EPA REGISTRATION NUMBER 100-1309 Vol. 1

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300

syngenta

FEDERAL EXPRESS

February 8, 2010

Document Processing Desk
Office of Pesticide Programs (H7504P)
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Mr. Thomas C. Harris IRB

SUBJECT: Emamectin Benzoate 4.0% Tree Injection **EPA REG. NO. 100-1309** -7
Submission of Final Printed Version of Labeling to Comply with EPA Approval Letter Dated November 13, 2009 and Reflecting the Notification Submitted December 9, 2009 to Change the Primary Brand Name

Dear Mr. Harris:

Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for **Emamectin Benzoate 4.0% Tree Injection** (EPA Reg. No. 100-1309) to comply with the EPA approval letter dated November 13, 2009 and reflecting the notification submitted December 9, 2009 to change the primary brand name. This final printed labeling corrects a typo in the footnote below the "Use Rate Table" to add back "medium high" from the list of rates in the first sentence, where it had been inadvertently omitted from the label copy.

This final printed labeling contains only a sub-set of the approved target pest as allowed by 40CFR 152.130(b). All approved target pest will, however, remain on the master label.

Label code is SCP 1309A-L1A 1109.

We trust that you will find this submission in order; however, should you have any questions, please contact me at 336.632-7207 or via e-mail at thomas.parshley@syngenta .com.

Sincerely,

Thomas J Parshley

Thomas J Parshley
NAFTA Senior Regulatory Product Manager

Enclosures: 2 copies of final printed version of labeling
EPA form 8570-1

2

Please read instructions on reverse before completing form.

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [x] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
100-1309	Thomas C. Harris	[ ] None [x] Restricted
4. Company/Product (Name) **Emamectin Benzoate 4.0% Tree Injection**	PM IRB	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[x] Final printed labels in response to Agency letter dated November 13, 2009

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).
Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for **Emamectin Benzoate 4.0% Tree Injection** (EPA Reg. No. 100-1309) to comply with the EPA approval letter dated November 13, 2009 and reflecting the notification submitted December 9, 2009 to change the primary brand name. This final printed labeling corrects a typo in the footnote below the "Use Rate Table" to add back "medium high' from the list of rates in the first sentence, where it had been inadvertently omitted from the label copy. This final printed labeling contains only a sub-set of the approved target pest as allowed by 40CFR 152.130(b). All approved target pest will, however, remain on the master label.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1 qt, 2 fl oz(1 liter)	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [x] Paper glued [ ] Stenciled [ ] Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J Parshley	NAFTA Sr. Regulatory Product Manager	336-632-7207

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.

2. Signature	3. Title	6. Date Application Received (Stamped)
Thomas J Parshley	NAFTA Sr. Regulatory Product Manager	
4. Typed Name: Thomas J Parshley	5. Date: February 8, 2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated

NOV 13 2009

PULL HERE TO OPEN

RESTRICTED USE PESTICIDE

DUE TO ACUTE TOXICITY TO HUMANS

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in ash trees (Fraxinus spp.)

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]*CAS No.155569-91-8*

Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309 EPA Est. 39578-TX-1

SCP 1309A-L1A 1109

®

1 quart, 2 fluid ounces (1 liter)

Net Contents

syngenta®

SCP 130-1309A-L1A

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	• 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.
If swallowed	• Call poison control center or doctor immediately for treatment advice. • Have person sip glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
NOTE TO PHYSICIAN Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**	

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of ash trees (*Fraxinus* spp.), including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

Emamectin Benzoate 4.0% Tree Injection

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgment of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Lepidoptera, Coleoptera, Hymenoptera)	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Sawfly	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers	Low to Medium	
	Longhorn borers- (Round-head borers excluding Asian longhorn beetles) **Scolytids (bark beetles)**	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-L1A 1109

RESTRICTED USE PESTICIDE

DUE TO ACUTE TOXICITY TO HUMANS

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in ash trees (*Fraxinus* spp.)

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8

Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

EPA Reg. No. 100-1309 EPA Est. 39578-TX-1

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Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-L1A 1109

1 quart, 2 fluid ounces (1 liter)

Net Contents

FIRST AID

If in eyes: 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.

If swallowed: Call poison control center or doctor immediately for treatment advice. Have person sip glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER: For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372.**

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place, away from children and pets. Keep from freezing.

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

Container Handling: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 rinse into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

syngenta®

RE: Treeage - need to bring current advertising/sales up-to-date

Thomas Harris to: tom.parshley 05/21/2010 10:05 AM

Cc: fred.pearson, janis.mcfarland, John Hebert, Meredith Laws

Tom,

Thank you for the prompt and complete follow-up to the issues EPA raised in my 5/11/10 email to you. I have to say that we would have preferred that Syngenta had actively monitored Arborjet's actions and noticed these problems yourselves rather than having EPA point them out. That said, Syngenta has done an excellent job in responding to EPA's concerns. The errors noted were corrected in a week and steps taken to prevent a reoccurrence. Syngenta has demonstrated good stewardship of your products and this is much appreciated by EPA. Thank you.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Tom: Attached is a letter Syngenta has sent to A... 05/20/2010 03:26:29 PM

From:	<tom.parshley@syngenta.com>
To:	Thomas Harris/DC/USEPA/US@EPA
Cc:	Meredith Laws/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, <fred.pearson@syngenta.com>, <janis.mcfarland@syngenta.com>
Date:	05/20/2010 03:26 PM
Subject:	RE: Treeage - need to bring current advertising/sales up-to-date

Tom: Attached is a letter Syngenta has sent to Arborjet in which we have requested in the strongest language possible that they address all of the issues raised in your May 11, 2010 e-mail and reiterated that Arborjet must honor the terms and conditions of our contract and agreements involving promotions, sales, and advertising for TREEage and fully comply with any and all FIFRA requirements relating to these areas. My understanding is Syngenta Lawn and Garden business management are meeting with Arborjet this week and these matters will be discussed. Also, our state registration group has contacted A. M. Leonard directly about their web page ad and information on the TREEage 24c material. As of yesterday morning, A. M. Leonard had removed any/all ad information for TREEage from their website, which is noted in the attached letter and will no longer be offering the product for sale. Thank you for bringing these matters to our attention. Syngenta does take stewardship of our products seriously and I would point out the language in the Syngenta letter that highlights this point. If there are any additional developments, I will most certainly bring these to your attention as a follow up to this communication.

Best regards,

Tom Parshley

-----Original Message-----
From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Tuesday, May 11, 2010 3:15 PM
To: Parshley Tom USGR
Cc: Pearson Fred USGR; Laws.Meredith@epamail.epa.gov;
Hebert.John@epamail.epa.gov
Subject: Treeage - need to bring current advertising/sales up-to-date

Tom,

Syngenta needs to work with your distribution network to ensure that the sales and advertising information currently being communicated regarding Treeage (100-1309) is up to date. Specifically, you need to make sure that all references to the now cancelled SLN labels are deleted and that current communication states that the product is a Restricted Use Pesticide for use only by certified applicators.

As you recall, Treeage was initially made available for use under a dozen FIFRA 24(c) Special Local Need (SLN) labels which accompanied a generically labeled (but not yet federally registered) bottle of product. EPA issued the Sec 3 registration for Treeage in 7/09 as a Restricted Use Pesticide with an amendment 11/09 to add the 2-year efficacy claim. After our discussion this past winter you cancelled all the SLNs as of 3/10, recalled all the generically labeled/non-registered product, and moved the Sec 3 product into production to have Treeage (as distributed by Arborjet) available in the market ASAP.

It was just brought to our attention that the May 2010 catalog for A. M. Leonard (241 Fox Drive, PO Box 816, Piqua, OH 45356. (800) 543-8955. www.amleo.com) offers Treeage for sale in their pesticide section. It states that the product is registered for use in certain states (i.e. it's referring to the SLNs), is effective for 2+ years, and states that the product is "not intended for homeowners". Obviously, there is a lead time required to print catalogs so I am not surprised to see the SLN product still referenced in print. However, the A. M. Leonard website still lists the SLN product as available as of today (5/11/10) even though the RUP Sec 3 was registered on 7/11/09 and the SLNs were cancelled on 3/12/10. The SLN product needs to be deleted from their lists of available products. It is unclear to me whether A. M. Leonard has the ability to authenticate and track sales of RUP products.

In addition, I just checked the Arborjet website. Arborjet lists the correct federally registered RUP label and has a fairly recent (4/26/10) list of states which have registered the product for use in their state. All is well here except one note on the main Treeage page (http://www.arborjet.com/products/tree-age.htm) which states "Treeage is not intended for homeowner use" and which leads to URL (http://www.arborjet.com/products/tree-age-disclaimer.pdf) where it states the following:

"Important
Our most recent product addition," TREE-äge", is receiving very positive press coverage and significant interest. As with any new product, it is critical that TREE-äge be properly applied and receive the highest degree of stewardship.
Additionally, tree injection and the control of EAB with TREE-äge are best performed by the Arborist or the Lawn and Landscape professional. As such, Tree-äge should only applied by industry professionals capable of assuring proper application. Homeowners can see the "contact us" section of this website to find an applicator in their area."

The Arborjet homeowner link and statement need to be updated to definitively state that Treeage is a RUP and can only be sold to and applied by a state certified applicator. "Not intended", "best performed", etc are misleading.

As good and responsible stewards of your products I appreciate your prompt attention to correcting these issues.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Notice of Material Breach of Licensing and Subregistrant Supply Agreement

ladoris.alston to: Thomas Harris 05/19/2010 02:12 PM

Cc: chris.howard

Mr. Harris, per Chris Howard's instructions, I am sending you a copy of the attached letter.

Thanks and best regards,

Ladoris Alston

Legal Department

syngenta

Phone 336-632-2451

Fax 336-632-2012

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

Arborjet Ltr-5-19-10.pdf

Chris Howard
Head, NAFTA Legal,
IP & Licensing for
Lawn and Garden

Syngenta Crop Protection, Inc
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

Tel. 336-632-7679
chris.howard@syngenta.com

syngenta

May 19, 2010

Mr. Peter Wild
Mr. Russ Davis
Arborjet Incorporated
99 Blueberry Hill Road
Woburn, MA 01890

Re: Notice of Material Breach of Licensing and Subregistrant Supply Agreement

Dear Russ and Peter:

The purpose of this letter is to provide Arborjet, Inc. ("Arborjet") with notice that it has materially breached the December 11, 2007 Licensing and Subregistrant Supply Agreement ("Agreement") between Syngenta Crop Protection, Inc. ("Syngenta") and Arborjet.

More specifically, Arborjet is once more in breach of FIFRA Section 12(a)(1)(B) and is yet again marketing and distributing Tree-äge insecticide without complying with applicable laws. In addition, Arborjet has failed to fulfill its obligations set forth in Paragraph 1.4(g) of the March 1, 2010 Amendment to the Agreement ("Amendment") by not providing Syngenta with the opportunity to review existing web site pages prior to posting the same to the internet. Syngenta firmly believes that Arborjet's conduct in this instance is a continuing breach by Arborjet, which Arborjet has failed to cure - even in spite of multiple notices from Syngenta. Nevertheless, Syngenta is providing Syngenta with this <u>final</u> thirty (30) day notice to comply with the Agreement and the Amendment.

FIFRA Section 12(a)(1)(B)
As we have informed you on multiple occasions, Section 12(a)(1)(B) of the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA") provides,

"[I]t shall be unlawful for any person in any State to distribute or sell to any person . . . any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration under Section 3."

Throughout the term of the Agreement, Arborjet has developed and circulated advertisements and other promotional materials which contain claims that are substantially different from those approved by the Environmental Protection Agency ("EPA") for the Tree-äge insecticide product.

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The Web Site
Most recently, on May 11, 2009, Syngenta received an email from EPA regarding Arborjet's latest failure to comply with FIFRA. In this instance, Arborjet's main page (http://www.arborjet.com/products/tree-age.htm) stated "Tree-äge is not intended for homeowner use" and lead the reader to a URL (http://www.arborjet.com/products/tree-age-disclaimer.pdf) which contains the following language:

"Important . . . Our most recent product addition, 'Tree-äge', is receiving very positive press coverage and significant interest. As with any new product, it is critical that Tree-äge be properly applied and receive the highest degree of stewardship. Additionally, tree injection and control of EAB with Tree-äge are best performed by the Arborist or the Lawn and Landscape professional. As such, Tree-äge should only be applied by industry professionals capable of assuring proper application. Homeowners can see the "contact us" section of this website to find an applicator in their area."

The pages identified above should definitively state that Tree-äge can only be sold to and applied by a state certified applicator. Phrases such as "not intended" and "best performed" are misleading and thus prohibited by EPA. In addition, the Arborjet main page, the page containing the above-referenced language and all pages which reference Tree-äge should include a clear statement indicating that Tree-äge is a Restricted Use Pesticide. These modifications are required to ensure Arborjet's compliance with FIFRA. As we have made clear time and time again, EPA and state regulatory agencies have a zero tolerance policy for violations of FIFRA and other related laws related to the sale and distribution of pesticide products designated as Restricted Use Pesticides.

Paragraph 1.4(g) of the Amendment
Significantly, Arborjet should also recall its obligation set forth in the Amendment to the Agreement at Paragraph 1.4(g):

"Existing Inventory of APPR. Arborjet shall provide Syngenta with copies of existing APPR in its possession as of the Effective Date within thirty (30) days after executing this Amendment for Syngenta to review and determine whether the same may be used for APPR activities."

Arborjet did not provide Syngenta with the opportunity to review all the materials referencing Tree-äge on its web site. As such, Syngenta insists that Arborjet remove all references to Tree-äge on its web site until Syngenta is provided with the opportunity to review and approve the same.

History of Arborjet's Violations of Law and Continuing Breach of Agreement
Syngenta has demanded that Arborjet cease creating and circulating advertising containing off-label claims multiple times during the term of the Agreement. To recap Arborjet's history with TREEäge and Syngenta's actions in response:

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- In May 2008, Syngenta notified Arborjet that Syngenta and the Ohio Department of Agriculture were concerned with Arborjet's misleading claims in magazine advertising.

- In October and November of 2008, Syngenta revisited the same issue with Arborjet regarding statements contained on Arborjet's web site and EPA's concern regarding the same.

- In February 2009, Dan Steltz provided Arborjet (via email to Russ Davis) with a protocol to follow to ensure Arborjet's advertisements were compliant with FIFRA and Syngenta's policies.

- In October 2009, Arborjet disregarded the aforementioned protocol by developing and circulating additional misleading ads. Syngenta required Arborjet to self-report the inappropriate recommendations contained in the October and November issues of *Tree Care Industry*.

- Most recently, in February 2009, Syngenta and Arborjet renegotiated the Agreement to provide Syngenta with control of all activities related to advertising and promotion.

Syngenta has provided Arborjet with multiple opportunities to cure its breach of the Agreement and would now like to make clear that it is not required to provide Arborjet with any additional notice regarding this ongoing problem. That said, we have taken into account Arborjet's explanation in this instance and are thus providing this final "notice" with respect to Arborjet's continuing breach of its obligations pursuant to the Agreement.

To be clear, in the event Syngenta identifies any future instances in which Arborjet, i) fails to comply with FIFRA as a result of its advertising or promotion of Tree-äge or ii) circulates any advertising or promotion regarding Tree-äge that has not been approved by Syngenta, Syngenta will terminate the Agreement effective immediately.

Communication with Arborjet Customers

In addition to highlighting Arborjet's latest noncompliance, EPA also provided direction regarding steps that should be taken with respect to Arborjet's customers that purchase and resell Tree-äge. More particularly, EPA asserted that we should ensure that all references in advertising and promotional materials made by such customers i) do not contain references to the now cancelled FIFRA Section 24(c) registrations and ii) clearly state that Tree-äge is a Restricted Use Pesticide.

Syngenta has already addressed this issue with one Arborjet customer (A.M. Leonard) who took down a non-compliant web page earlier this week. We now insist that Arborjet send a letter to all of its current and former customers consistent with the direction from EPA summarized herein. We request that you provide Syngenta with a draft of your proposed

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letter on or before Monday, May 24, 2010, for review and comment. If we do not receive such letter from you by this date, we will consider you in breach of the Agreement.

Sincerely,

Chris Howard

Chris Howard
Head, NAFTA Legal,
IP & Licensing for
Lawn and Garden

H:\051910CH1

cc: Scott Reasons
Dan Steltz
Tom Parshley
Larry Zang
Thomas Harris (via email to harris.thomas@epa.gov)

Treeage - need to bring current advertising/sales up-to-date
Thomas Harris to: tom.parshley 05/11/2010 03:14 PM
Cc: fred.pearson, Meredith Laws, John Hebert

Tom,

Syngenta needs to work with your distribution network to ensure that the sales and advertising information currently being communicated regarding Treeage (100-1309) is up to date. Specifically, you need to make sure that all references to the now cancelled SLN labels are deleted and that current communication states that the product is a Restricted Use Pesticide for use only by certified applicators.

As you recall, Treeage was initially made available for use under a dozen FIFRA 24(c) Special Local Need (SLN) labels which accompanied a generically labeled (but not yet federally registered) bottle of product. EPA issued the Sec 3 registration for Treeage in 7/09 as a Restricted Use Pesticide with an amendment 11/09 to add the 2-year efficacy claim. After our discussion this past winter you cancelled all the SLNs as of 3/10, recalled all the generically labeled/non-registered product, and moved the Sec 3 product into production to have Treeage (as distributed by Arborjet) available in the market ASAP.

It was just brought to our attention that the May 2010 catalog for A. M. Leonard (241 Fox Drive, PO Box 816, Piqua, OH 45356. (800) 543-8955. www.amleo.com) offers Treeage for sale in their pesticide section. It states that the product is registered for use in certain states (i.e. it's referring to the SLNs), is effective for 2+ years, and states that the product is "not intended for homeowners". Obviously, there is a lead time required to print catalogs so I am not surprised to see the SLN product still referenced in print. However, the A. M. Leonard website still lists the SLN product as available as of today (5/11/10) even though the RUP Sec 3 was registered on 7/11/09 and the SLNs were cancelled on 3/12/10. The SLN product needs to be deleted from their lists of available products. It is unclear to me whether A. M. Leonard has the ability to authenticate and track sales of RUP products.

In addition, I just checked the Arborjet website. Arborjet lists the correct federally registered RUP label and has a fairly recent (4/26/10) list of states which have registered the product for use in their state. All is well here except one note on the main Treeage page (http://www.arborjet.com/products/tree-age.htm) which states "Treeage is not intended for homeowner use" and which leads to URL (http://www.arborjet.com/products/tree-age-disclaimer.pdf) where it states the following:

"Important
Our most recent product addition," TREE-äge", is receiving very positive press coverage and significant interest. As with any new product, it is critical that TREE-äge be properly applied and receive the highest degree of stewardship.
Additionally, tree injection and the control of EAB with TREE-äge are best performed by the Arborist or the Lawn and Landscape professional. As such, Tree-äge should only applied by industry professionals capable of assuring proper application. Homeowners can see the "contact us" section of this website to find an applicator in their area."

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As good and responsible stewards of your products I appreciate your prompt attention to correcting these issues.

Tom Harris
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fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Material to be added to an e-Jacket/Jacket

Reg. # 100 - 1309 Decision # 430629

Description: amend label - drop stray conifer reference per NY SLITS question

1. Placement within the e-Jacket/jacket:

   ☑ Default: (chronological, top = newest)

   ☐ File Location: (eg. "before page 45 in .pdf")

   _____

2. ☐ Send to Data Extraction contractors this material:

   ☑ Newly stamped accepted label

   ☐ Notification

   ☐ New CSF

   ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: 3/24/10

Created March 22, 2010

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

3/24/2010

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

re: Treeage, EPA Reg. # 100-1309
label amendment submitted 3/24/2010 (D#430629)
accepted

Dear Mr. Parshley:

The revised labeling submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is ACCEPTABLE. This label amendment deletes a stray reference to conifers and clarifies that the product can only be used on ash trees.

Submit two (2) copies of your final printed labeling incorporating the above changes prior to releasing your product for shipment. If the above provisions 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 copy of the label stamped "accepted" is enclosed for your records.

Sincerely yours,

/S/

Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505C)
Harris.Thomas@epa.gov
(703) 308-9423

enclosures (1)

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in ash trees (*Fraxinus* spp.)

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft)

ACCEPTED
MAR 24 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 100-1309

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of ash trees (*Fraxinus* spp.), including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (ash trees) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer; excluding Asian longhorn beetles) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

This product is to be applied to ash trees only. Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
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For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

TREE-age 1309A-M(draft)clean-lg-3-24-10 000100-01309.20100324.pdf

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in ash trees (*Fraxinus* spp.)

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft)

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

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

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

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

Container Handling
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

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Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

TREE-age 1309A-M(draft) clean-lg-3-24-10 000100-01309.20100324.pdf

RE: >>> NEED 100-1309 LABEL AMENDMENT ASAP

tom.parshley to: Thomas Harris 03/24/2010 10:47 AM

Cc: Kable Davis, Venus Eagle, Meredith Laws, jxbrough, Data.Mgmt, kimberly.clark, pat.eay

---

Tom: Thanks for letting us know about the need to make a couple of changes to the Emamectin Benzoate 4% Tree Injection (TREEage) label. Syngenta should have caught the reference to conifers as well. Attached is the following information to facilitate the approval of the changes you requested:

Application for Pesticide Amendment, EPA Form 8570-1
PDF files that contain a highlighted and clean version of the label
Cover letter

Hopefully it will be possible to turn this around pretty quickly so as not to slow down NY or other state reviews. Please e-mail the approval back to me when review has been completed, so we may get things fixed on our end. The booklet was already at the printers for set up when your message arrived.

