p>< 30% canopy thinning and/or dieback</p>	<p>12.5 ml/in. dbh</p>	<p>In a county where EAB has not been detected and greater than 15 mi. from a known EAB infestation</p>	<p>Suspicious EAB symptoms</p>	<p>≥ 30% canopy thinning and/or dieback</p>	<p>12.5 ml/in. dbh *</p>	<p>< 30% canopy thinning and/or dieback</p>	<p>12.5 ml/in. dbh</p>	<p>No EAB symptoms</p>	<p>> 16 in. dbh</p>	<p>10 ml/in. dbh</p>	<p>8 - 16 in. dbh</p>	<p>8 ml/in. dbh</p>	<p>< 8 in. dbh</p>	<p>5 ml/in. dbh</p>
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<p>Gypsy Moth Tent Caterpillars Leaf miners Spruce Budworm Jack Pine Budworm Hemlock Woolly Adelgid Elm Leaf Beetle</p>	<p>8 ml per in. dbh</p>																								
<p>Sawflies</p>	<p>5 ml per in. dbh</p>																								

Note: dbh is the diameter of the tree in inches at breast height

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 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. Check any plastics for compatibility. Keep container tightly sealed when not in use. Do not store below 40 degrees Fahrenheit or above 100 degrees Fahrenheit. On a hot day, temperatures exceeding 100 degrees Fahrenheit are common in vehicles, especially when windows are closed. Do not expose to high temperatures for more than short periods of time. These actions may result in some degradation of the product. Keep bottles of TreeAzin out of direct sunlight.

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

Container Handling:

- **Plastic Containers:** Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill.

Conditions of Sale and Warranty


The directions for use of this product are believed to be adequate and must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Tree injury, ineffectiveness, or other unintended consequences may result due to such factors as weather conditions, presence or absence of other materials, or the manner of use or application, all of which are beyond the control of TreeAzin, the manufacturer, or the seller.

To the extent consistent with applicable law, BioForest Technologies Inc. makes no warranty of fitness of this product for any other purpose, beyond its uses under normal conditions in keeping with the statements made on this label.

TreeAzin™ Systemic Insecticide (EPA Reg. No. 82996 – 1)
Sublabel B: Residential Use

TreeAzin™ Systemic Insecticide

A solution containing azadirachtin for tree injections for use with tree injection devices to manage specific insect pests of forests, trees and landscape ornamentals in woodlot, urban and residential environments.

 **For Organic Gardening**

[add OMRI logo]

ACTIVE INGREDIENT:

Azadirachtin A + Azadirachtin B* 5%

OTHER INGREDIENTS 95%

TOTAL 100%

* Contains 0.42 lbs. of Azadirachtin A + B per gallon (50 gms. per liter)

KEEP OUT OF REACH OF CHILDREN
WARNING

FIRST AID	
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. • Call a poison control center or doctor for treatment advice.
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 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 by a poison control center or doctor. • Do not give anything to an unconscious person.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call your poison control center at 1-800-222-1222. For information on product, usage, etc., call 1-888-236-7378, Monday through Friday, 9 a.m. to 5 p.m. (Eastern time).</p>	

Net Contents: 20 ml, 1 liter (1.06 quart), or 2 liter (2.12 quarts)

EPA Reg. No. 82996 – 1

EPA Est. XXXX-Y

[Batch Number]

Manufactured by:
BioForest Technologies Inc.
105 Bruce Street
Sault Ste. Marie, ON P6A 2X6 Canada

[Optional marketing claims, may be used on any panel]

- *Pictures illustrating how to determine a trees circumference at breast height and performing the injection (i.e. drilling the hole at the proper angle, depth of drill hole and nozzle and canister placement in the tree etc.) may be added.*
- *Provides two (2) years protection against emerald ash borer.*
- *Injected directly into the tree for minimal personal, animal and environmental exposure..*
- *Rapid uptake and translocation of TreeAzin Systemic Insecticide after being injected into trees.*
- *Effective control of insect pests that consume tree leaves (e.g. gypsy moth, tent caterpillars, leaf miners), needles (budworms, sawflies), cambial tissue (e.g. Emerald ash borer) and sucking and piercing insects (e.g. Hemlock woolly adelgid).*
- *Trees saving trees*

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Warning: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses. Harmful if swallowed or absorbed through skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees Fahrenheit may cause bursting.

