

82996-1

4/13/2010

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 13, 2010

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

RE: Product Name: TreeAzin Systemic Insecticide
EPA Reg. No: 82996-1
Application for Label Notification dated March 15, 2010 to add a new pest
and make minor changes to label language.

Dear Mr. Messerschmidt:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PR Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Mr. Colin Walsh at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



<p>United States Environmental Protection Agency Washington, DC 20460</p>	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number BioForest Technologies Inc./ 82996 - 1	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BioForest Technologies Inc./ TreeAzin Systemic Insecticide	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) 105 Bruce Street Sault Ste. Marie, ON Canada P6A 2X6 <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"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
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Notification Accepted

Date: **APR 13 2010**

Reviewer: *C. Walsh*

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

Addition of a new, non-public health insect pest. Minor changes in label phrasing. No change in dosage, site, or use pattern.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			<input checked="" type="checkbox"/> Metal <input checked="" 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		4. Size(s) Retail Container		5. Location of Label Directions	
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		1, 2 Liter		<input type="checkbox"/> _____	
6. Manner in Which Label is Affixed to Product			<input checked="" 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 Olav Messerschmidt	Title Registration Agent	Telephone No. (Include Area Code) 517-881-0106
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Certification		6. Date Application Received (Stamped)
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.		
2. Signature 	3. Title Registration Agent	
4. Typed Name Olav Messerschmidt	5. Date March 15, 2010	

OMC Ag Consulting

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March 15, 2010

Ms. Linda Hollis
Biochemical Pesticides Branch Chief (PM #91)
Document Processing Desk (DPD) (NOTIF)
Biopesticides & Pollution Prevention Division (BPPD) – 7504P
U. S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460-0001

Subject: TreeAzin™ Systemic Insecticide
EPA Reg. No. 82996 – 1
Notification: addition of new pest and minor changes in phrasing

Dear Ms. Hollis:

We request to make the following changes to the subject label by Notification per PR Notice 98-10:

1. The addition of a new pest - hemlock woolly adelgid
2. Minor changes in phrasing

In support of this request, attached are the following documents:

- Application for Pesticide Registration (EPA Form 8570-1)
- One copy of the label with all proposed changes highlighted
- 5 copies of the draft label

PR Notice 98-10, Section IIB allows the addition of new, non-public health pests if the following conditions are met:

1. the registrant maintains efficacy data for each pest added;
2. the pest occurs on a specific site on the approved label;
3. the pest matches the type of product registered (e.g., a fungus may not be added to an insecticidal product);
4. the dosage, frequency, concentration or method of application do not change;
5. addition of the pest does not increase exposure of the pesticide to humans or the environment; and
6. the pests are not subject to quarantine by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture

All of the above conditions are met with the addition of hemlock woolly adelgid

The minor changes in phrasing are the following:

1. "inches" or "inch" has been replaced with "in."
2. Diameter of the tree at breast height (dbh) was previously given either in feet (4.5 feet) or inches (54 inches). It is now standardized to read 4.5 feet.
3. The example that was given is now uses the treatment of Emerald Ash Borer as a specific example.

Ph: 517-881-0106 ** Fax: 517-336-9788 ** email: omesserschmidt@comcast.net

- 4. The wording in a few phrases was moved in a different order for better grammar.

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.

To facilitate state registrations, a copy of the stamped approved label is requested.

If you have any questions, please don't hesitate to contact me directly at 517-881-0106 or by email at omesserschmidt@comcast.net

Sincerely,



Olav Messerschmidt,
Registration Agent for BioForest Technologies, Inc.

TreeAzin™ Systemic Insecticide For Professional 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 or other Organic Certifier 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: 1 liter (1.06 quart)

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

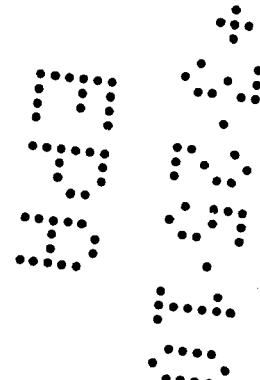
[Batch Number]

Notification Accepted

Date: APR 13 2010

Reviewer: C. Walsh

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



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.

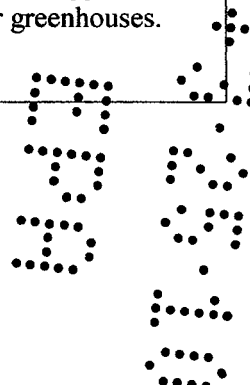
ENVIRONMENTAL HAZARDS

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.



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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: Please read the entire label and instructions for tree injection devices carefully before using TreeAzin. Failure to follow label directions and instructions may lead to unnecessary exposure to the applicator, bystanders and the environment.

This formulation is designed for use with the EcoJect[®] System for tree injections or with other manufacturers' tree injection devices that meet the label and dosage requirements. Follow the manufacturer's directions for use.

Apply TreeAzin undiluted. TreeAzin is a systemic insecticide. Therefore, to ensure optimum efficacy, it is necessary to inject TreeAzin into the active sapwood. Measure the diameter of the tree at breast height (dbh) (dbh is measured 4.5 ft. above ground). Refer to the application rates below to determine the appropriate dose rate.

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.

EcoJect[®] System: Instructions for Use

- 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.
- Each EcoJect canister holds 8 ml of TreeAzin. Divide the total dose required by 8 to determine the number of canisters needed.

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
3. Divide: 80 ml ÷ 8 ml/canister = 10 canisters

The Injection Hole

- Using a power drill and appropriate drill bit (e.g. 5/32 in. or 13/64 in.), 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 ½ -1 in. deep into the sapwood of the tree.

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The Injection

- Insert the narrow end of the EcoJect nozzle into the pre-drilled hole and push by hand or tap it gently into place with a hammer.
- Place the EcoJect canister gently over the nozzle and push until mated.
- 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 nozzle in place and remove the canister.
 - Gently tap the nozzle with a hammer and replace the canister to continue the injection.
 - 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.**
- Remove the empty injection canister separately from the nozzle and store for refilling.
- Remove the injection nozzle from the tree and place in a container with 99% alcohol. This cleans and disinfects the nozzles for reuse.

Carefully read the EcoJect® System “*Directions for Use*” for further information about the System.

Application Rates in Trees and Ornamentals

Pests Controlled	Dosage
Emerald Ash Borer	Preventative Treatment: 5 ml per in. dbh
	Symptomatic Tree Treatment: <ul style="list-style-type: none"> • 5 ml per in. dbh for trees < 8 in. dbh • 8 ml per in. dbh for trees 8-16 in. dbh • 10 ml per in. dbh for trees > 16 in. dbh
	Attacked Tree Treatment: 12.5 ml per in. dbh
Gypsy Moth Tent Caterpillars Leaf miners Spruce Budworm Jack Pine Budworm Hemlock Woolly Adelgid	8 ml per in. dbh
Sawflies	5 ml per in. dbh

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

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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. Shake well before using.

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:

- **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, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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. Crop 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.