Best regards,

Tom

-----Original Message-----
From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Tuesday, March 23, 2010 5:06 PM
To: Parshley Tom USGR
Cc: Davis.Kable@epamail.epa.gov; Eagle.Venus@epamail.epa.gov; Laws.Meredith@epamail.epa.gov; jxbrough@gw.dec.state.ny.us
Subject: >>> NEED 100-1309 LABEL AMENDMENT ASAP

Tom,

We just received a SLITS question from Jeanine Broughel in NY state. NY is processing an application from Arborjet for state registration of Treeage and found an error that we need to correct. When we limited the Sec 3 to just ash trees we meant to clean up all the references to other trees that were on the initial application. I thought we had them all but we missed one:

Directions for Use, Use Directions, Drill Depth (p. 6)
Delete the phrase "or 1-5/8" to 2" (conifers)" from the end of the first sentence. Ash trees fall under the hardwoods text that begins the sentence. The conifer text could confuse users into believing they can treat other trees.

>>>> Please email me a revised 100-1309 Sec 3 label (text .pdf) along with a brief cover letter and form 85701-1 (you can scan the letter & form if you need). I'll process the change immediately and send you back a new stamped Sec 3 label.

>>> Please inform Arborjet of the change so they can make the correction on their distributor label. NY will be telling them the same thing for their NY label. Arborjet should use the corrected label for all their state applications. Hopefully, they can just send replacement labels for any other state applications they've already submitted.

Give me a call if you have any questions.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

Application 8570-1--amendTREEageacorrecterrors.doc Emamectin Benzoate Tree Injection 1309A-M_draft_marked-lg-3-24-10.pdf

000100-01309.20100324 .pdf Cover Emamectin Benzoate 4.0% Tree Injection.pdf

syngenta

March 24, 2010

Document Processing Desk
Office of Pesticide Programs **(7505P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Thomas Harris

SUBJECT: SUBMISSION OF ADMINISTRATIVE AMENDMENT REQUEST FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION (TREEäge™) EPA REG. NO. 100-1309

Dear Mr. Harris:

Enclosed please find the following in support of an administrative amendment to the subject product to correct errors in the label text that were brought to our attention by your office yesterday.

- Application for Pesticide Amendment, EPA Form 8570-1
- PDFs of the revised product label (highlighted and clean versions included)

Please contact me at (336) 632-7207 if there are any questions concerning this submission or on the pending registration action for Emamectin Benzoate 4.0% Tree Injection.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Submission sent by e-mail

Please read instructions on reverse before completing form.

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [x] Amendment [ ] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-1309	2. EPA Product Manager Thomas Harris	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) Emamectin Benzoate 4% Tree Injection	PM# 4B	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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

[x] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below. New Product-nonfood use

Explanation: Use additional page(s) if necessary. (For Section I and Section II.). Administrative amendment to correct errors on the final label that were raised during NY state registration review. Expedited processing is requested as this is a Non-PRIA administrative amendment.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) Plastic tube
***Certification must**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1 pint to 55 gallons	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [x] Paper glued for tubes [ ] Stenciled [ ] Outer box is preprinted _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J. Parshley	Senior Reg. Product Manager	336-632-7207

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.

2. Signature	3. Title Regulatory Product Manager	6. Date Application Received **(Stamped)**
4. Typed Name Thomas J. Parshley	5. Date March 24, 2010	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Fw: Tree-Age label

Thomas Harris to: tom.parshley 03/23/2010 05:22 PM

Tom,

Too many emails flying off at once. Jeanine has another change listed below. I see this as not being as potentially confusing but you might as well make her change as well when you delete the "or 1-5/8" to 2" (conifers)" text as I stated in the email I just sent you.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

----- Forwarded by Thomas Harris/DC/USEPA/US on 03/23/2010 05:19 PM -----

From:	"Jeanine Broughel" <jxbrough@gw.dec.state.ny.us>
To:	<dleventhal@delta-ac.com>
Cc:	Thomas Harris/DC/USEPA/US@EPA, <tom.parshley@syngenta.com>
Date:	03/23/2010 05:12 PM
Subject:	Tree-Age label

Donna,
I reviewed the Tree-Age label and came across inconsistencies in the label directions. The product is labeled specifically for ash trees. However, under the "Drill Depth" section there is the following statement:
Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit.

This statement is confusing.

I checked with Thomas Harris of the EPA and he verified that a previous version of the EPA label did have other tree species, but it has been changed to ash trees only. The revision of the drill depth section was overlooked. He said that he was going to contact the basic registrant.

Also, there is a section toward the end of the label which is labeled "RESTRICTION" and it states "Do not apply to trees that may yield food consumed by humans or used in animal feed." Perhaps this should be clarified such as "This product is to be applied to ash trees only. Do not apply to trees that may yield food consumed by human or used in animal feed."

Once we receive an acceptable label for the Tree-Age product, we can proceed with registration.

If you have any questions, please let me know.

Jeanine

Jeanine Broughel
Pesticide Product Registration Section
NYSDEC
625 Broadway
Albany, New York 12233-7257
(518) 402-8768

>>> NEED 100-1309 LABEL AMENDMENT ASAP

Thomas Harris to: tom.parshley@syngenta.com 03/23/2010 05:06 PM

Cc: Kable Davis, Venus Eagle, Meredith Laws, jxbrough

Tom,

We just received a SLITS question from Jeanine Broughel in NY state. NY is processing an application from Arborjet for state registration of Treeage and found an error that we need to correct. When we limited the Sec 3 to just ash trees we meant to clean up all the references to other trees that were on the initial application. I thought we had them all but we missed one:

Directions for Use, Use Directions, Drill Depth (p. 6)
Delete the phrase "or 1-5/8" to 2" (conifers)" from the end of the first sentence. Ash trees fall under the hardwoods text that begins the sentence. The conifer text could confuse users into believing they can treat other trees.

>>>> Please email me a revised 100-1309 Sec 3 label (text .pdf) along with a brief cover letter and form 85701-1 (you can scan the letter & form if you need). I'll process the change immediately and send you back a new stamped Sec 3 label.

>>> Please inform Arborjet of the change so they can make the correction on their distributor label. NY will be telling them the same thing for their NY label. Arborjet should use the corrected label for all their state applications. Hopefully, they can just send replacement labels for any other state applications they've already submitted.

Give me a call if you have any questions.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Re: SLITS question (Tree-age)
Thomas Harris to: Kable Davis 03/23/2010 04:54 PM
Cc: Venus Eagle

I just spoke with Jeanine Broughel in NY. She actually has an Arbojet (distributor) label as part of an applicator for NY registration. That's a bit surprising to me since I had been told by Syngenta that they wanted to continue their SLNs since the Arborjet product would not be ready until summer. I guess they were able to push it through faster.

In any case, Jeanine is right. There is some stray text left over from the initial product submission which included many ornamental trees. This is confusing and needs to be dropped from the label.

I thought I had cleaned most out with the 11/09 stamped label but I missed this one. She will have NY push back on Arborjet to drop the "or 1-5/8" to 2" (conifers)" text from the NY label. I will email Tom Parshley at Syngenta and do the same for the Sec 3 product. I can do this label amendment electronically so I can stamp it as fast as I get the emailed label from Syngenta (hopefully this week).

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Kable Davis Tom- Please see the SLITS question below. W... 03/23/2010 02:49:57 PM

From:	Kable Davis/DC/USEPA/US
To:	Thomas Harris/DC/USEPA/US@EPA
Cc:	Venus Eagle/DC/USEPA/US@EPA
Date:	03/23/2010 02:49 PM
Subject:	SLITS question (Tree-age)

Tom-

Please see the SLITS question below. Would you please look into this? It concerns Tree-age.

Thanks...
Bo

U.S. Environmental Protection Agency

State Label Issue Tracking System

EPA Home > OPP Home > Label Request

SLITS Main Menu

Label Request

Requester: Jeanine Broughel (jxbrough@gw.dec.state.ny.us)

Entity: t

New York **Request Date:** 03/23/2010 **Due Date:** 03/25/2010

Product #: 000100-01309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTION
PC Code: 122806 Emamectin Benzoate
OPP Team: RM 07
Risk Manager Kable Davis (davis.kable@epa.gov)

Subject: Label Inconsistencies
Brief Desc:

The exclusive distributor product, Tree-Age (EPA Reg. No. 100-1309-74578), states that is for ash trees. However, the use directions contain instructions for hardwoods and conif

Detailed Desc:

The Tree-Age product is "an injected insecticide for two year control of listed arthropod p trees (Fraxinus spp.)." However, use directions for drill depth through the tree bark states 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers)." This is confusing because ash trees are a t hardwood and the label only specifies ash trees - no other hardwood and no softwood sp trees.
Can this product be used on any species of tree other than ash trees?
Thank you.
Jeanine Broughel

Close Acknowledge Respond

Material to be added to an e-Jacket/Jacket

Reg. # _____ Decision # _____

Description: Treeage SLNs - history & conversion to sec 3

1. Placement within the e-Jacket/jacket:

   ☐ Default: (chronological, top = newest)

   ☐ File Location: (eg. "before page 45 in .pdf")

   _____

2. ☐ Send to Data Extraction contractors this material:

   ☐ Newly stamped accepted label

   ☐ Notification

   ☐ New CSF

   ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: _____

Created March 22, 2010

NOTE TO FILE

date: 3/12/2010
from: Tom Harris, RD/IRB
re: history of Treeage SLNs

Treeage is a 4.0% liquid formulation of emamectin benzoate. The product is used straight or mixed with water, poured into commercial tree injection equipment, and injected into trees.

The Sec 3 application for 100-RGNO was received from Syngenta on 12/21/2007 for a general use product to be used on a variety of ornamental trees to control a variety of pests. The product was registered on 7/11/2009 as an RUP for use on ash trees only to control emerald ash borer. A subsequent amendment was approved 11/13/2009 adding a 2-year efficacy claim. A minor amendment was approved 3/24/2010 to remove stray text referring to non-ash sites.

On 3/27/2008 EPA received the first SLN application (WV080002). This was followed over the next year by similar SLNs in IL, IN, KY, MD, MI, MN, MO, OH, PA, VA, and WI. Even though the Sec 3 was not yet registered there was much interest in the product to control Emerald Ash Borer (EAB), an imported pest which had gained quarantine pest status. There were few alternatives (imidacloprid and dinotefuran will also control EAB; see those files for exactly when ~~they~~ chemical was registered for this use) and emamectin provided excellent and long lasting control.

To handle this unusual situation (an SLN on a unregistered Sec 3 product) we came up with the following approach. The product container was labeled with a minimal label with basic identification, handling, disposal statements, and a reference to see any applicable state label. There were no application instructions on the product container; instead, the SLN detailed the application instructions. Both container and SLN labels were general use.

When the Sec 3 was finally registered it was as a restricted use pesticide (RUP) due to acute tox to worker (eye II). Application was restricted to ash trees for EAB. Essentially, the accepted Sec 3 label duplicated the SLNs and eliminated the need for separate SLNs. However, Syngenta did not want to go into full scale production until a 2-year efficacy claim was added to the label. They had attempted to include this claim from the beginning but satisfactory efficacy data was not submitted until Fall 2009 with the resulting label approved on 11/13/2009. At this point, Syngenta had what they considered a marketable product but a contract agreement called for the end-use product to be actually marketed by a distributor, Arborjet. Due to contract negotiations and Arbojet's production schedule, final product was not anticipated to be available until summer 2010.

This was presenting a problem since a) some of the SLNs had expired, and b) EPA policy is that an SLN should be cancelled as soon as the use is registered on a Sec 3 product. This was further complicated by the fact that the Sec 3 product is a Restricted Use Pesticide. None of the initial product generic labels nor SLN labels were RUP and in fact some product had been sold to non-certified applicators.

After further discussion between EPA, Syngenta, and the states, Syngenta finally agreed to move up production of the Arborjet product so that it would be available to distributors in Spring 2010. Syngenta also pulled back all unsold product with the generic (no application instruction) labels from dealers. Finally, Syngenta agreed to exchange any product already in the hands of distributors or end-users for new, RUP labeled Sec 3 product. The SLNs were cancelled by Syngenta on 3/12/2010. Some states (eg. WI) have prepared Fact Sheets to communicate the situation to users. While it is possible that some confusion may continue and old product be used (illegally) during 2010, the situation should resolve itself when the limited supply of old product already in the user's hands is used up and the new Sec 3 RUP Arborjet product is sold.

At this time, Syngenta is pursuing expansion of the label to other trees. The key issue is the effect on pollinators. Given the 2-year efficacy this will be tricky. Studies will need to demonstrate how emamectin distributes in the tree and if pollinators are exposed to a toxic dose.

Treeage - emamectin, tree injection for Emerald Ash Borer
Sec 3 (100-1309) registered 7/11/2009

Summary Report

expiration date

Registration #	Name	Status	Restricted Use Product	Company #	Company Name	Percent Active Ingredient	Active Ingredient
IL080001	TREEAGE-AGE	Under Review (16-Apr-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expires 4/15/2013
IN080001	TREE-AGE	Under Review (25-Mar-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	no expiration given
KY090029	TREE-AGE	Under Review (09-Jun-2009)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expired 12/31/09
MD090001	TREE-AGE	Under Review (26-Feb-2009)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expired 12/31/09
MI080001	TREE-AGE	Under Review (28-Mar-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expires 12/31/14
MN080009	TREE-AGE	Under Review (03-Jul-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	no expiration given
MO080006	TREE-AGE	Under Review (21-Nov-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	no expiration given
OH080002	TREE-AGE	Under Review (25-Mar-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	no expiration given
PA090001	TREE-AGE	Under Review (02-Jan-2009)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expires 12/31/2014
VA080008	TREEAGE-AGE	Under Review (18-Nov-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expires 12/31/10 ?

OPPIN Query 3/9/2010, expirations edited 3/11/10

44

WI080005	TREE-AGE	Under Review (18-Nov-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expired 12/31/09 tin benzoate
WV080002	TREE-AGE	Under Review (28-Mar-2008)	N	100	SYNGENTA CROP PROTECTION, INC.	4	expires 12/31/10 ? tin benzoate

OPPIN Query 3/9/2010, expirations edited 3/11/10

emamectin emerald ash borer SLNs
Thomas Harris to: tom.parshley 03/09/2010 02:55 PM
Cc: Kable Davis, Meredith Laws

Tom,

We've had a number of discussions here on your proposal for handling use of Treeage during the 2010 growing season. Several issues are involved.

As I explained earlier, our normal policy is that all 24c/SLN labels must be cancelled once the same use is approved on a Section 3 registration. Your proposal circumvents this policy. The product was originally registered in July, 2009; there has been plenty of time since then to develop the marketed product to replace the SLNs which were a temporary measure to allow use of the product before it was federally registered. Also, there were twelve SLNs issued in 2009. This has gone beyond the definition of a LOCAL need and is not the proper use of an SLN label.

There is a possible legal problem with your proposal that requires further consultation with EPA's Office of Enforcement and Compliance Assurance (OECA). Changing to the EPA required Restricted Use Product (RUP) status may involve more than a simple re-stickering exercise. We need to make sure that re-stickering for this purpose is legal and to ensure that the new RUP status is correctly tracked and enforced by states, dealers, and users. We will be discussing this situation further with OECA.

The only reason we're considering your proposal is that the product is a tool to use on the quarantine pest emerald ash borer. Even that argument, however, is becoming less important since there are now several other products and SLNs available for control of this pest.

Before EPA makes a final decision, Meredith Laws (my branch chief) wants to discuss this situation with the states at the upcoming SFIREG meeting on 3/29/2010. EPA will make a final decision after that meeting. If Syngenta or the states wish to discuss this with Meredith they may contact her at laws.meredith@epa.gov (and cc: me) or (703) 308-7038.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

"tom.parshley@syngenta.com" Tom: Attached as we discussed is t... 03/01/2010 05:32:58 PM

From: "tom.parshley@syngenta.com" <tom.parshley@syngenta.com>
To: Thomas Harris/DC/USEPA/US@EPA
Cc: <fred.pearson@syngenta.com>, <janis.mcfarland@syngenta.com>
Date: 03/01/2010 05:32 PM
Subject: RE: Treeage SLN plans - need ASAP

Tom: Attached as we discussed is the letter from Syngenta that you requested which addresses the issues with the transition process from TREEage Section 24c registrations to Section 3 registrations in 2010, and our proposed solution. I am available to discuss this letter with you if needed. Please just give me a call.

Best regards,

Tom Parshley
Syngenta
336-632-7207

-----Original Message-----

From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Friday, February 26, 2010 12:27 PM
To: Parshley Tom USGR
Subject: Treeage SLN plans - need ASAP

Tom,

Just a reminder: I need a written request outlining your plans for the Treeage SLNs. [I know, the name changed but I don't remember the new one. Old name was catchy!] Please write up the request as a regular letter but then you can just convert it to a .pdf and email me it to me (you don't need to send paper unless there is something to MRID which I don't think there is in this case).

I would like to discuss your request with my management the week of 3/1 and get an answer back to you and the states ASAP since the use season is coming up in about a month.

Thanks.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

lettertreeage v9 (Final) (03-01-2010) (2).doc

RE: Treeage SLN plans - need ASAP
tom.parshley@syngenta.com to: Thomas Harris 03/01/2010 05:32 PM
Cc: fred.pearson, janis.mcfarland

History: This message has been forwarded.

Tom: Attached as we discussed is the letter from Syngenta that you requested which addresses the issues with the transition process from TREEage Section 24c registrations to Section 3 registrations in 2010, and our proposed solution. I am available to discuss this letter with you if needed. Please just give me a call.

Best regards,

Tom Parshley
Syngenta
336-632-7207

-----Original Message-----
From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Friday, February 26, 2010 12:27 PM
To: Parshley Tom USGR
Subject: Treeage SLN plans - need ASAP

Tom,

Just a reminder: I need a written request outlining your plans for the Treeage SLNs. [I know, the name changed but I don't remember the new one. Old name was catchy!] Please write up the request as a regular letter but then you can just convert it to a .pdf and email me it to me (you don't need to send paper unless there is something to MRID which I don't think there is in this case).

I would like to discuss your request with my management the week of 3/1 and get an answer back to you and the states ASAP since the use season is coming up in about a month.

Thanks.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

March 1, 2010

Document Processing Desk
Office of Pesticide Programs **(7505P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Thomas Harris

SUBJECT: PROPOSAL TO ADDRESS SALE AND USE OF EXISTING INVENTORY FOR FIFRA SECTION 24C LABELED MATERIAL OF EMAMECTIN BENZOATE 4% TREE INJECTION (TREE-ÄGE™), EPA REGISTRATION NO. 100-1309

Dear Mr. Harris:

The purpose of this letter is to summarize recent discussions between our offices regarding the sale and use of the Emamectin Benzoate 4% Tree Injection Product ("the Product") currently housed in retail and warehousing locations. Syngenta Crop Protection, Inc. ("Syngenta") seeks EPA approval of a plan to enable licensed applicators to use existing Product to treat ash trees for control of Emerald Ash Borer ("EAB"), an APHIS quarantine pest, in time for the spring (March-May) application as described more particularly below.

Background

As you are aware, Syngenta currently has FIFRA Section 24(c) registrations in eight (8) states for the Product (IL, IN, MI, MN, OH, PA, VA, and WV). Four (4) additional Section 24(c) registrations expired at the conclusion of 2009 (MO, KY, WI and MD). In July of 2009, Syngenta obtained a FIFRA Section 3 registration for the Product with a limited label to control EAB in ash trees. Subsequently, in December 2009, EPA approved an amended label including the addition of a claim of "extended control" for up to two (2) years. Arborjet is and has been Syngenta's exclusive distributor for the Product under the brand name TREEäge.

Syngenta participated in a series of discussions with EPA late last year about transitioning the Product from a Section 24(c) registration to a Section 3 registration. At that time, Syngenta requested that the Section 24(c)

registrations be maintained and/or renewed in the aforementioned twelve (12) states so that the Product would be available for EAB control in ash trees until the approval of an expanded label for TREEäge to provide for use on more species of trees. In December 2009, EPA indicated Syngenta and Arborjet should instead sell the product under a Section 3 registration beginning in 2010, and that it would not support the continuation or renewal of 24(c) registrations. EPA explained that one of its primary concerns is that the Product is now registered as a Restricted Use Pesticide ("RUP") – a distinction which was not included in the Section 24(c) registrations.

Status of the Section 3 Registration

Since July of 2009, Syngenta and Arborjet have been engaged in contractual discussions regarding the sale and distribution of the Product, which should be resolved shortly. Because of the timing associated with the completion of these negotiations, there has been a significant delay in submitting and obtaining Section 3 registration of the Product in the states for sale this spring. Specifically, regarding this delay:

- The above-referenced Syngenta/Arborjet negotiations have delayed the transition of the Section 24(c) registration to an Arborjet Supplemental Registration of Distributor Section 3 registration since EPA granted the original TREEäge Section 3 registration in July 2009, and more recently (December 2009), EPA approved an amended label for the Product including a name change and an extended claim of two (2) years control for EAB.