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Please read the entire label and instructions for the TreeAzin Tree Protection System carefully before performing tree injections. Failure to follow label directions and instructions may lead to unnecessary exposure to the applicator, bystanders and the environment.

TreeAzin Tree Protection System: Instructions for Use

TreeAzin is a systemic insecticide. Therefore, to ensure optimum efficacy, it is necessary to inject TreeAzin into the active sapwood.

- Use a tape measure to determine the tree's circumference to the nearest inch at breast height (4½ feet above ground).
- Refer to the Application Rates in Trees and Ornamentals chart for the appropriate dosage
- Each TreeAzin Tree Protection System canister holds 20 ml of TreeAzin. The correct number of canisters is based on the pest to be treated and the circumference of the tree at 4½ feet above ground.

Injection times will vary by tree species, weather conditions, time of year and time of day, but injection times are improved when trees are maintained and watered.

Application Rates in Trees and Ornamentals

Tree circumference in inches	Emerald Ash Borer Preventative Treatment	*Emerald Ash Borer Symptomatic or Attacked Tree Treatment	Gypsy moth, Tent caterpillars, Leaf miners, Hemlock woolly adelgid, Spruce Budworm, Jack Pine Budworm	Sawflies
Number of canisters (20ml/canister) to be used in Trees and Ornamentals				
9	2	2	2	2
13	2	3	2	2
16	2	3	2	2
19	2	4	2	2

12/14

22	2	4	3	2
25	2	5	3	2
28	2	6	4	2
31	3	6	4	3
35	3	7	4	3
38	3	8	5	3
41	3	8	5	3
44	4	9	6	4
47	4	9	6	4
50	4	10	6	4
53	4	11	7	4
57	5	11	7	5
60	5	12	8	5
63	5	13	8	5
66	5	13	8	5
69	6	14	9	6
72	6	14	9	6
75	6	15	10	6
79	6	16	10	6
82	7	16	10	7
85	7	17	11	7
88	7	18	11	7
91	7	18	12	7
94	8	19	12	8
97	8	19	12	8
100	8	20	13	8
104	8	21	13	8
107	9	21	14	9
110	9	22	14	9
113	9	23	14	9
116	9	23	15	9
119	10	24	15	10
122	10	24	16	10
126	10	25	16	10
157	13	31	20	13
188	15	38	24	15

*Emerald Ash Borer - Signs and Symptoms of Symptomatic or Attacked trees – A sign is physical damage to a tree, such as a gallery, a “D” shaped hole, or a feeding notch in the leaf, resulting from attack. A symptom is a tree’s response to attack and includes premature yellowing of foliage, dead branches, thinning crowns, or bark cracks.

The effectiveness of TreeAzin in controlling Emerald ash borer may be reduced when an ash tree has greater than 30% dead braches or thinning crown.

The Injection Hole

- Using a power drill and a 3/16 in. drill bit, drill a hole at a 20 to 45 degree downward angle into the tree approximately 6-12 inches above ground. To facilitate the effective distribution of TreeAzin Systemic Insecticide into the vascular tissue of the tree, use a new, sharp drill bit.
- The hole should extend through the bark and be approximately ½ -1 inches deep into the sapwood of the tree.

The Injection

- Insert the narrow end of the TreeAzin Tree Protection System canister nozzle into the pre-drilled hole and gently tap into place using a rubber mallet. .
- Place the canister gently on the nozzle and screw the canister on the nozzle in a clockwise direction until the nozzle and canister are firmly mated.
- Gently tap the mated nozzle and canister into the drilled hole to ensure the canister is seated properly in the drilled hole.
- Grip the canister firmly and then turn the top cap clockwise ¼ turn.
- The canister will begin to discharge into the injection hole.
- Immediately check the area around the nozzle for signs of leakage:
 - If leakage is observed, carefully hold the canister and tap the canister further into the pre-drilled hole.
 - Repeat if leakage is still observed.
- Repeat the procedure for the rest of the injection sites.
- **When the injection is completed, wait for 1-2 minutes before removing the canister and nozzle. This allows the injection site to de-pressurize and avoids pesticide spillage.**

Carefully read the TreeAzin Tree Protection System “Use Directions” for further information about the System.

STORAGE and DISPOSAL

Pesticide Storage:

Store in a cool dry place out of reach of children and pets and away from direct sunlight, windows, flames and other sources of heat or ignitions.

Pesticide Disposal, and Container Handling:

Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Conditions of Sale and Warranty

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