- Arborjet recently retained a regulatory consultant to assist with obtaining state registrations for the Product once the contractual issues are resolved. Arborjet's consultant will not be able to begin the process of registering the Product in the states until late spring to early summer.

- At this juncture, it appears that a Section 3 registered Product will not be available in time for the spring 2010 application season. Accordingly a solution is needed that can be agreed upon by EPA, the states, Arborjet and Syngenta to make the product available to users.

Proposed Solution to Utilize Inventory of Section 24(c) Labeled Material

Syngenta would like to propose a solution to enable licensed applicators in the aforementioned twelve (12) states to use existing inventories of Section 24(c) labeled material currently located in Syngenta and Arborjet warehouses and third party retail locations until such time as an individual state grants a Section 3 registration or until December 31, 2010 (whichever occurs first).

More specifically, Syngenta requests permission to affix a sticker identifying the Product as a RUP to all existing inventory and to revise the 24(c) label accompanying the Product to also include this information.

The following provides a summary of our recent telephone discussion including the suggestions made by your office, as well as how Syngenta's proposed solution can meet EPA's expectations:

1. **EPA REQUEST**: EPA requested that Syngenta consider canceling all remaining active 24(c) registrations for TREE-age Products and then re-apply for 24(c) registrations with an updated label, including the RUP designation and the extended control claim, in the key twelve (12) states.

   SYNGENTA RESPONSE: Syngenta agrees to cancel all current Section 24(c) registrations for the Product and to reapply for new Section 24(c) registrations with updated labeling. These labels will be issued new SLN Nos by the states.

2. **EPA REQUEST**: EPA asked Syngenta to consider adding the EPA Registration No. 100-1309 (Emamectin Benzoate 4% Tree Injection/TREE-age) to all container labeling in its and Arborjet's possession and upon receiving Product from third party locations.

   SYNGENTA RESPONSE: Given that no state registrations currently exist and are unlikely to be available until after the spring use season, adding the EPA Section 3 Registration No. 100-1309 to the container labeling does not appear workable at this time. Syngenta instead requests permission to affix stickers to the limited quantity of existing Section 24containers, in which we identify the Product as an RUP. This process would be efficient, cost-effective and meet EPA's stated goal of ensuring licensed applicators are aware of the RUP designation. This plan would also ensure that Product is available in time for spring application to control this APHIS quarantine pest.

3. **EPA REQUEST**: EPA asked Syngenta to add an expiration date to each 24(c) label highlighting that the 24(c) registration would not be valid in 2011 and to re-label all material remaining in the channel at the end of 2010.

   SYNGENTA RESPONSE: Syngenta agrees to include the expiration date on existing inventory of Product at all of the locations identified herein. In addition, Syngenta will work with Arborjet to ensure that all unsold Section 24(c) Product within each of the twelve (12) states is returned and relabeled as requested by EPA at the conclusion of 2010.

Please call me at (336) 632-7207 to discuss this matter at your earliest convenience.

Sincerely,

Thomas J. Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Internal deliberative information

Material to be added to an e-Jacket/Jacket

Reg. # 100-1309 Decision # 425116

Description: Notification - primary product name change

1. Placement within the e-Jacket/jacket:

   ☒ Default: (chronological, top = newest)

   ☐ File Location: (eg. "before page 45 in .pdf")

2. ☒ Send to Data Extraction contractors this material:

   ☐ Newly stamped accepted label

   ☒ Notification

   ☐ New CSF

   ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: 2/5/10

Created October 1, 2009

Material to be added to an e-Jacket/Jacket

Reg. # 100-1309 Decision # —

Description: FPL

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated 7/11/2009

1. Placement within the e-Jacket/jacket:

   ☑ Default: (chronological, top = newest)

   ☐ File Location: (eg. "before page 45 in .pdf")

2. ☐ Send to Data Extraction contractors this material:

   ☐ Newly stamped accepted label

   ☐ Notification

   ☐ New CSF

   ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: JAN 27 2010

Created October 1, 2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

2/5/2010

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

re: Emamectin Benzoate 4.0% Tree Injection, EPA Reg. # 100-1309
label notification submitted 12/9/2009 (D#425116)
stamped notification

Dear Mr. Parshley:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the product listed above. This notification changes the primary brand name of the product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The Confidential Statement of Formula (CSF) and/or label submitted with the application has (have) been stamped "Notification" and will be placed in our records.

Sincerely yours,

/S/

Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505P)
Harris.Thomas@epa.gov
(703) 308-9423

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300

syngenta

December 9, 2009

Document Processing Desk (Notif)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATT: Linda Arrington

SUBJECT: TREE-äge™
EPA REG. NO. 100-1309
NOTIFICATION PER EPA PR NOTICE 98-10:
CHANGE PRIMARY BRAND NAME TO "EMAMECTIN BENZOATE 4.0% TREE INJECTION"

Dear Ms. Arrington:

Syngenta Crop Protection Inc., is submitting this notification for TREE-äge™ (EPA Reg. No. 100-1309) to change the primary brand name to **"Emamectin Benzoate 4.0% Tree Injection"**, as allowed by EPA Pr Notice 98-10. Two copies of labeling (one with changes highlighted) are attached.

The label code is SCP 1309A-M (Notif-name).

To complete this Notification, EPA form 8570-1 is enclosed.

Thank you in advance for approving this request. However, should you have any questions, please contact me at 336.632-7207 or via e-mail at thomas.parshley@syngenta.com.

Sincerely,

Thomas J Parshley

Thomas J Parshley
Sr. Regulatory Product Manager

Enclosures: 2 copies labeling (1 highlighted with changes)
EPA Form 8570-1

Please read instructions on reverse before completing form.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[x] Other

OPP Identifier Number
NOTIFICATION

Application for Pesticide - Section I

1. Company/Product Number **TREE-äge™**	2. EPA Product Manager Thomas C. Harris	3. Proposed Classification [ ] None [x] Restricted
4. Company/Product (Name) 100-1309	PM# IRB 07	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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	

NOTIFICATION
FEB 05 2010

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[ ] Other - Explain below.

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

Syngenta Crop Protection Inc., is submitting this notification for TREE-äge™ (EPA Reg. No. 100-1309) to **change the primary brand name to "Emamectin Benzoate 4.0% Tree Injection",** as allowed by EPA PR Notice 98-10. Two copies of labeling (one with changes highlighted) are attached.
The label code is SCP 1309A-M (Notif-name).

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[x] Yes* [ ] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1 pint-55 gallons	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[ ] Lithograph
[x] Paper glued
[ ] Stenciled
[ ] Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J Parshley	Sr. Regulatory Product Manager	336-632-7207

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	
Thomas J Parshley	Sr. Regulatory Product Manager	
4. Typed Name Thomas J Parshley	5. Date December 9, 2009	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

EPA-FRM [G - CA-DOC - REGAFFRS] 6/5/97 - bb

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in ash trees (*Fraxinus* spp.)

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

NOTIFICATION

FEB 05 2010

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(Notif-name)

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of ash trees (*Fraxinus* spp.), including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer; excluding Asian longhorn beetles) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2009 Syngenta

For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(Notif-name)

TREE-age 1309A-M(Notif-name)clean-lg-12-9-09

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in ash trees (*Fraxinus* spp.)

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(Notif-name)

_____
Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

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

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

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

Container Handling
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

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P.O. Box 18300
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SCP 1309A-M(Notif-name)

TREE-age 1309A-M(Notif-name)clean-lg-12-9-09

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300

syngenta

FEDERAL EXPRESS

August 24, 2009

Document Processing Desk
Office of Pesticide Programs (H7504P)
Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Mr. Thomas C. Harris IRB

SUBJECT: TREE-age™ EPA REG. NO. 100-1309
Submission of Final Printed Version of Labeling to Comply with the Conditions of Registration Required in EPA Approval Letter Dated July 11, 2009.

Dear Mr. Harris:

Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for **Tree-age** (EPA Reg. No. 100-1309) to comply with the Conditions of Registration required in the EPA approval letter dated July 11, 2009. All changes required in the Agency letter have been made.

We trust that you will find this submission in order; however, should you have any questions, please contact me at 336.632-7207 or via e-mail at thomas.parshley@syngenta .com.

Sincerely,

Thomas J Parshley

Thomas J Parshley
NAFTA Senior Regulatory Product Manager

Enclosures: 2 copies of final printed version of labeling
EPA form 8570-1

xPlease read instructions on reverse before completing form.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
100-1309	Thomas C. Harris	[x] None [ ] Restricted
4. Company/Product (Name) **Tree-age™**	PM IRB	

5. Name and Address of Applicant *(Include ZIP Code)*
Syngenta Crop Protection, Inc.
P. O. Box 18300
Greensboro, NC 27419

[ ] *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

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[x] Final printed labels in response to Agency letter dated July 11, 2009

[ ] "Me Too" Application.

[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).
Syngenta Crop Protection, Inc. hereby submits 2 copies of final printed version of labeling for **Tree-age** (EPA Reg. No. 100-1309) to comply with the Conditions of Registration required in the EPA approval letter dated July 11, 2009. All changes required in the Agency letter have been made.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J Parshley	NAFTA Sr. Regulatory Product Manager	336-632-7207

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
Thomas J Parshley	NAFTA Sr. Regulatory Product Manager
4. Typed Name	**5. Date**
Thomas J Parshley	August 24, 2009

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

RESTRICTED USE PESTICIDE
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FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

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Injected insecticide for the control of listed arthropod pests in ash trees (*Fraxinus* spp.)

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See additional precautionary statements and directions for use on label in booklet.

EPA Reg. No. 100-1309 EPA Est. 39578-TX-1

Product of China
Formulated in the USA

SCP 1309A-L1 0709

1.06 quarts (1 liter)
Net Contents

syngenta®

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
7/11/2009

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

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Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal),
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)
Call
1-800-888-8372

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- shoes and socks
- protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of ash trees (*Fraxinus* spp.), including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood.

USE DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements (for example, the Arborjet Tree Injection Systems) for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Avoid injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above

45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary. Apply once per year.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product per tree	Medium ml. product per tree	Medium - High ml. product per tree	High ml. product per tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium and high rates are based on the professional judgment of the applicator as to what constitutes a low, medium or high infestation.
Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees[1]

Tree Tissue	Target Pest	Recommended Rate[2]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

[1]Apply once per year.
[2]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTIONS

- Do not apply to trees that may yield food consumed by humans or used in animal feed.
- Avoid treating trees that are moisture stressed or suffering from herbicide damage.

STORAGE AND DISPOSAL

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

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

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

Container Disposal
Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

TREE-äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company

©2009 Syngenta

For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-L1 0709

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
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EPA Reg. No. 100-1309 Product of China
EPA Est. 39578-TX-1 Formulated in the USA

SCP 1309A-L1 0709

1.06 quarts (1 liter)
Net Contents

syngenta

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

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HOT LINE NUMBER: For 24-Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident), Call **1-800-888-8372.**

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

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©2009 Syngenta

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-L1 0709

Material to be added to an e-Jacket/Jacket

Reg. # 100-1309 Decision # 421584

Description: Add 2-year efficacy claim

1. Placement within the e-Jacket/jacket:

   ☑ Default: (chronological, top = newest)

   ☐ File Location: (eg. "before page 45 in .pdf")

2. ☑ Send to Data Extraction contractors this material:

   ☑ Newly stamped accepted label

   ☐ Notification

   ☐ New CSF

   ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: 11/13/09

Created October 1, 2009

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

11/13/2009

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

re: Treeage, EPA Reg. # 100-1309
label amendment submitted 10/6/2009, revised 11/13/2009 (D#421584)
accepted

Dear Mr. Parshley:

The revised labeling submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is ACCEPTABLE. This label amendment adds a two-year efficacy claim for certain pests in ash trees.

Submit two (2) copies of your final printed labeling incorporating the above changes prior to releasing your product for shipment. If the above provisions 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 copy of the label stamped "accepted" is enclosed for your records.

Sincerely yours,

Thomas C. Harris
Biologist
Insecticide Rodenticide Branch
Registration Division (7505C)
Harris.Thomas@epa.gov
(703) 308-9423

enclosures (1)

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

TREE-äge™

Injected insecticide for two year control of listed arthropod pests in ash trees (Fraxinus spp.)

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft-b)

ACCEPTED
NOV 13 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
EPA. Reg. No: 100-1309

Net Contents

000100-01309.20091113.b.pdf

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of ash trees (Fraxinus spp.), including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer; excluding Asian longhorn beetles) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.

TREE- äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2009 Syngenta

For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft-b)

TREE-age 1309A-M(draft-b)marked-lg-11-13-09 000100-01309.20091113.b.pdf

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

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Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
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EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft-b)

Net Contents

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NOTE TO PHYSICIAN

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©2009 Syngenta
Manufactured for:
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P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft-b)
TREE-age 1309A-M(draft-b) clean-lg-11-13-09 000100-01309.20091113.b.pdf

RE: 100-1309 2-year efficacy claim

tom.parshley to: Thomas Harris 11/13/2009 02:14 PM

Tom: Here is the revised labeling as requested. Thanks for completing the review and resolving the claim so expeditiously.

Best regards

Tom

-----Original Message-----
From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Friday, November 13, 2009 11:48 AM
To: Parshley Tom USGR
Subject: 100-1309 2-year efficacy claim

Tom,

Attached is the review of your latest emamectin 2-year efficacy claim for tree injection. It passed this time. You're still limited to ash trees but you have added pests and can use the 2-year efficacy claim.

Bo does have a few label changes listed at the end of the review. Most are straightforward. I do have a comment on #4 concerning treating moisture stressed. If you leave it in the restriction section then it should be a mandatory statement and so "avoid" must be dropped as Bo states. However, if this is a truly advisory statement (i.e. you're warning the user that it won't work well under these conditions [and you don't want to hear whinning if it doesn't work!]) then you can keep "avoid" but put the statement somewhere else. You already have similar warnings up front on p6 in the "when to treat" section. You can include the moisture stress, herbicide damage concepts there with "avoid".

Just email me back a revised label and I should be able to stamp this label.

(See attached file: 000100-01309.2 year efficacy.MRID478901.20091105.acceptable.pdf)

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

TREE-age 1309A-M_draft-b_marked-lg-11-13-09.pdf 000100-01309.20091113.b.pdf

100-1309 2-year efficacy claim
Thomas Harris to: tom.parshley 11/13/2009 11:48 AM

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000100-01309.2 year efficacy.MRID478901.20091105.acceptable.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
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harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

EFFICACY REVIEW

PRODUCT: Tree-äge

REG. NUMBER: 100-1309

DATE: November 5, 2009

GLP: No

BARCODE: D371253

DECISION: 421584

CHEMICAL: Emamectin benzoate (4%)

CHEMICAL NUMBER: 122806

PURPOSE: Review data to support the addition of 2-year emerald ash borer claim to the propose label.

MRIDS: *47878901. Cox, D.; Cosky, S. (2009) Emamectin Benzoate ME (A16297A) – Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees: Multiple Year Performance Data for Emerald Ash Borer: Addendum 2 to Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection. 74 p.*

ASSOCIATED REVIEWS: Agency review dated November 6, 2008 (D358155)
- MRID 47465501

Agency review dated May 28, 2009 (D364365)
- MRID 47691001

TEAM REVIEWER: Tom Harris

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist 11-5-09

BACKGROUND:

Tree-äge (EPA Reg. No. 100-1309) is an injected insecticide intended for the control of numerous tree pests, including emerald ash borers. Please see Agency review dated May 28, 2009 (D364365) which reviewed data that were determined to be

inadequate to support the addition of 2-year control claims for emerald ash borers. MRID 47878901 has been submitted in an attempt to add a 2-year control claim for arthropod pests in ash trees. The Directions for Use (Table 1) contain a detailed table which outlines the number of injection sites and amount of product used based on the diameter of the tree at breast height (DBH). The proposed label contains the follow claims:

- *"Injected insecticide for two year control of listed arthropod pests in ash trees."*

- *"This product must be placed into active sapwood, and will actively control pests for up to two years."*

MRID 47878901 is comprised of a large number of field trials (the majority are continuations of previously submitted trials), laboratory trials and University letters of support. **Only relevant data are outlined within this review.**

Table 1. Tree-Age; Directions for Use[1]

Tree Diameter	Low (ml/tree)	Medium (ml/tree)	Medium-High (ml/tree)	High (ml/tree)	Injection Sites
4 – 6	15	25	50	-	3
7 – 9	20	40	80	-	4
10 – 12	30	55	110	165	5
13 – 15	35	70	140	210	6
16 – 18	40	75	150	225	7
19 – 21	50	100	200	300	8
22 – 24	-	115	230	345	10
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61 – 63	-	310	620	930	26
64 – 66	-	325	650	975	27
67 – 69	-	340	680	1020	28
70 – 72	-	355	710	1065	30

[1] *Higher rates tend to provide longer residual and control of more difficult insects*

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

47878901. Cox, D.; Cosky, S. (2009) Emamectin Benzoate ME (A16297A) – Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees: Multiple Year Performance Data for Emerald Ash Borer: Addendum 2 to Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection. 74 p.

Site 1; East Lansing, Michigan

MRID 47878901 outlines the continuation of trials described in detail in MRID 47465501. For experimental design specifics, see Agency review dated November 6, 2008 (D358155).

Results-

Table 2. East Lansing, Michigan; Canopy Dieback

Treatment (g AI/DBH)	Application Date	Percent Canopy Dieback			
		2006	2007	2008	2009
Tree-age 0.4 g	Sept., 2005	7.3%	12.8%	19.3%	13.8%
Tree-age 0.2 g	May, 2007	11.8%	17.3%	12.8%	13.1%
Tree-age 0.1 g	May, 2007	17.0%	11.4%	29.8%	10.4%
Control	-	16.0%	28.5%	51.3%	58.1%

In 2009, the percent canopy dieback of trees treated with Tree-age ranged from 10.4% (0.1g) to 13.8% (0.4%) as compared 58.1% of dieback within the untreated trees.

Table 3. East Lansing, Michigan; Larval Density

Treatment (g AI/DBH)	Application Date	Larvae per m^2	
		2007	2008
Tree-age 0.4 g	Sept., 2005	0	0
Tree-age 0.2 g	May, 2007	0	0
Tree-age 0.1g	May, 2007	0	0
Control	-	6.9	28.7

In both 2007 and 2008, no emerald ash borer larvae were found within trees treated with Tree-age as compared to 28.7 per m^2 found within the untreated trees (2008).

Site 2; Adrian, Michigan

MRID 47878901 outlines the continuation of trials described in detail in MRID 47465501. For experimental design specifics, see Agency review dated November 6, 2008 (D358155).

Results-

Table 4. Adrian, Michigan; Canopy Dieback

Treatment (g AI/DBH)	Application Date	Percent Canopy Dieback			
		2006	2007	2008	2009
Tree-age (0.4 g)	June, 2006	14.4%	11.1%	12.3%	7.2%
Tree-age (0.4 g)	June, 2006	16.0%	11.6%	13.0%	20.0%
Control 1	-	-	12.0%	58.3%	89.5%
Control 2	-	15.6%	10.3%	64.0%	-

The percent canopy dieback from trees treated with Tree-age ranged from 7.2% (2009) to 20.0% (2009) as compared to canopy dieback from untreated trees which reached 64.0% (control 2; 2008) and 89.5% (control 1; 2009).

Table 5. Adrian, Michigan; Larval Density

Treatment (g AI/DBH)	Application Date	Larvae per m^2	
		2007	2008
Tree-age 0.4 g	June, 2006	2.4	0
Control	-	6.2	23.6

In 2008, no emerald ash borer larvae were found within trees treated with Tree-age as compared to 23.6 per m^2 found within the untreated trees.

Site 3; Toledo, Ohio (Blackthorne site)

MRID 47878901 outlines the continuation of trials described in detail in MRID 47465501. For experimental design specifics, see Agency review dated November 6, 2008 (D358155).

Results-

Table 6. Toledo, Ohio (Blackthorne site); Canopy Dieback

Treatment (g AI/DBH)	Application Date	Percent Canopy Dieback		
		2007	2008	2009
Tree-age (0.1 g)	June, 2006	0%	3%	25%
Tree-age (0.2 g)	June, 2006	0%	3%	55%
Tree-age (0.4 g)	June, 2006	0%	10%	60%
Control	-	8%	53%	96%

In 2009, the percent canopy dieback of trees treated with Tree-age ranged from 25% (0.1g) to 60% (0.4%) as compared 96% of dieback within the untreated trees.

Table 7. Toledo, Ohio (Blackthorne site); Emergence Holes

Treatment (g AI/DBH)	Application Date	Percent Canopy Dieback		
		2007	2008	2009
Tree-age (0.1 g)	June, 2006	0%	3%	25%
Tree-age (0.2 g)	June, 2006	0%	3%	55%
Tree-age (0.4 g)	June, 2006	0%	10%	60%
Control	-	8%	53%	96%

In 2009, the number of adult emergence holes found within trees treated with Tree-age ranged from 2.9 (0.1 g) to 10.1 (0.2 g) as compared to 24.6 holes found within the untreated trees.

Letters of Support

1. Dr. Deborah G. McCullough; Michigan State University
2. Dr. David R. Smitley; Michigan State University
3. Dr. Daniel A. Herms; Ohio State University

RECOMMENDATIONS:

The submitted data support the addition of 2-year control claims for emerald ash borers in ash trees to the Tree-age label (EPA Reg. No. 100-1309). The following recommendations apply:

1. The submitted data support the following claims found on the pending label:

   - *"Injected insecticide for two year control of listed arthropod pests in ash trees (Fraxinus spp.)"*

   - *"This product must be placed into active sapwood, and will actively control pests for up to two years."*

2. Within the **USE DIRECTIONS** section of the label, revise *"Avoid injured areas or areas with decay."* to read *"Do not inject into injured areas or areas with decay."*

3. On page eight of the label, revise *"Recommended Rate"* to read *"Application Rate"*.

4. Within the **RESTRICTIONS** section of the label, revise *"Avoid treating trees that are moisture stressed or suffering from herbicide damage."* to read *"Do not apply to trees that are moisture stressed or suffering from herbicide damage."*

5. Under the **Longhorn borers** portion of the **Application in Trees** section of the label, include the disclaimer "*excluding Asian longhorn beetles*".

6. Within the **USE DIRECTIONS** section of the label, revise "*Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3).*" to read "*The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3).*"

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

October 14, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 07-OCT-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 859906

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: Amendment

Billable: Yes No

Company: 100 SYNGENTA CROP PROTECTION, INC.

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 100-1309 Product Name: TREEAGE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 06-Oct-2009 OPP Rec'vd Date: 07-Oct-2009

Front End Date: 07-Oct-2009 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	
Study	
CSF	

View/Edit

Fast Track: New Ingredient:

Receipt Description:

Amendment to add 2-year extended claim for control of Emerald Ash Borer on Ash Trees w/data

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Syngenta Crop Protection, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

478789-00

syngenta

Federal Express

October 6, 2009

Document Processing Desk **(AMEND)**
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Mr. Thomas Harris, IRB

SUBJECT: AMENDMENT REQUEST TO ADD 2-YEAR EXTENDED CONTROL CLAIM FOR EMERALD ASH BORER AND REVISING CONTAINER HANDLING SECTION TO COMPLY WITH PR NOTICE 2007-4. PRIA ACTION R340 FOR TREEAGE™, EPA REG. NO. 100-1309

Dear Mr. Harris:

Enclosed please find the following information in support of the subject amendment request:

- Receipt for payment of PRIA Fee
- Application for Pesticide Amendment, EPA Form 8570-1
- Certification with Respect of Citation of Data, EPA Form 8570-34
- Five copies of revised product labeling (one copy highlighted to indicate changes)
- Label Certification Form and a compact disk (CD) that contains the highlighted revised product labeling
- Data Matrix, EPA Form 8570-35
- Three copies each of a transmittal document
- One (1) data volume containing efficacy data and analysis plus letters of support from noted university researchers who have conducted numerous studies in ash trees for control of Emerald Ash Borer (EAB)

The purpose of this amendment is to seek approval of addition of a two-year control claim for EAB on ash trees. In addition, Syngenta is also revising the Container Handling section to comply with PR Notice 2007-4.

Syngenta believes the efficacy surrounding this product and use clearly demonstrate two years and more control of EAB from a single application. This action has been discussed with Kable "Bo" Davis of your office prior to this submission being made.

syngenta

Fees for Services

This action is subject to PRIA and the appropriate fee category is R-340 with a fee of $3444 and a processing time of 4 months. Please contact me at (336) 632-7207 if there are any questions concerning this submission. Thank you for your kind consideration of this request.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Attachments (forms, labeling, CD, data submission)

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Amendment Request to Add 2-Year Extended Control Claim for Emerald Ash Borer and Revising Container Handling Section to Comply with PR Notice 2007-4. PRIA Action R340 for Treeage, EPA Reg. No. 100-1309.

3. Transmittal Date

10/06/2009

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
47878901	2 OF 2	Addendum 2 - Emamectin Benzoate ME (A16297A) - Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees - Multiple Year Performance Data for Emerald Ash Borer (EPA MRID No. 47465501), T004223-07, (A16297A_50026)	810.1000

COMPANY OFFICIAL THOMAS J. PARSHLEY (NAME) — Thomas J Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION

COMPANY CONTACT: THOMAS J. PARSHLEY (NAME) — (336) 632-7207 (PHONE)

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

October 8, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-421584
EPA File Symbol or Registration Number: 100-1309
Product Name: TREEAGE
EPA Receipt Date: 07-Oct-2009
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, INC.

BUNNIE KONAT
SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{859906I~

This package includes the following

- ○ New Registration
- ◉ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S-	859906
EPA File Symbol/Reg. No.	100-1309
Pin-Punch Date:	10/7/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: $ 3,444

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Tompkins Date: 10/8/09

Remarks:

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 10-7-09

Experts In-Processing Signature: MF Harrington Date 10-8-09 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 100-1309	EPA Receipt Date: 10-7-09

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	no			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			X
	a) List study (or studies) not included with application			

Comments:

DATA PASSED 86-5 REVIEW. AA 10/15/09

MRID 478789

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Eay Pat USGR

From: paygovadmin@mail.doc.twai.gov
Sent: Tuesday, October 06, 2009 10:10 AM
To: Eay Pat USGR
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24VR3PRQ
Agency Tracking ID: 74083067771

Account Holder Name: Janis McFarland
Transaction Type: Sale
Billing Address: P.O. Box 18300
City: Greensboro
State/Province: NC
Zip/Postal Code: 27419
Country: USA
Card Type: Visa
Card Number: **********6187
Payment Amount: $3,444.00
Transaction Date: Oct 6, 2009 10:10:28 AM

Decision Number:
Registration Number: 100-1309

Syngenta Crop P[illegible]ion, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

Federal Express

October 6, 2009

Document Processing Desk **(AMEND)**
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Thomas Harris, IRB**

SUBJECT: **AMENDMENT REQUEST TO ADD 2-YEAR EXTENDED CONTROL CLAIM FOR EMERALD ASH BORER AND REVISING CONTAINER HANDLING SECTION TO COMPLY WITH PR NOTICE 2007-4. PRIA ACTION R340 FOR TREEAGE™, EPA REG. NO. 100-1309**

Dear Mr. Harris:

Enclosed please find the following information in support of the subject amendment request:

- Receipt for payment of PRIA Fee
- Application for Pesticide Amendment, EPA Form 8570-1
- Certification with Respect of Citation of Data, EPA Form 8570-34
- Five copies of revised product labeling (one copy highlighted to indicate changes)
- Label Certification Form and a compact disk (CD) that contains the highlighted revised product labeling
- Data Matrix, EPA Form 8570-35
- Three copies each of a transmittal document
- One (1) data volume containing efficacy data and analysis plus letters of support from noted university researchers who have conducted numerous studies in ash trees for control of Emerald Ash Borer (EAB)

The purpose of this amendment is to seek approval of addition of a two-year control claim for EAB on ash trees. In addition, Syngenta is also revising the Container Handling section to comply with PR Notice 2007-4.

Syngenta believes the efficacy surrounding this product and use clearly demonstrate two years and more control of EAB from a single application. This action has been discussed with Kable "Bo" Davis of your office prior to this submission being made.

syngenta

Fees for Services

This action is subject to PRIA and the appropriate fee category is R-340 with a fee of $3444 and a processing time of 4 months. Please contact me at (336) 632-7207 if there are any questions concerning this submission. Thank you for your kind consideration of this request.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Attachments (forms, labeling, CD, data submission)

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Amendment Request to Add 2-Year Extended Control Claim for Emerald Ash Borer and Revising Container Handling Section to Comply with PR Notice 2007-4. PRIA Action R340 for Treeage, EPA Reg. No. 100-1309.

3. Transmittal Date

10/06/2009

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
	2 OF 2	Addendum 2 - Emamectin Benzoate ME (A16297A) - Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees - Multiple Year Performance Data for Emerald Ash Borer (EPA MRID No. 47465501), T004223-07, (A16297A_50026)	810.1000

COMPANY OFFICIAL THOMAS J. PARSHLEY
(NAME)

Thomas J Parshley
(SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION

COMPANY CONTACT: THOMAS J. PARSHLEY
(NAME)

(336) 632-7207
(PHONE)

Please read instructions on reverse before completing form.

EPA United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [x] Amendment [ ] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-1309	2. EPA Product Manager Mr. Thomas Harris	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) TREEäge™	PM# 4B	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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

[x] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated ____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated ____

[ ] "Me Too" Application.

[ ] Other - Explain below. New Product-nonfood use

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

Amendment to add 2-year extended claim for control of Emerald Ash Borer on Ash Trees w/data. In addition, Syngenta is also revising the Container Handling section to comply with PR Notice 2007-4.

This action is subject to PRIA and the appropriate fee category is R-340 action with a fee of $3444, and a processing time of 4 months, which has been prepaid.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) Plastic tube ____
***Certification must**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information [x] Label [ ] Container	4. Size(s) Retail Container 1 pint to 55 gallons	5. Location of Label Directions [x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [x] Paper glued for tubes [ ] Stenciled [ ] Outer box is preprinted ____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J. Parshley	Senior Reg. Product Manager	336-632-7207

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.

2. Signature Thomas J Parshley	3. Title NAFTA Senior, Regulatory Product Manager Professional Products	6. Date Application Received **(Stamped)**
4. Typed Name Thomas J. Parshley	5. Date October 6, 2009	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Syngenta Crop Protection, PO Box 18300, Greensboro, NC 27419	100-1309
Active Ingredient(s) and/or representative test compound(s)	Date
Emamectin Benzoate	10/6/2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name
Tree Injection for Ash Trees	TREE-age™

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ *I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).*

☒ *I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).*

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
Thomas J Parshley	10/6/ 2009	Thomas J. Parshley NAFTA Senior Regulatory Product Manager

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[G:CA-DOC.Regaffrs]Epa-frm 8570-34:bpt:9/24/98

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DATA MATRIX

Date: 9/30/2009 | Reg. No: 100-1309 | Page 1 of 16

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: Treeage

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
Cite-All	Cite-All	Cite-All (AHE	AGRICULTURAL HAN	PER	
Cite-All	Cite-All	Cite-All (ART	AGRICULTURAL REE	PER	
Cite-All	Cite-All	Cite-All (FES	FIFRA ENDANGERED	PER	
Cite-All	Cite-All	Cite-All (ORE	OUTDOOR RESIDENT	PER	
Cite-All	Cite-All	Cite-All (REJ	RESIDENTIAL EXPOS	PER	
Cite-All	Cite-All	Cite-All (SDT	SPRAY DRIFT TF	PER	
830.1550	Product identity and compostition	47309301	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	47309301	SYNGENTA	OWN	
830.1620	Description of production process	47309301	SYNGENTA	OWN	
830.1650	Description of Formulation process	47309301	SYNGENTA	OWN	
830.1670	Discussion of formation of impurities	47309301	SYNGENTA	OWN	
830.1750	Certified limits	47309301	SYNGENTA	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 9/30/2009

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DATA MATRIX

Date: 9/30/2009 | Reg. No: 100-1309 |

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: Treeage

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.1800	Enforcement analytical method	47309301	SYNGENTA	OWN	
830.6302	Color	47309302	SYNGENTA	OWN	
830.6303	Physical state	47309302	SYNGENTA	OWN	
830.6304	Odor	47309302	SYNGENTA	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	47309302	SYNGENTA	OWN	
830.6315	Flammability	47309302	SYNGENTA	OWN	
830.6316	Explodability	47309302	SYNGENTA	OWN	
830.6317	Storage Stability	47309302	SYNGENTA	OWN	
830.6319	Miscibility	47309302	SYNGENTA	OWN	
830.6320	Corrosion characteristics	47309302	SYNGENTA	OWN	
830.7000	pH	47309302	SYNGENTA	OWN	
830.7100	Viscosity	47309302	SYNGENTA	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.7300	Density/relative density/bulk density	47309302	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47309303	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47309304	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	47309305	SYNGENTA	OWN	
870.2400	Acute eye irritation	47309306	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47309307	SYNGENTA	OWN	
870.2600	Skin sensitization	47309308	SYNGENTA	OWN	
870.3100	90-Day oral toxicity	42743620	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743621	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743622	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743623	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42794201	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3100	90-Day oral toxicity	43868103	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743620	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743621	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743622	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743623	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42794201	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	43868103	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	42743625	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	44007902	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743631	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743632	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743634	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	
Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3700	Prenatal developmental toxicity study	42743635	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743636	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42743633	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42851511	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42743624	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42851510	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42868902	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868105	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743637	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743638	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.5000	Genetic Toxicity tests	42743639	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851512	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851513	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851514	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851515	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851516	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851517	MERCK & CO., INC.	OWN	
870.5100	Bacterial reverse mutation test	47002111	SYNGENTA	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743611	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743614	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743626	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743627	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: Treeage

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	42743618	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743619	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743624	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743628	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743629	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743630	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851503	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851504	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851505	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851506	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851507	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851508	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	42851509	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851510	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42868902	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	43868104	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743640	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743641	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	44030601	MERCK & CO., INC.	OWN	
870.7600	Dermal penetration	43850113	MERCK & CO., INC.	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47465501	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47691001	SYNGENTA	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850108	MERCK & CO., INC.	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850109	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: Treeage

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.5400	Algal toxicity, Tiers 1 and 2	43850108	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850109	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43850126	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43943301	MERCK & CO., INC.	OWN	
875.2600	Biological Monitoring	43943301	MERCK & CO., INC.	OWN	
850.3020	Honey bee acute contact toxicity	42851530	MERCK & CO., INC.	OWN	
850.3030	Honey bee toxicity of residues on foliage	43393006	MERCK & CO., INC.	OWN	
161-1	Hydrolysis - laboratory	42743642	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
161-2	Photodegradation in water - laboratory	43404301	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43850114	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	43404302	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	44010001	MERCK & CO., INC.	OWN	
161-4	Photodegradation in Air	44007906	MERCK & CO., INC.	OWN	
161-4	Photodegradation in Air	44007907	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43235101	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43404303	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43850115	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	44007905	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	44010001	MERCK & CO., INC.	OWN	
162-2	Anaerobic Soil Metabolism	43850116	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: Treeage

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
163-1	Leaching and adsorption/desorption -- laboratory	42743643	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	43850117	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43404304	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43850118	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater dap	42743603	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater dap	44007901	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393001	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393002	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393003	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007912	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007913	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007914	MERCK & CO., INC.	OWN	

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Date: 9/30/2009	Reg. No: 100-1309	Page 12 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	
Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1035	Mysid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007914	MERCK & CO., INC.	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 9/30/2009

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Date: 9/30/2009 | Reg. No: 100-1309 |

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: Treeage

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1055	Bivalve acute toxicity test (embryo larval)	43393001	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393002	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393003	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007912	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007913	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007914	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42743602	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42851529	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393001	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393002	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393003	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43850106	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	
Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1075	Fish acute toxicity test, freshwater and marine	44007912	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007913	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007914	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1350	Mysid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1400	Fish early-life stage toxicity test	43393004	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1400	Fish early-life stage toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	45833001	SYNGENTA	OWN	
850.1710	Oyster BCF	43393005	MERCK & CO., INC.	OWN	
850.1730	Accumulation in fish – waiver	43393005	MERCK & CO., INC.	OWN	
850.1850	Aquatic organism accumulation	43393005	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42743601	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42868905	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851527	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851528	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850104	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850105	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	
Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.2300	Avian reproduction test	44007910	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007911	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	
Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			AGRICULTURAL HAN	PER	
			AGRICULTURAL REE	PER	
			FIFRA ENDANGERED	PER	
			OUTDOOR RESIDENT	PER	
			RESIDENTIAL EXPOS	PER	
			SPRAY DRIFT TF	PER	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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DATA MATRIX

Date: 9/30/2009	Reg. No: 100-1309	Page 12 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Treeage	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 9/30/2009

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

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			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
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Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 9/30/2009

157

Certification with Respect to Label Integrity

Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-1309	October 6, 2009	000100-01309.20091006.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Thomas J Parshley
Signature

October 6, 2009
Date

Thomas J Parshley
Name (typed)

Sr. Regulatory Product Manager
Title

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

TREE-äge™

Injected insecticide for two yearthe control of listed arthropod pests in ash trees (Fraxinus spp.)

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft)

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of ash trees (Fraxinus spp.), including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Avoid injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary. ~~Apply once per year.~~

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees[1]

Tree Tissue	Target Pest	Recommended Rate[12]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

[1]~~Apply once per year.~~
[21]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTIONS

- Do not apply to trees that may yield food consumed by humans or used in animal feed.
- Avoid treating trees that are moisture stressed or suffering from herbicide damage.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Handling~~Disposal~~

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.
~~Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.~~

TREE- äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company

©2009 Syngenta

For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

TREE-age 1309A-M(draft)marked 10-6-09-lg

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

TREE-äge™

Injected insecticide for the control of listed arthropod pests in ash trees (Fraxinus spp.)

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft)

Net Contents

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Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

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If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

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Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

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

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

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

Container HandlingDisposal
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or 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 and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and 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.
~~Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.~~

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Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

TREE-age 1309A-M(draft)marked 10-6-09-lg

Privileged attorney-client communication

Re: Fw: questions: emamectin SLN & Sec 3 coordination
Thomas Harris to: Erin Koch 07/28/2009 12:21 PM
Cc: John Hebert

[redacted]

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Erin Koch [redacted] 07/28/2009 11:59:08 AM

From: Erin Koch/DC/USEPA/US
To: Thomas Harris/DC/USEPA/US@EPA
Date: 07/28/2009 11:59 AM
Subject: Re: Fw: questions: emamectin SLN & Sec 3 coordination

[redacted]

Thomas Harris [redacted] 07/28/2009 11:47:53 AM

From: Thomas Harris/DC/USEPA/US
To: Erin Koch/DC/USEPA/US@EPA
Cc: Robert Perlis/DC/USEPA/US@EPA
Date: 07/28/2009 11:47 AM
Subject: Re: Fw: questions: emamectin SLN & Sec 3 coordination

[redacted]

Privileged attorney-client communication

[redacted]

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Erin Koch [redacted] 07/28/2009 11:26:16 AM

From: Erin Koch/DC/USEPA/US
To: Thomas Harris/DC/USEPA/US@EPA
Cc: Robert Perlis/DC/USEPA/US@EPA
Date: 07/28/2009 11:26 AM
Subject: Re: Fw: questions: emamectin SLN & Sec 3 coordination

---

[redacted]

Thomas Harris [redacted] 07/24/2009 11:50:08 AM

From: Thomas Harris/DC/USEPA/US
To: Robert Perlis/DC/USEPA/US@EPA
Cc: Erin Koch/DC/USEPA/US@EPA
Date: 07/24/2009 11:50 AM
Subject: Fw: questions: emamectin SLN & Sec 3 coordination

Bob,

[redacted]

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

----- Forwarded by Thomas Harris/DC/USEPA/US on 07/24/2009 11:48 AM -----

From: Thomas Harris/DC/USEPA/US
To: Erin Koch/DC/USEPA/US@EPA
Cc: John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA
Date: 07/23/2009 01:34 PM
Subject: questions: emamectin SLN & Sec 3 coordination

Erin,

[redacted]

[redacted]

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

7/23/2009

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: Treeage, EPA Reg. # 100-1309
reviews associated with initial registration

Dear Mr. Parshley:

Enclosed please find a copy of the following reviews associated with the initial registration of the above product:

product chemistry	SMathur, 4/2/2008
acute toxicology	EMcAndrew, 6/3/2008
efficacy	KDavis, 11/6/2008
efficacy	KDavis, 5/28/2009
occupational exposure	KO'Rourke, 7/24/2008
ecological effects	BAnderson, 1/13/2009

The acute toxicology profile for this product is:

Acute oral toxicity	III	Acceptable	MRID	47309303
Acute dermal toxicity	IV	Acceptable	MRID	47309304
Acute inhalation toxicity	IV	Acceptable	MRID	47309305
Primary eye irritation	II	Acceptable	MRID	47309306
Primary dermal irritation	IV	Acceptable	MRID	47309307
Dermal sensitization	Negative	Acceptable	MRID	47309308
signal word	Warning			

Sincerely yours,

/S/

Thomas C. Harris
Insecticide / Rodenticide Branch
Registration Division (7505C)
Office of Pesticide Programs
harris.thomas@epa.gov
(703) 308-9423

enclosures (6)

Privileged attorney-client communication

questions: emamectin SLN & Sec 3 coordination
Thomas Harris to: Erin Koch
Cc: John Hebert, Meredith Laws

07/23/2009 01:34 PM

Erin,

[redacted]

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Internal deliberative information

initial
stamped
label
(registration notice)

Tree-age: stamped label
Thomas Harris to: tom.parshley 07/11/2009 09:35 PM
Cc: janis.mcfarland, John Hebert, Meredith Laws

Tom,

Attached please find the stamped label for Tree-age, EPA Reg. # 100-1309. Paper copy is in the mail. I will send copies of the reviews when I return to the office on 7/21/09.

While this registers the product we are both aware that this is an interim step to the market label you are seeking. We will continue to discuss the 2-year efficacy claim (if you can supply the additional information noted in the last efficacy review that would be useful). We will also continue to discuss expanding the sites beyond ash trees in light of pollinator issues.

I know this involved a flurry of activity at the last minute to meet the PRIA deadline. I appreciate your willingness to work together to get this initial label completed.

000100-0RGNO.20090711.reg notice.stamped label.scan.ocr.pdf

Also, here's the marked-up label with addition notes. This will explain some of the changes I made to the stamped label and also indicate a few other changes that you should make on the label as we work on an amendment.

000100-0RGNO.20090710.treeageC.EPA comments.print image.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

U.S. ENVIRONMENTAL PROTECTION AGENCY **Office of Pesticide Programs** **Registration Division (7505C)** **Ariel Rios Building** **1200 Pennsylvania Ave., NW** **Washington, D.C. 20460**	EPA Reg. Number: 100-1309	Date of Issuance: July 11, 2009
NOTICE OF PESTICIDE: x Registration ___ Reregistration (under FIFRA, as amended)	Term of Issuance: conditional Name of Pesticide Product: Tree-age	

Name and Address of Registrant (include ZIP Code):

Thomas Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) and (B) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Per the indicated EPA Guidelines, submit, cite, or request a waiver for the following within the time period indicated measured from the effective date of this registration.
   a. one year storage stability (830.6317) tested at 0, 3, 6, 9, 12 months (within 18 months)
   b. corrosion characteristics (830.6320) tested at 0, 3, 6, 9, 12 months (within 18 months)

3. Make the following label changes before you release the product for shipment:
   a. Revise the EPA Registration Number to read, "EPA Reg. No. 100-1309."
   b. On page 1, add scientific name so site reads "ash trees (Fraxinus spp.)".
   c. On page 1 immediately below ingredient statement, add "contains 0.36 lbs. emamectin per gallon."
   d. On page 5 in the Directions for Use (DFU), add scientific name so site reads "ash trees (Fraxinus spp.)".
   e. On page 6 in the DFU, delete section labeled "resinous conifers."
   f. On page 6 in the DFU/Environmental Conditions, delete sentence that reads "Watering the tree prior to injection is therefore required if they are drought or heat stressed."
   g. On top of page 7 in the Use section, add "Apply once per year."
   h. On page 7 in the Rate Table, add "product" so column headers read "ml. product/tree".

(continued)

Signature of Approving Official: /S/ Thomas C. Harris Biologist Insecticide Rodenticide Branch Registration Division (7505P)	Date: JUL 11 2009

i. On page 7 in first footnote to Rate Table, delete first sentence beginning "Product/1" DBH: Low - 2.5 ...."
j. On page 7 in second footnote to Rate Table, delete the sentence "for control, be within +- 1 injection site of this number per tree."
k. On page 8 in Application in Trees table, delete row labeled "seed and cone".
l. On page 8 in first footnote to Application in Trees table, change sentence to read "Apply once per year."
m. On page 8 in first footnote to Application in Trees table, delete first sentence beginning "Low = 2.5 ml ...."

4. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label stamped "accepted with comments" is enclosed for your records.

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

TREE-äge™

Injected insecticide for the control of listed arthropod pests in ash trees

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-xxxxx

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP xxxxxA-M(draft-c TREE-äge)

ACCEPTED
With COMMENTS
In EPA Letter Dated:
JUL 11 2009
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
100-1309

Net Contents

000100-0RGNO.20090710.treeageC.PDF

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- shoes and socks
- protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of ash trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood.

USE DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Avoid injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits.

Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Watering the trees prior to injection is therefore required if they are drought or heat stressed.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE*

Tree Diameter (DBH) (Inches)	Low ml./tree	Medium ml./tree	Medium - High ml./tree	High ml./tree	Number of Injection Sites**
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

* **Product/1" DBH: Low= 2.5 ml/1"DBH; Medium= 5 mls/1"DBH; High= 10 mls/1"DBH.** The use of low, medium and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.
**For control, be within ± 1 injection site of this number per tree.
Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees[1]

Tree Tissue	Target Pest	Recommended Rate[2]	Comments
Seed and Cone	Pine Cone Worm (Dioryctria spp)	Medium to High	For control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

1 Apply once per season.
2 Low= 2.5 ml/1"DBH; Medium= 5 mls/1"DBH; High= 10 mls/1"DBH. Use low to medium rates as preventive treatments. Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTIONS

- Do not apply to trees that may yield food consumed by humans or used in animal feed.
- Avoid treating trees that are moisture stressed or suffering from herbicide damage.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Disposal

Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

TREE- äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2009 Syngenta

For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP xxxxxA-M(draft-c TREE-äge)

TREE-age xxxxxA-M(draft-c)clean-7-10-09-lg 000100-xxxxx.20090710.treeageC.pdf

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED
APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION,
AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED
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TREE-äge™

Injected insecticide for the control of listed arthropod pests in ash trees

Active Ingredient:
Emamectin Benzoate[1] 4.0%
Other Ingredients: 96.0%
Total: 100.0%

[1]CAS No.155569-91-8

KEEP OUT OF REACH OF CHILDREN.

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Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-xxxxx

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP xxxxxA-M(draft-c TREE-äge)

Net Contents

label version = 000100-0RGNO.20090710.treeageC.pdf

Summary of Comments on Microsoft Word - TREE-age xxxxA-M_draft-c_clean-2-7-10-09-lg.doc

Page: 1

Author: tharri02 Subject: Inserted Text Date: 7/11/2009 8:23:46 PM
add:

(Fraxinus spp.)

Author: tharri02 Subject: Rectangle Date: 7/11/2009 8:25:10 PM
ADD:

"Contains 0.36 lbs. emamectin per gallon."

Author: tharri02 Subject: Text Box Date: 7/11/2009 8:43:32 PM
label version = 000100-0RGNO.20090710.treeageC.pdf

This page contains no comments

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. 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.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

This page contains no comments

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- shoes and socks
- protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

This page contains no comments

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of ash trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood.

USE DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Avoid injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits.

Page: 5

Author: tharri02 Subject: Inserted Text Date: 7/11/2009 8:27:46 PM
add:

"(Fraxinus spp.)"

Author: tharri02 Subject: Inserted Text Date: 7/11/2009 8:27:21 PM
add: (optional)

"rights of ways, "

Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

~~Resinous Conifers~~

~~In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.~~

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. ~~Watering the trees prior to injection is therefore required if they are drought or heat stressed.~~

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

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Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:28:35 PM
delete

Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:30:17 PM
delete

I don't think you want to go here.
1) It's too vague. How much water?
2) May be unenforceable. Certainly would keep the lawyers busy if it went to court.
Leave it out for now and we can discuss this.

USE

Use as formulated or dilute with equivalent ~~1 to 3 volumes~~ of water or more, as necessary. [redacted]

USE RATE TABLE*

Tree Diameter (DBH) (Inches)	Low ml./tree	Medium ml./tree	~~Medium - High~~ ml./tree	High ml./tree	Number of Injection Sites**
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

~~* Product/1" DBH: Low= 2.5 ml/1"DBH; Medium= 5 mls/1"DBH; High= 10 mls/1"DBH.~~ The use of low, medium and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.
~~**For control, be within ± 1 injection site of this number per tree.~~
Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Page: 7

Author: tharri02 Subject: Rectangle Date: 7/11/2009 8:31:21 PM
add:

"Apply once per year."

Just to repeat this important fact rather than only having it appear in a footnote to pest table.

Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:32:47 PM
delete

Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:45:01 PM
delete

Author: tharri02 Subject: Inserted Text Date: 7/11/2009 8:32:19 PM
insert "product" so it reads

"ml. product/tree"

Repeat for all column headers

Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:33:27 PM
delete

Nice idea but this conflicts with quantities in table. Leave out for now and we can discuss.

Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:34:58 PM
delete

Again, nice idea but the number of sites in table conflict with earlier statement to inject about every 6". Besides, I don't think the number of sites is that critical, it's how much chemical you get into tree that's important. Leave out for now; we can discuss.

Applications in Trees[1]

Tree Tissue	Target Pest	Recommended Rate[2]	Comments
~~Seed and Cone~~	~~Pine Cone Worm (Dioryctria spp)~~	~~Medium to High~~	~~For control apply in the fall for early season pests or at least 30 days before insect attack.~~
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Eucalyptus, Pine Sawyer) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

1 Apply once per ~~season.~~
2 ~~Low= 2.5 ml/1"DBH; Medium= 5 mls/1"DBH; High= 10 mls/1"DBH.~~ Use low to medium rates as preventive treatments. Use medium to high rates for remedial and longer residual control.

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Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:35:42 PM
delete

Rest of pests can stay but this one is obviously not applicable for ash trees.

Author: tharri02 Subject: Replacement Text Date: 7/11/2009 8:36:42 PM
change "season" to "year".

Season used for annual crops that have multiple life cycles per year. Not applicable to trees.

Author: tharri02 Subject: Cross-Out Date: 7/11/2009 8:37:41 PM
delete

see earlier note
rest of footnote can stay

Page: 9

Author: tharri02 Subject: Highlight Date: 7/11/2009 8:39:49 PM
ok for now but this should be updated to PR Notice 2007-4

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTIONS

- Do not apply to trees that may yield food consumed by humans or used in animal feed.
- Avoid treating trees that are moisture stressed or suffering from herbicide damage.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Disposal

Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

TREE- äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

This page contains no comments

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP xxxxxA-M(draft-c TREE-äge)

FW: TREE-AGE revision
tom.parshley to: Thomas Harris 07/10/2009 04:40 PM
Cc: janis.mcfarland

Tom: I know it's after 2PM, but we did the best we could with such short notice to address label issues, given their complexity and the concerns raised by both Syngenta and EPA. The highlighted label shows the corrections we have made in an attempt to address as many of the issues raised as possible. Syngenta will be contacting your office to work post registration to obtain a review of the already submitted bee information to address the pollinator issue so we may achieve more tree species, and to resolve the 2-year extended control claim need that we have for this product. We would like to quickly resolve these two areas in the upcoming few months so next season we have the label pretty much as we originally envisioned.

Best regards,

Tom

From: Gold Lorraine USGR
Sent: Friday, July 10, 2009 2:28 PM
To: Parshley Tom USGR
Subject: TREE-AGE revision
Importance: High

Tom, attached are the revised marked and clean versions of the Tree-age label.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

000100-xxxxx.20090710.treeageC.PDF

TREE-age xxxxA-M_draft-c_marked-7-10-09-lg.pdf

DATE OUT: 02 / APR / 2008

FEE

SUBJECT: **FEE.PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: D348523 **File Symbol No.:** 100-RGNO
PRODUCT NAME: TREE-age
COMPANY: Syngenta Crop Protection Incorporation
FOOD USE [ ] **INTEGRATED FORMULATION [ ]**
PCC: 122806; **Decision No.** 387891; **Action Code:** R310

FROM: Shyam B. Mathur
Product Chemistry Team Leader
Technical Review Branch / RD (7505P)

SBMathur 04/02/08

TO: Tom Harris / John Hebert, RM 07
Insecticide-Rodenticide Branch / RD (7505P)

INTRODUCTION:

The registrant has submitted product chemistry data in support of the registration application for the proposed end-use product. The registrant has submitted the product chemistry data corresponding to group A & B under MRID Nos. 473093-01 & 473093-02.The registrant has submitted CSF's for basic & alternate formulations (both dated 12-13-07) along with the product label. TRB has been asked to evaluate product chemistry data submitted and determine the acceptability of the proposed basic and alternate CSF's.

SUMMARY OF FINDINGS

1. The proposed end use product contains Emamectin Benzoate technical [97%] as the active ingredient with product label claim of 4.0%.

2. The CSF's of basic & alternate formulations (both dated 12-13-07) are filled out correctly & completely. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF's for basic & alternate formulations are in compliance with PR Notice 91-2. All the inert ingredients present in the formulation are approved by the Agency (IIAB, 01-02-08). The certified limits for the AI and inert ingredients are in compliance with standard certified limit table set forth in 40CFR§158.350(b)(2), except for three inert ingredients. The registrant has proposed wider limits for these inert ingredients and has provided the proper justifications. The data submitted corresponding to guidelines 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the product chemistry data requirements of 40CFR§158.320 & 158.350 respectively [MRID No. 473093-01].

3. The data submitted corresponding to guideline 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), and 830.1670 (discussion on the formation of impurity) satisfy the data requirements of 40CFR §158.325, §158.335, & §158.340 respectively [MRID No. 473093-01].

4. The data submitted corresponding to guideline 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.355. A validated HPLC-UV method was used for the determination of the active ingredients in the proposed end use product. The HPLC-UV method employed a Hypersil BDS C18, 150 mm x 4.6 mm, 3 µm with external standard quantification [MRID No. 473093-01].

5. The data submitted corresponding to guideline 830 series subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR158.190, excluding one year storage stability (830.6317) and corrosion characteristics (830.6320) data [MRID No. 473093-01].

6. The registrant has indicated that one year studies for the guidelines 830.6317(one year storage stability) and 830.620 (corrosion characteristics) under warehouse conditions are in progress and the results will be submitted to the Agency on completion. It is recommended that observations must be made at 0, 3, 6, 9, and 12 month interval periods.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The product chemistry data submitted for the guidelines 830 Series Subgroup A & Subgroup B are acceptable, except for one year storage stability & corrosion characteristics studies.

2. The proposed CSF's for basic and alternate formulations (both dated 12-13-07) are acceptable.

3. The registrant must submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) studies on completion.

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (basic & alt CSF's)	A	12-13-07
830.1600. Beginning Materials	A	473093-01
830.1650. Formulation Process	A	" " "
830.1670. Discussion of Impurities	A	" " "
830.1700. Preliminary Analysis	NA	
830.1750. Certified Limits (basic & alt CSF's)	A	12-13-07
830.1800. Enforcement Analytical Method (cited)	A	473093-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	A	Blue	473093-02
830.6303. Physical State	A	Liquid	" " "
830.6304. Odor	A	Aromatic	" " "
830.6314. Oxidation/Reduction Action	A	Not an oxidizing substance	" " "
830.6315. Flammability	A	> 220°F	" " "
830.6316. Explodability	A	Not explosive	" " "
830.6317. Storage stability	I	1 year in progress	
830.6319. Miscibility	NA		
830.6320. Corrosion Characteristics	I	1 year in progress	
830.6321. Dielectric Breakdown. Voltage	NA		
830.7000. pH	A	3-6 [1% aqueous dispersion] /25°C	473093-02
830.7100. Viscosity	A	42mPa/s 20°C	" " "
830.7000. Density/Bulk Density	A	1.076 g/ml @ 20°C	" " "

Explanations: A = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

830.1800. Enforcement analytical method: (MRID 473093-01)

The active ingredient was determined by HPLC-UV method with external standard quantification.

Equipment & Parameters

The following details are examples of suitable equipment and conditions for its use.

Chromatograph:	Agilent 1100 Series Quarternary Pump Agilent 1100 Series Autosampler Agilent 1100 Series Thermostatted Column Compartment
Detector:	Agilent 1100 Series Diode Array Detector layer thickness: 10 mm detection wavelength: 245 nm (UV detection), 5 nm bandwidth output voltage: 1 V
Column:	Hypersil BDS C18 particle size: 3 µm column length: 150 mm column i.d.: 4.6 mm
Column temperature:	40°C
Size of sample:	5 µl of reference / test solution from Section 3.1.2
Flow rate:	1.0 ml/minute
Duration of chromatography:	approx. 14 minutes
Mobile phase (isocratic):	75% acetonitrile / 25% deionized water / 0.8 ml/L ethanolamine

Retention times:

Emamectin benzoate B1b = 6.3 minutes

Emamectin benzoate B1a = 7.7 minutes

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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

03/JUN/2008

MEMORANDUM

Subject:	Name of Pesticide Product:	TREE-age
	EPA File Symbol:	100-RGNO
	DP Barcode:	D348524
	Decision No.:	387891
	Action Code:	R310
	PC Code:	128806 (emamectin benzoate)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew
Harris
6-9-08

To: Thomas Harris, RM Team 07
Insecticide -Rodenticide Branch
Registration Division (7505P)

Applicant: Syngenta Crop Protection, Inc.
P. O. Box 18300
Greensboro, NC 27419

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Emamectin benzoate	4.0
Inert Ingredient(s):	96.0
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests review of acute toxicity data for 100-RGNO.

BACKGROUND: Syngenta Crop Protection, Inc. has submitted a six pack of acute toxicity studies to support the proposed product, TREE-age, EPA File Symbol 100-RGNO. The studies were conducted at Eurofins/Product Safety Laboratories, Inc. with assigned MRID numbers 473093-03 to -08. CSFs dated December 13, 2007 for a basic formulation and one alternate formulation are included in the submission. An Agency contractor, Oak Ridge National Laboratory, conducted the primary review of the studies. TRB performed the secondary review and made changes as necessary.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for TREE-age, EPA File Symbol 100-RGNO, is as follows:

Acute oral toxicity	III	Acceptable	MRID 47309303
Acute dermal toxicity	IV	Acceptable	MRID 47309304
Acute inhalation toxicity	IV	Acceptable	MRID 47309305
Primary eye irritation	II	Acceptable	MRID 47309306
Primary skin irritation	IV	Acceptable	MRID 47309307
Dermal sensitization	Negative	Acceptable	MRID 47309308

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for the proposed product as obtained from the Label Review System:

PRODUCT ID #: 000100-01309

PRODUCT NAME: TREE-age

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

SPANISH SIGNAL WORD: AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Wear: Long-sleeved shirt and long pants, socks, shoes, and gloves.

First Aid:

If in eyes:
-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 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 by a poison control center or doctor.
-Do not give anything to an unconscious person.

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-xxx-xxxx for emergency medical treatment information.

DATA EVALUATION RECORD

EMMAMECTIN BENZOATE
[EMMAMECTIN BENZOATE ME (042.9) (A16297A)]

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [OPPTS 870.1100; OECD 425]
ACUTE DERMAL TOXICITY - RAT [OPPTS 870.1200; OECD 402]
ACUTE INHALATION TOXICITY - RAT [OPPTS 870.1300; OECD 403]
ACUTE EYE IRRITATION - RABBIT [OPPTS 870.2400; OECD 405]
ACUTE DERMAL IRRITATION - RABBIT [OPPTS 870.2500; OECD 404]
DERMAL SENSITIZATION - GUINEA PIG [OPPTS 870.2600; OECD 406]

MRID 47309303, 47309304, 47309305, 47309306, 47309307, and 47309308

Prepared for
Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Task Order No. 1-18

Primary Reviewer:
Susan Chang, M.S.

Signature: S S Chang
Date: MAY 08 2008

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: Tim Borges
Date: MAY 08 2008

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: MAY 08 2008

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L.A. Wilson
Date: MAY 08 2008

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

Reviewer: ORNL **Date:** April 1, 2008
Risk Manager (EPA): 07

STUDY TYPE: Acute Oral Toxicity – Rat; OPPTS 870.1100; OECD 425

TEST MATERIAL: Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid, specific gravity 1.067 g/mL)

CITATION: Durando, J. (2007) Emamectin Benzoate ME (042.9) (A16297A) – Acute Oral Toxicity Up and Down Procedure in Rats. Study Number 23029. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. December 5, 2007. MRID 47309303.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 47309303), nine fasted, young adult female Sprague-Dawley rats (age: 9-11 weeks; body weight: 170-230 g; source: Ace Animals, Inc., Boyertown, PA) were given a single dose of Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770) as received at doses of 175, 550, 1750, or 5000 mg/kg bw by gavage and observed for 14 days.

All 5000 mg/kg animals died within one day of dosing. All other animals survived the study. One 1750 mg/kg animal had reduced fecal volume on days 2-4 and one 1750 mg/kg animal was hypoactive 5 hours post dosing and had reduced fecal volume on day 1. These animals appeared active and healthy starting on day 2 or 5 until the end of the study. The other surviving animals appeared active and healthy throughout the study. All surviving animals gained weight throughout the study. All decedents were hypoactive and had hunched posture and one decedent had piloerection prior to death. The decedents had red intestines. No gross abnormalities were noted from any surviving animal at necropsy.

Females estimated LD_{50} = 3129 mg/kg bw (Approximate 95% confidence interval is 1750 to 5000 mg/kg bw)

Emamectin Benzoate ME (042.9) (A16297A) is in EPA Toxicity Category III.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 425) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

AOT425statpgm (Version: 1.0) Test Results and Recommendations
Acute Oral Toxicity (OECD Test Guideline 425) Statistical Program

Date/Time: Monday, March 31, 2008, 2:47:41 PM
Data file name: work.dat
Last modified: 3/31/2008 2:47:39 PM

Test/Substance: Emamectin Benzoate ME (042.9) (A16297A)
Test type: Main Test
Limit dose (mg/kg): 5000
Assumed LD_{50} (mg/kg): Default
Assumed sigma (mg/kg): 0.5

Recommended dose progression: 5000, 1750, 550, 175, 55, 17.5, 5.5, 1.75

DATA:

Test Seq.	Animal ID	Dose (mg/kg)	Short-term Result	Long-term Result
1	3101	175	O	O
2	3102	550	O	O
3	3103	1750	O	O
4	3104	5000	X	X
5	3105	1750	O	O
6	3106	5000	X	X
7	3107	1750	O	O
8	3108	5000	X	X

(X = Died, O = Survived)

Dose Recommendation: The main test is complete.

Stopping criteria met: 5 reversals in 6 tests. LR criterion.

SUMMARY OF LONG-TERM RESULTS:

Dose	O	X	Total
175	1	0	1
550	1	0	1
1750	3	0	3
5000	0	3	3
All Doses	5	3	8

Statistical Estimate based on long term outcomes:

Estimated LD_{50} = 3129 (Based on an assumed sigma of 0.5).
Approximate 95% confidence interval is 1750 to 5000.

Animals were dosed as follows:

Animal Number	Sex	Dose Level (mg/kg)	Long-Term Outcome
3102	F	175	S
3103	F	550	S
3104	F	1750	S
3105	F	5000	D
3106	F	1750	S
3107	F	5000	D
3108	F	1750	S
3109	F	5000	D

S = Survival, D = Death
Animal No. 3101 was dosed at limit dose of 5000 mg/kg. Due to the mortality in this animal, a main test was conducted.

A. **Mortality:** All 5000 mg/kg animals died within one day of dosing. All other animals survived the study.

B. **Clinical observations:** One 1750 mg/kg animal had reduced fecal volume on days 2-4 and one 1750 mg/kg animal was hypoactive 5 hours post dosing and had reduced fecal volume on day 1. These animals appeared active and healthy starting on day 2 or 5 until the end of the study. The other surviving animals appeared active and healthy throughout the study. All surviving animals gained weight throughout the study. All decedents were hypoactive and had hunched posture and one decedent had piloerection prior to death.

C. Gross necropsy: The decedents had red intestines. No gross abnormalities were noted from any surviving animal.

D. Reviewer's conclusions: This reviewer agrees with the study author regarding the acute oral LD_{50}.

Reviewer: ORNL **Date:** April 1, 2008
Risk Manager (EPA): 07

STUDY TYPE: Acute Dermal Toxicity – Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid, specific gravity 1.067 g/mL)

CITATION: Durando, J. (2007) Emamectin Benzoate ME (042.9) (A16297A) – Acute Dermal Toxicity in Rats. Study Number 23030. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. December 5, 2007. MRID 47309304.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 47309304), five male and five female young adult Sprague-Dawley rats (age: 9-10 weeks; body weight: males: 275-303 g and females: 189-226 g; source: Ace Animals, Inc., Boyertown, PA) were dermally exposed for 24 hours on an area of approximately 10% of the total body surface area on the clipped dorsal trunk to 5000 mg/kg bw Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; pH not reported) as received. The test material was applied evenly over the dose area and covered with a gauze pad. The gauze and the trunk were wrapped with Durapore tape. The animals were observed for 14 days.

All animals survived, and gained weight and appeared active and healthy throughout the study. Erythema and edema were noted on the dose site of two males and two females on day 1. No gross abnormalities were noted at necropsy.

LD_{50} Males > 5000 mg/kg bw
LD_{50} Females > 5000 mg/kg bw
LD_{50} Combined > 5000 mg/kg bw

Emamectin Benzoate ME (042.9) (A16297A) is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dose (mg/kg bw)	Mortality/Number Tested		
	Males	Females	Combined
5000	0/5	0/5	0/10

A. **Mortality:** All animals survived the study.

B. **Clinical observations:** All animals appeared active and healthy throughout the study. Erythema and edema were noted on the dose site of two males and two females on day 1.

C. **Gross necropsy:** No gross abnormalities were noted at necropsy.

D. **Reviewer's conclusions:** This reviewer agrees with the study author regarding the acute dermal LD_{50}.

Reviewer: ORNL **Date:** April 1, 2008
Risk Manager (EPA): 07

STUDY TYPE: Acute Inhalation Toxicity – Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid)

CITATION: Durando, J. (2007) Emamectin Benzoate ME (042.9) (A16297A) – Acute Inhalation Toxicity in Rats. Study Number 23031. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. December 5, 2007. MRID 47309305.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 47309305), five male and five female young adult Sprague-Dawley rats (age: 11-12 weeks; body weight: males: 332-396 g and females: 232-260 g; source: Ace Animals, Inc., Boyertown, PA) were exposed by nose-only inhalation to Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770) for 4 hours and 1 minute at a concentration of 2.54 mg/L. The animals were then observed for 14 days. The MMADs were 2.5 and 2.6 µm and the GSD 1.83 and 1.85 at 1.5 and 3 hours, respectively.

All animals survived and gained weight during the study. One male had red ocular discharge upon removal from the chamber through day 2. One female was hypoactive and had irregular respiration upon removal from the chamber through day 1. Thereafter, these two animals appeared active and healthy. All other animals were active and healthy throughout the study. No gross abnormalities were noted in any animal at necropsy.

LC_{50} Males > 2.54 mg/L
LC_{50} Females > 2.54 mg/L
LC_{50} Combined > 2.54 mg/L

Emamectin Benzoate ME (042.9) (A16297A) is in EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirements for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Gravimetric Conc. (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
				Males	Females	Combined
253.98	2.54	2.5, 2.6	1.83, 1.85	0/5	0/5	0/10

Test Atmosphere / Chamber Description: The exposure atmosphere was generated using a 1/4 inch JCO atomizer (Spraying Systems Co.), FC3 fluid cap (Robert Miller Associates), and 70 SS air cap (Spraying Systems Co.). The test material was metered to the atomization nozzle through Tygon tubing using a pump. Filtered air was supplied by an air compressor connected to the spray atomization nozzle. Additional compressed mixing air from a compressed air tank was introduced into the chamber to help uniformly distribute the test atmosphere. Animals were individually housed in polycarbonate holding rubes which were sealed to the chamber during exposure. The exposure chamber was a Mini Nose-Only Chamber (ADG Developments Ltd.).

Gravimetric Conc. (mg/L):	**2.54**
Chamber Volume (L):	**6.7**
Total Airflow (L/min):	**25.7**
Temperature	**21-23°C**
Relative Humidity	**68-73%**
Time to equilibrium:	**1.2 minutes**

Test atmosphere concentration: During exposure, gravimetric samples were collected six times from the breathing zone of the animals, using glass fiber filters. Filter papers were weighed before and after collection to determine the mass collected. The value was divided by the total volume of air sampled to determine the chamber concentration.

Particle size determination: Particle size for each exposure concentration was determined twice using an eight-stage Andersen cascade impactor. The test material concentration collected at each stage was determined gravimetrically. The mass median aerodynamic diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes.

A. **Mortality:** All animals survived the study.

B. **Clinical observations:** One male had red ocular discharge upon removal from the chamber through day 2. One female was hypoactive and had irregular respiration upon removal from

the chamber through day 1. Thereafter, these two animals appeared active and healthy. All other animals were active and healthy throughout the study. All animals gained weight during the study.

C. Gross necropsy: No gross abnormalities were noted in any animal at necropsy.

D. Reviewer's conclusions: This reviewer agrees with the study author regarding the acute inhalation LC_{50}.

Reviewer: ORNL **Date:** April 1, 2008
Risk Manager (EPA): 07

STUDY TYPE: Primary Eye Irritation – Rabbit; OPPTS 870.2400; OECD 405

TEST MATERIAL: Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid)

CITATION: Durando, J. (2007) Emamectin Benzoate ME (042.9) (A16297A) – Primary Eye Irritation in Rabbits. Study Number 23032. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. December 5, 2007. MRID 47309306.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 47309306), 0.1 mL of undiluted Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; pH not reported) was instilled into the conjunctival sac of the right eye of three female young adult New Zealand White rabbits (source: Robinson Services, Inc., Clemmons, NC). The untreated eye served as a control. Prior to instillation, 2-3 drops of ocular anesthetic (Tetracaine Hydrochloride Ophthalmic solution) were placed into both the treated and control eye of each animal.The animals were observed for 72 hours and at 4, 7, 10, and 14 days post-instillation.

Corneal opacity was noted on 3/3 rabbits one hour after test material instillation with clearance on one rabbit by 24 hours and on two rabbits by day 14. Iritis was noted on 3/3 rabbits one hour through 24 hours after test material instillation with clearance on one rabbit by 48 hours and on two rabbits by day 14. Positive conjunctival irritation was noted on 3/3 rabbits one hour after test material instillation with clearance on one rabbit by 48 hours, on another rabbit by day 10, and on the third rabbit by day 14. The highest maximum mean total score was 27.7, recorded 24 hours after test material instillation.

In this study, Emamectin Benzoate ME (042.9) (A16297A) was severely irritating. Emamectin Benzoate ME (042.9) (A16297A) is in EPA Toxicity Category II for primary eye irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

	Number "positive"/Number treated							
	Hours				days			
Observations	**1**	**24**	**48**	**72**	**4**	**7**	**10**	**14**
Corneal Opacity	3/3	2/3	2/3	2/3	2/3	2/3	2/3	0/3
Iritis	3/3	3/3	2/3	2/3	2/3	2/3	2/3	0/3
Conjunctivae:								
Redness*	3/3	3/3	2/3	2/3	2/3	2/3	1/3	0/3
Chemosis*	3/3	1/3	1/3	1/3	1/3	0/3	0/3	0/3
Discharge**	3/3	3/3	2/3	2/3	0/3	0/3	0/3	0/3

* Score of 2 or more required to be considered "positive"
** Discharge is not a positive effect according to the grading scale

A. **Observations:** Corneal opacity was noted on 3/3 rabbits one hour after test material instillation with clearance on one rabbit by 24 hours and on two rabbits by day 14. Iritis was noted on 3/3 rabbits one hour through 24 hours after test material instillation with clearance on one rabbit by 48 hours and on two rabbits by day 14. Positive conjunctival irritation was noted on 3/3 rabbits one hour after test material instillation with clearance on one rabbit by 48 hours, on another rabbit by day 10, and on the third rabbit by day 14.

B. **Results:** Emamectin Benzoate ME (042.9) (A16297A) was severely irritating. The highest maximum mean total score was 27.7, recorded 24 hours after test material instillation.

C. **Reviewer's conclusions:** This reviewer agrees with the study author that the test material was severely irritating.

Reviewer: ORNL **Date:** April 1, 2008
Risk Manager (EPA): 07

STUDY TYPE: Primary Dermal Irritation – Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid)

CITATION: Durando, J. (2007) Emamectin Benzoate ME (042.9) (A16297A) – Primary Skin Irritation in Rabbits. Study Number 23033. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. December 5, 2007. MRID 47309307.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 47309307), three male young adult New Zealand White rabbits (source: Robinson Services, Inc., Clemmons, NC) were dermally exposed to 0.5 mL of undiluted Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; pH not reported) for 4 hours on a 6 cm^2 area of the clipped dorsal skin that was covered with a gauze patch. The patch and trunk were wrapped with semi-occlusive Micropore tape. Elizabethan collars were placed on the rabbits. The animals were observed and irritation was scored at 1, 24, 48, and 72 hours after patch removal.

Very slight erythema was noted on 3/3 rabbits 30-60 minutes after patch removal with clearance on one rabbit by 24 hours, on another rabbit by 48 hours, and on the third rabbit by 72 hours.

In this study, the formulation was slightly irritating based on the Primary Irritation Index (PII) of 0.5. Emamectin Benzoate ME (042.9) (A16297A) is in EPA Toxicity Category IV for primary dermal irritation.

This study is classified as acceptable. It does satisfy the guideline requirements for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Animal Number	Sex	Hours			
		1	24	48	72
3501	M	1/0[a]	1/0	1/0	0/0
3502	M	1/0	1/0	0/0	0/0
3503	M	1/0	0/0	0/0	0/0
Severity of Irritation – Mean Score		1.0	0.7	0.3	0.0

[a] Erythema/edema

A. **Observations:** Very slight erythema was noted on 3/3 rabbits 30-60 minutes after patch removal with clearance on one rabbit by 24 hours, on another rabbit by 48 hours, and on the third rabbit by 72 hours.

B. **Results:** Emamectin Benzoate ME (042.9) (A16297A) was slightly irritating. The Primary Irritation Index (PII) is 0.5.

C. **Reviewer's conclusions:** This reviewer agrees with the study author that the test material was slightly irritating.

Reviewer: ORNL **Date:** April 1, 2008
Risk Manager (EPA): 07

STUDY TYPE: Dermal Sensitization – guinea pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid)

CITATION: Durando, J. (2007) Emamectin Benzoate ME (042.9) (A16297A) – Dermal Sensitization Study in Guinea pigs (Buehler Method). Study Number 23034. Eurofins/Product Safety Laboratories, 2394 US Highway 130, Dayton, NJ 08810. December 5, 2007. MRID 47309308.

SPONSOR: Syngenta Crop Protection, Inc., 410 Swing Road, Greensboro, NC 27419-8300

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 47309308) with Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; pH not reported), 30 female young adult Hartley albino guinea pigs (body weight: 323-380 g; source: Elm Hill Breeding Labs, Chelmsford, MA) were tested using the Buehler Method. The test animals were induced with 0.4 mL of undiluted test material for six hours using occlusive 25 mm Hill Top Chambers that were secured and wrapped with non-allergenic adhesive tape. The procedure was repeated once each week for three consecutive weeks. Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites. The naive control animals were treated with 0.4 mL of undiluted test material under occlusion at challenge. Reactions were scored 24 and 48 hours after test material applications.

After three consecutive weekly inductions, no positive dermal reactions were noted from any animal after challenge.

Based on the results of this study, Emamectin Benzoate ME (042.9) (A16297A) was not a dermal sensitizer. The mean challenge scores were 0.00 and 0.03 for naive control and test animals, respectively, at 24 hours and 0.00 for naive control and test animals at 48 hours.

This study is classified as acceptable. It does satisfy the guideline requirements for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the guinea pigs.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

PROCEDURE:

A. **Induction**: The animals were induced and challenged according to the Buehler method. The dorsal and flank areas of 20 test guinea pigs were clipped prior to each treatment. For induction, 0.4 mL of undiluted test material was applied to the animal using an occlusive 25 mm Hill Top Chamber and secured with non-allergenic adhesive tape. The chamber was removed after six hours and excess test material removed. The procedure was repeated once each week for three consecutive weeks. Reactions were scored 24 and 48 hours after the induction applications.

B. **Challenge**: Twenty-seven days after the first induction, the test animals were challenged with 0.4 mL of undiluted test material under occlusion to naive sites for 6 hours. Reactions were scored 24 and 48 hours after challenge application.

C. **Naive control:** The dorsal and flank areas of 10 naive control animals were clipped prior to treatment. At challenge, the naive control group was treated with 0.4 mL of undiluted test material for 6 hours. Reactions were scored 24 and 48 hours following challenge application.

RESULTS and DISCUSSION:

A. **Reactions and durations**: Very faint usually non-confluent erythema was noted on 12/20 test animals over the course of three inductions. Very faint usually non-confluent erythema was noted on 1/20 test animals 24 hours after challenge with clearance by 48 hours. The naive control animals had no irritation after challenge. The test material was not a dermal sensitizer.

B. **Positive control**: The report included the results of a positive control (alpha-hexylcinnamaldehyde) study #21953 conducted within six months of the current study; the results were appropriate.

C. **Reviewer's conclusion**: This reviewer agrees with the study author that the test material was not a dermal sensitizer.

1. **DP BARCODE:** DP348524
2. **PC CODE:** 122806
3. **CURRENT DATE:** April 1, 2008
4. **TEST MATERIAL:** Emamectin Benzoate ME (042.9) (A16297A) (Emamectin Benzoate, 4.03% w/w; Batch ID 511770; clear blue liquid, specific gravity 1.067 g/mL)

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Eurofins/Product Safety Laboratories 23029/December 5, 2007	47309303	Females estimated LD_{50} = 3129 mg/kg bw	III	A
Acute dermal toxicity/rat Eurofins/Product Safety Laboratories 23030/December 5, 2007	47309304	LD_{50} Males > 5000 mg/kg bw LD_{50} Females > 5000 mg/kg bw LD_{50} Combined > 5000 mg/kg bw	IV	A
Acute inhalation toxicity/rat Eurofins/Product Safety Laboratories 23031/December 5, 2007	47309305	LC_{50} Males > 2.54 mg/L LC_{50} Females > 2.54 mg/L LC_{50} Combined > 2.54 mg/L	IV	A
Primary eye irritation/rabbit Eurofins/Product Safety Laboratories 23032/December 5, 2007	47309306	Severely irritating	II	A
Primary dermal irritation/rabbit Eurofins/Product Safety Laboratories 23033/December 5, 2007	47309307	Slightly irritating	IV	A
Dermal sensitization/Guinea pig Eurofins/Product Safety Laboratories 23034/December 5, 2007	47309308	Not sensitizing	-	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived

EFFICACY REVIEW

PRODUCT: Tree-Age

FILE SYMBOL: 100-RGNO

DATE: November 6, 2008

GLP: No

BARCODE: D358155

DECISION: 387891

CHEMICAL: Emamectin benzoate (4%)

CHEMICAL NUMBER: 122806

PURPOSE: Review data to support product registration.

MRIDS: 47465501. Cox, D.; Cosky, S. (2008) Emamectin Benzoate (A 16297A)- Product Performance Data Supporting the Conrol of Emerald Ash Borer, *Agrilus planipennis* and Asian Longhorn Borer, *Anoplophora glabripennis* Following Trunk Injection in Trees: Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection. 84 p.

TEAM REVIEWER: Tom Harris

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist 11-6-08

SECONDARY EFFICACY REVIEWER: Joanne Edwards, M.S., Entomologist Joanne L Edwards 11/6/08

BACKGROUND:

Tree-Age (EPA File Symbol 100-RGNO) is an injected insecticide intended for the control of numerous tree pests, including emerald ash borers and Asian longhorn beetles. The dosage varies depending upon tree diameter (see Table 1). The proposed label references the following website: www.syngenta-us.com.

Currently, there are already two Tree-Age SLN products registered (WV080002; OH080002) for the control of emerald ash borers. The registrations of both products were supported by the submission of efficacy data (see Agency Review dated April 18, 2008; D351729; D351728). The submission was comprised of adult mortality, larval

density and canopy dieback data and was conducted by Michigan State University (multiple geographic locations).

Table 1. Tree-Age; Directions for Use[1]

Tree Diameter	Low (ml/tree)	Medium (ml/tree)	Medium-High (ml/tree)	High (ml/tree)	Injection Sites
4 – 6	15	25	50	-	3
7 – 9	20	40	80	-	4
10 – 12	30	55	110	165	5
13 – 15	35	70	140	210	6
16 – 18	40	75	150	225	7
19 – 21	50	100	200	300	8
22 – 24	-	115	230	345	10
25 – 27	-	130	260	390	11
28 – 30	-	145	290	435	12
31 – 33	-	160	320	480	13
34 – 36	-	175	350	525	15
37 – 39	-	190	380	570	16
40 – 42	-	205	410	615	17
43 – 45	-	220	440	660	18
46 – 48	-	235	470	705	20
49 – 51	-	250	500	750	21
52 – 54	-	265	530	795	22
55 – 57	-	280	560	840	23
58 – 60	-	295	590	885	25
61 – 63	-	310	620	930	26
64 – 66	-	325	650	975	27
67 – 69	-	340	680	1020	28
70 – 72	-	355	710	1065	30

[1] *Higher rates tend to provide longer residual and control of more difficult insects*

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

47465501. Cox, D.; Cosky, S. (2008) Emamectin Benzoate (A 16297A)- Product Performance Data Supporting the Conrol of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees: Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection. 84 p.

EMERALD ASH BORER DATA

The objective of this study was to determine the effective dose rates of Tree-Age when applied via tree injections. Additionally, the duration of control from a single application was examined. This submission is comprised of data from multiple test sites

located within Michigan and Ohio. Depending upon the site, product performance was evaluated through observations on canopy dieback, adult mortality and larval density.

Site 1- Troy, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of 10 trees per dosage. Trees injected with emamectin benzoate were treated with the following rates: 0.1 g ai/inch DBH, 0.2 g ai/inch DBG, 0.4 g ai/inch DBH, 0.5 g ai/inch DBH and 0.6 ai/inch DBH. All trees were between 12 and 26 years old and ranged in diameter from 7 to 24 inches (DBH). The initiation of the study was May/June 2005. To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in ~1 month after treatment in 2005 and again in summer 2006.

Results-

Table 2. Results; Troy, Michigan

Treatment	Rate (g ai/inch DBH)	2005		2006	
		Larval Density (per m^2)	% Die-back	Larval Density (per m^2)	% Die-back
Control	-	59.2	19	All Control Trees Dead	
Emamectin Benzoate	0.1	0	17	0	17
Emamectin Benzoate	0.2	0	25	0	27
Emamectin Benzoate	0.4	0	31	0	28
Emamectin Benzoate	0.5	0	27	0	21
Emamectin Benzoate	0.6	0	42	0	34

The percent canopy dieback for trees treated with emamectin benzoate (all doses) remained approximately the same between 2005 and 2006 or improved. There was no larval activity found in any of the trees treated with emamectin benzoate in either 2005 or 2006.

Site 2- East Lansing, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of approximately 10 trees per dosage. Trees injected with emamectin benzoate were treated with the following rates: 0.1 g ai/inch DBH, 0.2 g ai/inch DBG, and 0.4 g ai/inch DBH. All trees were between 14 and 28 years old and ranged in diameter from 10 to 24 inches (DBH). To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in summer 2006 and 2007.

Results-

Table 3. Results; East Lansing, Michigan

Treatment	Dose	Treatment Date	% Canopy Die-Back	
			2006 Die-back	2007 Die-back
Emamectin Benzoate	0.4 g ai/inch DBH	Sept. 2005	7.3	12.9
Emamectin Benzoate	0.4 g ai/inch DBH	Sept. 2005	12.5	9.9
Emamectin Benzoate	0.2 g ai/inch DBH	May 2007	20.3	17.4
Emamectin Benzoate	0.1 g ai/inch DBH	May 2007	18.5	23.1
Control	-	-	16.0	28.8

The percent canopy die-back in 2007 for trees treated with emamectin benzoate ranged from 9.9% (0.4 g ai/inch DBH; Sept. 2005) to 23.1% (0.1 g ai/inch DBH; May 2007), while the percent canopy die-back from control trees was 28.8%.

In 2007, there was no larval activity found in any of the trees treated with emamectin benzoate in 2006 or 2007, while there were approximately 19.2 larvae per m^2 found in the control trees.

Site 3- Adrian, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of approximately trees 10 per dosage. Trees injected with emamectin benzoate were treated at a rate of 0.4 g ai/inch DBH in June 2006. All trees were between 14 and 28 years old and ranged in diameter from 6 to 26 inches (DBH). To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in summer 2007.

Results-

Table 4. Results; Adrian, Michigan

Treatment	Rate	Percent Canopy Die-back		Larvae (per m^2)
		2006 Die-back	2007 Die-back	
Emamectin Benzoate	0.4 g ai/inch DBH	7.3	5.5	2.4
Control	-	9.0	16.0	6.3

The percent canopy die-back from trees treated with 0.4 g/ai inch DBH emamectin benzoate was 5.5% in 2007, as compared to 16% in the control trees. There were 2.4 larvae per m^2 in the treatment trees as compared to 6.3 larvae per m^2 in the control trees.

Sites 4 & 5- Toledo, Ohio

Archwood Study

The experimental design consisted of treating a total of 12 trees with 0.4 g/ai inch DBH emamectin benzoate in June 2006. In 2007, observations on canopy die-back and larval density (number exit holes) were compared to control trees and recorded.

Blackthorn Study

The experimental design consisted of treating trees with the following rates of emamectin benzoate: 0.1 g ai/inch DBH, 0.2 g ai/DBH, 0.4 g ai/inch DBH and 0.8 g ai/inch DBH. There were a total of 4 trees per dosage. In 2007, observations on canopy die-back and larval density (number exit holes) were compared to control trees and recorded.

Results-

Table 5. Results; Archwood Study (Toledo, Ohio)

Treatment	Dosage	# Exit Holes	% Die-back
Emamectin Benzoate	0.4 g ai/inch DBH	0.67	0
Control	-	3.92	7.5

The percent die-back of trees treated with 0.4 g ai/inch DBH emamectin benzoate was 0%, as compared to 7.5% in the controls. There were a mean total of 0.67 exit holes found in the treatment trees, as compared to 3.92 in the controls.

Table 6. Results; Blackthorn Study (Toledo, Ohio)

Treatment	Dosage	# Exit Holes	% Die-back
Emamectin Benzoate	0.1 g ai/inch DBH	0.25	0
Emamectin Benzoate	0.2 g ai/inch DBH	0.50	0
Emamectin Benzoate	0.4 g ai/inch DBH	0.25	0
Emamectin Benzoate	0.8 g ai/inch DBH	0	0
Control	-	2.75	7.5

The percent die-back of trees treated with emamectin benzoate ranged from 0 (0.8 g ai/inch DBH) to 0.50 (0.2 g ai/inch DBH), as compared 2.75 holes found in the control trees. The percent canopy die-back from trees treated with emamectin benzoate was 0% for all dosages, as compared to 7.5% in the controls.

Site 6- Wolverine Campgrounds (Michigan)

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of 30 trees per treatments. All trees ranged in diameter from 6.6 to 13.2 inches. Trees injected with emamectin benzoate were treated with the following rates: 0.1 g for DBH $\leq$ 6.5 inches, 0.15 g for DBH 6.5 to

10 inches and 0.2 g for DBH ≥ 10 inches. All trees were treated in May, 2007. Bioassays were conducted in mid-June, early July and late July to assess the percent survival of adult emerald ash borers caged with leaves taken from treated trees for 4 days.

Results-

There were 100% mortality of adult beetles caged with leaves taken from trees treated with emamectin benzoate for all three dates, as compared to ~18% (July) to ~57% (June) mortality of adult beetles caged with leaves taken from trees injected with imidacloprid.

Site 7- Strongsville, Ohio

The experimental design consisted of treating trees with a variety of different pesticides. Trees injected with emamectin benzoate were treated with 0.4 g ai/inch DBH and averaged in diameter of 4.3 to 8.0 inches. Trees were inspected for signs of emerald ash borer infestation 42 – 43 DAT and 145 – 146 DAT.

Results-

There were no signs of emerald ash borer infestation on any of the trees.

ASIAN LONGHORN BEETLE DATA

2000 Field Experiment

The experimental design consisted of treating elm, popular and willow trees with one of three insecticides (12 trees per treatment). For the purpose of this review, only emamectin trees will be discussed. All trees were between 8 to 10 years old. Emamectin benzoate was injected at a rate of 0.2 g/cm up to 15 cm DBH with an additional 0.6 g/cm for each 5 cm increment in DBH. All injections were made from June 11-14, 2000. On September 2, 2000, the numbers of dead adult beetles around the base (within 5 m of the trunk) of all elm and popular trees were collected and tallied. Due to a disturbance, beetles were not collected around the willow trees. On October 25-30, 2000, 6 trees from each treatment group were cut down to inspect for larval density.

Results-

Table 7. Chinese Data; Adult Mortality

Treatment	Mean # of Dead Adults		
	Elm	Popular	Willow[1]
Emamectin Benzoate	0.3	4.7	-
Control	1.2	0.2	-

[1] *Dead adults not collected due to disturbance*

The mean number of adult Asian longhorn beetles found under trees treated with emamectin benzoate ranged from 0.3 (elm) to 4.7 (popular).

Table 8. Chinese Data; Larval Density

Treatment	Larvae Per m^2		
	Elm	Popular	Willow
4 Month Post-Injection-			
Emamectin Benzoate	3.4	33.6	6.4
Control	11.7	39.9	21.9
12 Month Post-Injection-			
Emamectin Benzoate	4.8	21.2	4.0
Control	11.5	24.2	19.1

The number of larvae per m^2 of trees treated with emamectin benzoate after 12 months ranged from 4.0 (willow) to 21.2 (popular), while the number of larvae per m^2 in control trees ranged from 11.5 (elm) to 24.2 (popular).

RECOMMENDATIONS:

The submitted data support the registration of Tree-Age (EPA File Symbol 100-RGNO) and the addition of claims for the control of Emerald Ash Borers for up to one year. The following recommendations apply:

1. On the first page of the label, revise the claim "*Injected insecticide for the control for arthropod pest in trees*" to read "*Injected insecticide for the control of listed arthropod pests in trees*".

2. The first page of the label includes the statement "*See additional precautionary statements and directions for use on label [in booklet]*". Has the referenced "booklet" been submitted for review? Does it contain additional directions for use that are not on the label?

3. Delete the words "*optimal*" and "*optimally*" throughout the label. The use of these words can be found within the following label sections: **APPLICATION TO TREES** (page 5), **GENERAL DIRECTIONS** (page 5), **ENVIRONMENTAL CONDITIONS** (page 6), **MONITOR TREE HEALTH and PEST INFESTATIONS** (page 6) and **APPLICATION IN TREES** (page 8). In addition, make the following changes:

    a. Within the **APPLICATION TO TREES** (page 5) section of the label, revise "*To assure optimum effectiveness, this product must be placed into active sapwood.*" to read "*This product must be placed into active sapwood.*"

b. Within the **GENERAL DIRECTIONS** (page 5) section of the label, revise "***Placement of Application/Injection Sites:*** *for optimum distribution, inject at the base of the tree.*" to read "***Placement of Application/Injections Sites:*** *inject at the base of the tree.*"

4. On page 6 of the label, revise the sentence "*Tree-age may also be effective as a curative treatment against some pests, such as...*" to read "*Tree-age may also be effective as a remedial treatment against some pests, such as...*"

5. Within the **USE RATE TABLE** section of the label, delete the sentence "*Higher rates tend to provide longer residual and control of more difficult to control pests.*" This statement is unclear as to what is meant by "*...longer residual....*" and "*....control of more difficult to control pests.*"

6. Within the **USE RATE TABLE** section of the label, make the following changes concerning injection sites:

   a. Revise "***Average No. Injection Sites***" to read "***No. Injection Sites***".

   b. The footnote "*The number of injection sites listed is a guide for approximately how many are needed per size of tree.*" is too vague and must be deleted.

   c. Revise the footnote "*For optimal control, it is recommended to be with ± 1 injection site of this number per tree.*" to read "*For control, be within ± 1 injection site of this number per tree.*"

7. Recommended rates (ranging from low to high) per pest are outlined on page 8 of the label. These directions do not adequately describe when it is appropriate to apply each rate. These directions must be expanded upon.

   For example: The label states that the recommend rates for emerald ash borers are from "*low*" to "*high*". However, it doesn't explain when it is appropriate to apply the "*low*" rate and when it is appropriate to apply the "*high*" rate.

8. Page 8 of the label includes the sentence "*For optimal control apply at least 2-3 weeks before economic threshold is predicted.*" How is an applicator to know when economic threshold is predicted? To retain this statement, the label must include information on how to predict economic threshold or advice on who to contact to find out.

9. The label does not adequately state the reapplication interval. The label must be revised to clearly address this.

10. The submitted data are not adequate to support the addition of Asian longhorn beetles to the label (see comments below). All references to this pest must be deleted from the label.

    a. The submitted study only had data for one test site. To have this pest added on in the future, there must be acceptable data from at least three geographically separated areas.

    b. The submitted data for adult beetle mortality were inadequate. In addition to willow trees being removed from the trials due to a "disturbance", there were more dead beetles collected from the control elm trees than from elm trees treated with emamectin benzoate. To have this pest added back on in the future, additional data showing that this product kills both immature and adult beetles must be submitted.

11. The **GENERAL DIRECTIONS** on page 5 of the label are extremely vague on how to determine DBH. The label language "*Often the diameter is determined from measuring the...*" is not strong enough. The label must be revised to clearly state how to determine DBH.

    In addition, this section of the label contains multiple typographical errors. Throughout this section of the label, delete the quotation mark following DBH.

12. Within the **WHEN TO TREAT** section of the label, delete the sentence "Foliar pests may be controlled within 1-2 weeks after treatment under ideal conditions." This statement must be supported by data.

13. Within the **WHEN TO TREAT** section of the label, the sentence "*The primary route of toxicity is through ingestion, but may also be lethal upon contact.*" must be deleted or revised. What is meant by "*...but may also be lethal upon contact*"? Is this referring to direct contact of the pesticide and the pest, contact of a treated trees bark and the pest or contact of the treated trees leaves and the pest? In addition, is there data to support this?

14. The **WHEN TO TREAT** section of the label contains the following sentences: "*Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Watering the trees prior to injection may enhance the uptake of Tree-Age.*" If this is truly the case, then the **DIRECTIONS FOR USE** must include a statement similar to the following: "*Applications to drought or heat stressed trees require watering prior to injection.*"

15. Within the **APPLICATION TO TREES** section of the label, revise the sentence "*Tree-Age is for control of mature and immature arthropod pests of trees...*" to read "*Tree-Age is for control of listed mature and immature arthropod pests of trees...*"

EFFICACY REVIEW

PRODUCT: Tree-äge

FILE SYMBOL: 100-RGNO

DATE: May 28, 2009

GLP: No

BARCODE: D364365

DECISION: 387891

CHEMICAL: Emamectin benzoate (4%)

CHEMICAL NUMBER: 122806

PURPOSE: Review data to support the addition of 2-year emerald ash borer claim to the propose label.

MRIDS: *47691001. Cosky, S.; Cox, D. (2009) Emamectin Benzoate ME (A16297A): Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees (Multiple Year Performance Data for Emerald Ash Borer): Addendum to Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection, Inc. 53 p.*

TEAM REVIEWER: Tom Harris

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist

SECONDARY EFFICACY REVIEWER: Joanne Edwards, M.S., Entomologist

5-28-09 Joanne S. Edwards 5/28/09

BACKGROUND:

Tree-äge (EPA File Symbol 100-RGNO) is an injected insecticide intended for the control of numerous tree pests, including emerald ash borers. Please see Agency review dated November 6, 2008 (D358155) which reviewed data that were determined to be adequate to support product registration and the addition of 1-year control claims for emerald ash borers. MRID 47691001 has been submitted in an attempt to add a 2-year control claim for the same pest.

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

47691001. Cosky, S.; Cox, D. (2009) Emamectin Benzoate ME (A16297A): Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees (Multiple Year Performance Data for Emerald Ash Borer): Addendum to Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection, Inc. 53 p.

Smitley, East Lansing, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of approximately trees 10 per dosage. Trees injected with emamectin benzoate were treated at a rate of 0.4 g ai/inch DBH in fall of 2005. All trees were between 14 and 28 years old and ranged in diameter from 10 to 24 inches (DBH). To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in 2006, 2007 and 2008.

Results:

Table 1. East Lansing, MI- Canopy Dieback

Treatment	Date Applied	Canopy Dieback		
		2006	2007	2008
Tree-äge[1]	Fall, 2005	7.3%	12.9%	19.3%
Merit 200 SL[2]	Spring, 2006 2008	20.3%	19.4%	41.8%
Control	-	16.0%	28.8%	51.3%

[1] *0.4 g ai/inch DBH (emamectin benzoate)*
[2] *0.6 g ai/inch DBH (imidacloprid)*

The canopy dieback for trees treated with 0.4 g ai/inch DBH Tree-age ranged from 7.3% (2006) to 19.3% (2008).

Table 2. East Lansing, MI- Larval Density

		New Galleries/m^2		Larvae/m^2	
Treatment	Date Applied	2007	2008	2007	2008
Tree-äge[1]	Fall, 2005	0.00	0.66	0.00	0.00
Merit 200 SL[2]	Spring, 2006 2008	-	4.97		5.38
Control	-	7.43	30.78	6.86	28.71

[1] *0.4 g ai/inch DBH (emamectin benzoate; tree injected)*
[2] *0.6 g ai/inch DBH (imidacloprid; tree injected)*

There were no larvae found in 2007 or 2008 for trees treated with 0.4 g ai/inch DBH Tree-äge in 2005. The number of new galleries per meter squared for trees treated with Tree-äge ranged from 0 (2007) to 0.66 (2008).

Toledo, Ohio (site 1; Archwood site)

The experimental design consisted of treating (tree injection) trees with a Tree-äge or Ima-jet (imidacloprid) at a rate of 0.4 g ai/inch DBH. There were a total of approximately trees 12 per dosage. Trees injected with emamectin benzoate were treated on June 5, 2006. All trees ranged in diameter from 13 to 24 inches (DBH). To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) was observed in 2006, 2007 and 2008.

Results:

Table 3. Toledao, Ohio- Canopy Dieback (site 1)

Treatment	Date Applied	Percent Canopy Dieback		
		2006	2007	2008
Tree-äge	June 2006	0%	0%	0%
Ima-jet	June 2006 & 2007	0%	0%	0%
Control	-	0%	6%	51%

The canopy dieback for trees treated with 0.4 g ai/inch DBH Tree-age was 0% in both 2007 and 2008, while the percentage of dieback in the controls reached 51%.

Toledo, Ohio (site 2; Blackthorne site)

The experimental design consisted of treating trees with Tree-äge at a rates ranging from 0.1 to 0.8 g ai/inch DBH. There were a total of 4 trees per treatment. Trees injected with emamectin benzoate were treated on June 14, 2006. The diameters of the trees were not provided. To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) was observed in 2007 and 2008.

Results:

Table 4. Toledao, Ohio- Canopy Dieback (site 2)

Treatment	Rate g ai/inch DBH	Percent Canopy Dieback	
		2007	2008
Tree-äge	0.1	0%	3%
	0.2	0%	3%
	0.4	0%	10%
	0.8	0%	0%
Control		8%	53%

The percent canopy dieback for trees treated with Tree-äge in 2006 was 0% (all rates) in 2007 and ranged from 0% (0.8 g ai/inch DBH) to 10% (0.4 g ai/inch DBH). The percent canopy dieback in the untreated trees reached 53% in 2008.

Michigan State University- 3 Sites

Site 1- Interstate 96
Site 2- Seven Lakes
Site 3- Wolverine Campgrounds

Michigan State University submitted data comprised from three separate sites. A total of 175 ash trees ranging in diameter of 6 to 13 inches were included. Trees treated with Tree-äge were injected with varying rates ranging from 0.1 to 0.2 g ai/inch BDH (depending upon tree diameter). Applications of Tree-äge were made on May 22, 2007. To determine efficacy, adult beetle bioassays were conducted in June, July and August, 2007 and June and July, 2008. Larval density was evaluated in 2007 and 2007.

Results-

Trees treated with Tree-age were extremely effective at both killing adult beetles exposed to leaves and reducing larval densities. It should be noted however that the submitted data do not support a two year claim. The phrase "two years control" implies control for a total of 24 months. If original treatments were conducted in May, 2007, efficacy would need to be observed in May, 2009.

RECOMMENDATIONS:

1. The submitted data do not support the addition of a two year claim. To obtain this claim in the future, additional data must be submitted demonstrating that the product is efficacious two years (24 months) post treatment. Ideally, the submission would consist of the following:
    a. larval density data for at least 2 additional sites
    b. adult mortality data
    c. available residue data

2. Please note that all of the label comments referenced in the Agency review dated November 6, 2008 (D358155) still apply.

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: 24 July 2008

SUBJECT: Emamectin Benzoate; Occupational and Residential Risk Assessment for Proposed Use of Emamectin Benzoate on Tree Nuts and as a Tree Injection.

PC Code: 122806
Decision No.: 384481, 387891
Petition No.: NA
Assessment Type: Single Chemical/No Aggregate
TXR No.: NA
MRID No.: NA

DP Barcode: D347923, D354525
Registration No.: 100-904, 100-RGNO
Regulatory Action: Section 3
Case No.: NA
CAS No.: 155569-91-8
40 CFR: 180.505

FROM: Kelly O'Rourke, Biologist
Registration Action Branch 3
Health Effects Division (7509P)

THROUGH: Jack Arthur, ORE Assessment Team Leader
Registration Action Branch 3
Health Effects Division (7509P)

TO: John Hebert/Tom Harris, PM Team #07
Insecticide/Rodenticide Branch
Registration Division (7505P)

I. CONCLUSIONS

The TREE-äge™ label is not acceptable as written. This label needs to restrict use to application by certified applicators only, based on the acute primary eye toxicity of the product. In addition, the pounds of active ingredient per gallon need to be specified on the first page, and gloves need to be added to the personal protective equipment (PPE) section for handlers. The Proclaim® Insecticide label already specifies the necessary gloves and coveralls for airblast applicators. With these mitigation measures, occupational margins of exposure (MOEs) reach/exceed the levels of concern (LOC) of 300 and 1,000, and therefore, are not of concern.

II. ACTION REQUESTED

Provide an occupational and residential exposure and risk assessment for the proposed tree injection and foliar tree nut uses.

III. BACKGROUND/ EXECUTIVE SUMMARY

The registrant, Syngenta Crop Protection, Inc., requests the registration of the product TREE-äge™, containing the insecticide emamectin benzoate as an injected insecticide for the control of arthropod pests in trees, and a new use of Proclaim® Insecticide, as a foliar use on tree nut crops. This memorandum assesses the occupational and residential exposure risks from emamectin benzoate for the proposed uses. An aggregate human health risk assessment is presented in a separate Health Effects Division (HED) memorandum. Emamectin benzoate, is also known as emamectin. In this memorandum, the ANSI name emamectin will be used.

Use Profile

Emamectin is currently registered as a restricted-use pesticide (i.e., for use by certified applicators only) for the control of lepidopterous larvae (worms/caterpillars) on cotton, fruiting vegetables, leafy vegetables, pome fruit, and tobacco. It is also conditionally registered as a cockroach bait. The proposed formulations include:

1) an emulsifiable concentrate (TREE-äge™), containing 4.0 percent active ingredient (ai), for use as an injected insecticide for the control of arthropod pests in ornamental trees. It is proposed for use with injection systems that are marketed to both residential and professional users, however, **the <u>product's</u> acute primary eye toxicity findings indicate a requirement for restriction to use by certified applicators only.** Applications are proposed at rates of 0.0014 to 0.10 pounds ai per tree (depending on the diameter) using injection devices such as Arborjet Tree Injection Systems; and
2) a water-dispersible granule (Proclaim® Insecticide), containing 5.0 percent ai, for control of lepidopterous larvae, leafminers, and spider mites on tree nut crops. Multiple foliar applications are proposed at 0.010 to 0.015 lb ai per acre (A), using ground equipment only (aerial application is not permitted), with 7- to 14-day intervals between applications. The proposed maximum seasonal rate is 0.045 lb ai/A/season. The pre harvest interval (PHI) is 14 days.

Hazard Profile

Short-/intermediate-term occupational handler exposure is possible via the dermal and inhalation routes. In addition, postapplication exposure may occur for the tree nut scenario via the dermal and inhalation (from dusty harvesting techniques) routes. All endpoints were selected from a 15-day oral neurotoxicity study in the mouse. Dermal and inhalation exposures were combined and then compared to the short-term oral NOAEL of 0.075 mg/kg/day. The endpoint includes moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve (LOAEL of 0.1 mg/kg/day). The dermal absorption rate of 1.8% used in this assessment is based on a dermal absorption study in the Rhesus monkey, while an inhalation absorption rate of 100% was assumed. The level of

concern (LOC) for short-term exposure is a margin of exposure (MOE) less than 300 [uncertainty factors (UFs) include: 10X for interspecies extrapolation, 10X for intraspecies variation; and 3X modifying factor (UF_M) to account for the steepness of the dose-response curve and the severity of effects at the LOAEL (death and neuropathology)]. The LOC for intermediate-term exposure is an MOE less than 1000, which includes a 10X UF_M (rather than 3X) to account for the additional uncertainty of using a short-term study for an intermediate-term risk assessment. Emamectin is classified as "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

Occupational Exposure/Risk

No chemical-specific handler exposure data were submitted in support of these proposed Section 3 registration actions. It is the policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1, as presented in PHED Surrogate Exposure Guide (8/98), to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available (HED Science Advisory Council for Exposure Draft Policy # 7, dated 1/28/99).

The results of the **occupational handler** exposure and risk assessment indicate that most of the scenarios have MOEs above the short-term LOC of 300 with baseline clothing (sleeve shirt, long pants, shoes and socks). **To reach an MOE of 300 for tree injection, or 1,000 or more, which is necessary for intermediate-term exposure, additional personal protective equipment (PPE) is necessary for the following scenarios: 1) mix/load for tree injection (gloves) and 2) application using airblast (gloves and coveralls).** Note that a more effective exposure mitigation approach for the airblast application scenario would be the use of an enclosed cab as an engineering control. When appropriate mitigation is used, none of the scenarios are of concern. Per the Worker Protection Standard (WPS), the minimum level of PPE for handlers is based on the acute toxicity of the end-use product. The Registration Division is responsible for ensuring that PPE listed on the product label is in compliance with WPS.

A chemical-specific dislodgeable foliar residue (DFR) study on celery (MRID#: 44007903) was submitted for a previous action on emamectin, and the results were considered for the postapplication assessment of the tree nut use. In addition to these DFR data, the interim transfer coefficient guidance developed by HED's Science Advisory Council for Exposure, which includes proprietary data from the Agricultural Re-entry Task Force (ARTF) database (SOP # 3.1), was used in estimating dermal postapplication exposures. Inhalation exposure during dusty mechanical harvesting activities (e.g., wind rowing/sweeping) is a special concern and is not addressed with transfer coefficients. While no chemical-specific exposure data were submitted to support the evaluation of this scenario, the airblast application scenario is believed to represent a reasonable worst-case surrogate estimate of inhalation exposure during these dusty harvesting activities (although the medium on which the residues are suspended is water rather than soil).

Occupational postapplication risks were assessed for irrigation, scouting, thinning, pruning, and mechanical harvesting of tree nuts. The short- and intermediate-term **dermal MOEs for occupational postapplication are greater than the LOC 1,000 on the second day after application** (indicating an REI of 2 days); and therefore, are **not of concern**.

The **inhalation MOE for mechanical harvesting** (based on the airblast scenario) **is 1,900**. The **total MOE for mechanical harvesting** (from the combined airblast inhalation exposure and the transfer coefficient-based dermal exposure) **is 1,600**, which is greater than the LOC of 1,000. Therefore, this scenario is **not of concern**.

The proposed label for Proclaim® Insecticide has a 48-hour REI. The technical material is in Acute Toxicity Category 1 for primary eye irritation; therefore, the 48-hour REI on the label is required, and is in compliance with the Agency's Worker Protection Standard.

Residential Exposure/Risk

The proposed product TREE-äge™ is intended for use with injection systems that are marketed to both residential and professional users. However, the acute primary eye toxicity findings for this product show corneal involvement and irritation that persists for more than 7 days, which is a criterion for restriction to use by certified applicators only (40 CFR, §152.170). Therefore, the label must be changed to reflect this, and **residential handler** exposure is not expected. Residential **postapplication exposure following tree injection treatment is not expected.**

The conditionally registered product, Optigard ™ Cockroach Bait (EPA Reg. No. 100-1290), while not a restricted use pesticide, is labeled for use by professional pest control operators (PCOs) only, and not for use in residential areas. Therefore, **residential exposure is not expected for this use.**

IV. RESULTS/DISCUSSION

1.0 Hazard Profile

Table 1 presents a summary of the endpoints that the Hazard Identification Assessment Review Committee selected for emamectin (TXR. No. 0051605, 03/05/03). Also included are endpoints for incidental oral exposure which were subsequently chosen by the risk assessment team. A summary of the acute toxicity categories for the technical material are included in Table 2.

Table 1. Summary of Toxicological Dose and Endpoints for Emamectin

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months) Incidental Oral	Oral study NOAEL= **0.075** mg/kg/day	**Occupational** LOC for MOE = **N/A** **Residential LOC** for MOE: - **300** for Short-term - **1000** for Intermed-term	**15-day mouse** LOAEL = **0.1** mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months) Dermal	Oral study NOAEL= **0.075** mg/kg/day (dermal absorption rate = **1.8** %)	**Occupational and Residential LOC** for MOE: - **300** for Short-term - **1000** for Intermed-term	**15-day mouse** LOAEL = **0.1** mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Long-Term Dermal (>6 months)	Long term dermal exposure is not expected. Therefore, quantification of risk is not necessary.		
Short-Term (1 to 30 days) and Intermediate-Term (1 to 6 months) Inhalation	Oral study NOAEL= **0.075** mg/kg/day (inhalation absorption rate = 100%)	**Occupational and Residential LOC** for MOE: - **300** for Short-term - **1000** for Intermed-term	**15-day mouse** LOAEL = **0.1** mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve.
Long-Term Inhalation (>6 months)	Long term dermal exposure is not expected. Therefore, quantification of risk is not necessary.		
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

Table 2. Acute Toxicity of Emamectin Technical				
Guideline No.	**Study Type**	**MRID#**	**Results**	**Toxicity Category**
870.1100	Acute Oral- Rats	42851519	LD_{50} for L-656,748-038 = 53 mg/kg	II
870.1200	Acute Dermal- Rabbits (EC)	43850111	LD_{50} > 2.0 mg/kg	III
870.1300	Acute Inhalation- Rats	43868101	LC_{50} > 0.10 mg/L	IV
870.2400	Primary Eye Irritation- Rabbits	42743615	Severe irritation	I
870.2500	Primary Skin Irritation- Rabbits	42743616	No dermal irritation	IV
870.2600	Dermal Sensitization- Guinea pigs	42743617	Not a dermal sensitizer	-

2.0 Use Profile

Currently, emamectin is registered as a restricted use pesticide on cotton, fruiting vegetables, leafy vegetables, pome fruit, and tobacco, and as a cockroach bait (conditional registration). The proposed uses are for tree injection and foliar application to tree nut crops. The use profile proposed for this Section 3 registration request is summarized in Table 3.

Table 3. Summary of Use Pattern/Formulation Information					
Formulation Type	**Application Method**	**Use Site**	**Application Rate**	**Application Interval**	**Preharvest Interval**
TREE-äge™ (emulsifiable concentrate) 4.0% ai	Injection Devices (such as Arborjet Tree Injection Systems)	Ornamental Trees	0.0014 to 0.10 (lb ai/ tree) depending on the diameter	NS	N/A
Proclaim® Insecticide (WDG) 5.0% ai	Airblast [1]	Tree Nuts	0.10 to 0.015 (lb ai/A)	7 to 14 days [2]	14 days

[1] Aerial applications are prohibited, and product is not to be applied through any type of irrigation system.
[2] The seasonal application rate is not to exceed 0.045 lb ai/A (i.e., 3 applications at the maximum rate).

3.0 Occupational Exposure

3.1 Handler Exposure and Risk

TREE-äge™ (4.0% ai emulsifiable concentrate, EPA Reg. No. 100-RGNO) may be applied with injection devices (such as Arborjet Tree Injection Systems) to ornamental trees at a rate of 0.0014 to 0.10 lb ai/tree. The tree diameter determines the number of injection sites, and the amount injected at each site averages approximately 36 mL product (0.0034 lb ai), based on the high rate. The value used in the exposure calculation for the amount of ai handled is based on an assumption that a professional applicator could perform up to 160 injections in an 8-hr workday. This was estimated based on information from Arborjet's website (www.arborjet.com) indicating that one injection could take a little as 3 minutes (2-4 minutes to set up and 1-2 minutes to inject).

Proclaim® Insecticide (5.0% ai water-dispersible granule, EPA Reg. No. 100-904) is proposed for multiple foliar applications at rates of 0.010 to 0.015 lb ai/A, using ground equipment only (aerial application and chemigation are not permitted).

No chemical-specific exposure data were submitted in support of this registration request. The unit exposure values from the following scenarios listed in the Surrogate Exposure Guide of the "Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1," (August 1998) were used to estimate dermal and inhalation exposure to occupational handlers:

- Mix/Load: Liquid, Open Mixing (to assess loading into tree injection device, application is a closed system, therefore, additional exposure is expected to be negligible)
- Mix/Load: Dry Flowable, Open Mixing to Support Airblast application (The unit exposures listed for "dry-flowable, open mixing and loading" in PHED Surrogate Exposure Guide were selected to estimate handler exposure to Proclaim® Insecticide, which is a water-dispersible granule formulation)
- Application, Airblast: Open Cab
- Application, Airblast: Enclosed Cab

Exposure inputs and risk estimates are summarized in Table 4. The LOC for occupational risk is an MOE of less than 300 for short-term exposure, and an MOE of less than 1000 for intermediate-term exposure. MOEs were first calculated for handlers wearing "baseline" clothing, which includes: long sleeve shirt, long pants, shoes and socks. For the scenarios that are of concern at baseline, results from adding personal protective equipment (PPE) or engineering controls are also presented. The tree nuts scenarios have MOEs above the short-term LOC of 300 with baseline clothing, however the tree injection scenario does not. To reach an MOE of 300 for tree injection, or 1,000 or more, which is necessary for intermediate-term exposure, additional PPE is necessary for the following scenarios: 1) mix/load for tree injection (gloves [not indicated in the proposed label]) and 2) application using airblast (gloves and coveralls [these are indicated in the proposed label]). Note that a more effective exposure mitigation approach for the airblast application scenario would be the use of an enclosed cab as an engineering control. When appropriate mitigation is used, none of the scenarios are of concern. Per the Worker Protection Standard (WPS), the minimum level of PPE for handlers is

based on the acute toxicity of the end-use product. The Registration Division is responsible for ensuring that PPE listed on the product label is in compliance with WPS.

Table 4. Short-/Intermediate-Term MOEs for Occupational Handlers of Emamectin						
Exposure Scenario	**Route of Exposure**	**Unit Exposure (mg/lb ai)[1]**	**Application Rate (lb ai/Site or Acre)[2]**	**Area Treated (Sites or A/day)[3]**	**Daily Dose (mg/kg/day)[4]**	**Short-/ Intermed-Term MOE[5]**
Tree Injection						
Mix/Load: Liquid, Open Loading into Tree Injection Device	Dermal (baseline)	2.9	0.0034 (lb ai/ injection site)	160 Injection Sites	0.00041	180
	Dermal (w/gloves)	0.023			0.0000032	23,000
	Inhalation	0.0012			0.0000093	8,000
				Total (baseline):	0.00041	**180**
				Total (w/ gloves):	0.000013	**6,000**
Tree Nuts						
Mix/load: Dry Flowable, Open Mixing to Support Airblast Application	Dermal	0.066	0.015 (lb ai/A)	40 Acres	0.000010	7,400
	Inhalation	0.00077			0.0000066	11,000
				Total:	0.000017	**4,500**
Application, Airblast: **Open Cab**	Dermal (baseline)	0.36	0.015 (lb ai/A)	40 Acres	0.000056	1,400
	Dermal (w/gloves & coveralls)	0.22			0.000034	2,200
	Inhalation	0.0045			0.000039	1,900
				Total (baseline):	0.000094	**800**
				Total (w/ gloves & coveralls):	0.000073	**1,000**
Application, Airblast: **Enclosed cab**	Dermal	0.019	0.015 (lb ai/A)	40 Acres	0.0000029	26,000
	Inhalation	0.00045			0.0000039	19,000
				Total:	0.0000068	**11,000**

[1] Baseline unit exposure values represent long pants, long sleeved shirts, shoes, socks and no respirator. Values for dermal (baseline, gloves, and coveralls) and inhalation exposure are reported in the PHED Surrogate Exposure Guide dated August 1998.
[2] Application rates are based on maximum values found in proposed labels: TREE-äge™ (Reg. No. 100-RGNO, based on "high" rate) and Proclaim® Insecticide (5.0% ai water-dispersible granule, EPA Reg. No. 100-904).
[3] Daily area treated is based on the area that can be reasonably applied in a single day, based on the application method and formulation/packaging type (professional judgment and standard EPA/OPP/HED value for tree injection and tree nut scenarios, respectively).
[4] Daily Dose (mg/kg/day) = (Unit Exposure * % Absorption * Application rate * Area treated) / 70 kg; where dermal absorption is 1.8% and inhalation absorption is assumed to be 100%.
[5] Short-/Intermediate-Term MOE = NOAEL (0.075 mg/kg/day, for dermal and inhalation exposure) / Daily Dose. The short-term LOC is 300 and the intermediate-term LOC is 1,000.

3.2 Occupational Postapplication Exposure and Risk

Occupational postapplication exposure following tree injection treatment is not expected. However, postapplication exposure is possible for workers entering treated orchards to tend or harvest tree nut crops.

Chemical-specific dislodgeable foliar residue (DFR) data were submitted for a previous petition (MRID# 44007903), and were used in support of this Section 3 registration:

> MK-0244 0.16 EC, an emulsifiable concentrate formulation containing 2.15 percent emamectin benzoate, was applied by groundboom at a single rate of 0.015 lbs ai/acre to celery at a test site in the County of Santa Cruz in California. Two applications were made, with an interval of 7 days between applications. Following the second application, four replicate samples were taken from the treated plot at each sampling interval. Leaf punch samples were collected at 24 hours before sampling, then at 2-4 hours and 1, 3, 7 and 14 days after the second application. All but one replicate were below the level of detection by day 14. The estimated half-life of total MK-0244 residues (from a regression analysis) was 0.94 day, with an r^2 value of 0.91. Samples were also collected from a control plot.

From a secondary review (T. Swackhammer, HED, 11/23/01, D279209), it was determined that the study met most of the requirements of the Series 875.2100 Guidelines. Areas where the study was deficient included: DFR data were collected from only one geographically distinct area; only two applications were made, while as many as three (at the maximum rate) are permitted by the label; no tank mix samples were collected; and information on the purity of the test substance was not provided.

Although these deficiencies were not sufficient to preclude use of the data for the petition cited, use of results of this study for the current petition leads to additional uncertainties: 1.) the use of an emulsifiable concentrate in the study, while a water-dispersible granular formulation is being requested for use on tree nuts; and 2.) the need to extrapolate the results of residue dissipation from groundboom application on celery to an airblast application on tree nuts.

Because of these uncertainties, the standard assumption of 20 percent of the application rate was used as the initial DFR, and the residue decline observed in the study was used to estimate the daily dissipation.

The transfer coefficients used in this assessment are from an interim transfer coefficient policy developed by HED's Science Advisory Council for Exposure using proprietary data from the Agricultural Re-entry Task Force (ARTF) database (policy # 3.1). It is the intention of HED's Science Advisory Council for Exposure that this policy will be periodically updated to incorporate additional information about agricultural practices in crops and new data on transfer coefficients. Much of this information will originate from exposure studies currently being conducted by the ARTF, from further analysis of studies already submitted to the Agency, and from studies in the published scientific literature.

Inhalation exposure during dusty mechanical harvesting activities such as shaking, wind rowing/sweeping, and vacuuming is a special concern and is not addressed with transfer coefficients. Data from the aerobic soil metabolism study for emamectin indicate that the half-life in a sandy loam soil (in the absence of light) is 193.4 days. In addition, emamectin was found to have a high soil K_{oc} (25832 mL/g), indicating a high degree of sorption to soil particles. No chemical-specific exposure data were submitted to support the evaluation of this scenario. However, the airblast application scenario, evaluated previously in the handler exposure section, is believed to represent a reasonable worst case surrogate estimate of inhalation exposure during these dusty harvesting activities. While the medium on which the residues are suspended is water, rather than soil, the concentration of ai in the water is estimated to be greater than that in the soil/dust medium. It is assumed that airblast water is introduced into the air at the same rate or higher than dust from mechanical harvesting activities.

A summary of the postapplication dermal exposure and risk assessment is provided in Table 5. The short- and intermediate-term dermal MOEs for postapplication are greater than 1,000 on the second day after application (indicating an REI of 2 days); and therefore, are not of concern.

The inhalation MOE for mechanical harvesting is 1,900 (see the airblast scenario shown previously in Table 4). The total MOE for mechanical harvesting (from the combined airblast inhalation exposure and the transfer coefficient-based dermal exposure) is 1,600, which is greater than the LOC of 1,000. Therefore, this scenario is not of concern.

The proposed label for Proclaim® Insecticide has a 48-hour REI. The technical material is in Acute Toxicity Category 1 for primary eye irritation; therefore, the 48-hour REI on the label is required, and is in compliance with the Agency's Worker Protection Standard.

Table 5. Exposure and Risk Assessment for Occupational Postapplication Activities on Tree Nuts

Days After Application (t)	Dislodgeable Foliar Residue ($\mu g/cm^2$)[1]	Transfer Coefficient (cm^2/hr)[2]	Activity[2]	Daily Dose[3] (mg/kg/day)	Short-/Intermed. Term Dermal MOE[4]
0	0.034	100	Mechanical harvest - shaking	0.0000069	11,000
0	0.034	500	Irrigation, scouting, thinning, weeding	0.000035	2,200
0	0.034	2,500	Harvesting/poling, pruning, thinning	0.00017	430
1	0.017			0.000086	870
2	0.0084			0.000043	1,700

[1] Dislodgeable Foliar Residue, or DFR, ($\mu g/cm^2$) = Application rate (0.015 lb ai/A) x CF (4.54E+8 $\mu g/lb$) x CF (2.47E-8 A/cm^2) x Initial Fraction of ai Retained on the Foliage (standard value = 0.2) x [(1- Fraction of Residue That Dissipates Daily [0.5 - from celery DFR study])$^{\text{Postapplication day}}$].

[2] Transfer coefficients are taken from the HED Science Advisory Council (SAC) for Exposure Policy 003.1 (August 2000), which include data supplied by the Agricultural Reentry Task Force.

[3] Daily Dose = (DFR x Absorption Factor of 0.018 x 0.001 mg/μg x Dermal Transfer Coefficient x 8-hr) / 70-kg Body weight

[4] MOE = NOAEL/Daily Dose; where Short-/Intermediate-Term Dermal NOAEL = 0.075 mg/kg/day. Short-term LOC is 300; Intermediate-term LOC is 1000.

[5] The pre-harvest interval (PHI) is 14 days, therefore, harvesting would not occur until after this point.

4.0 Non-Occupational/Residential Exposure

4.1 Residential Handler Exposure and Risk

The proposed product TREE-äge™ is intended for use with injection systems that are marketed to both residential and professional users. However, the acute primary eye toxicity findings for this product show corneal involvement and irritation that persists for more than 7 days, which is a criterion for restriction to use by certified applicators only (40 CFR, §152.170). Therefore, the label must be changed to reflect this, and residential handler exposure will not be expected.

The conditionally registered product, Optigard ™ Cockroach Bait (EPA Reg. No. 100-1290), while not a restricted use pesticide, is labeled for use by professional pest control operators (PCOs) only. Therefore, no residential handler exposure is expected for this use.

4.2 Residential Postapplication Exposure and Risk

Residential postapplication exposure following tree injection treatment is not expected. The conditionally registered cockroach bait is labeled for use by PCOs only, and not for use in residential areas. Therefore, residential exposure is not expected for this use.

4.3 Off Target Non-Occupational Exposure

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for emamectin. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

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

January 13, 2009

PC Code: 122806
DP Barcode: 351736

MEMORANDUM

Subject: Ecological risk assessment for emamectin benzoate use as a tree injection insecticide to control arthropod pests

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Attached please find the Environmental Fate and Effects Division's (EFED) environmental risk assessment for the proposed new use of emamectin benzoate as a tree injection insecticide to control arthropod pests. Key findings of this risk assessment are as follows.

There is no standard methodology currently used by EFED to evaluate potential ecological risks from tree injection of insecticides. However, this screening level risk assessment identified potential risks to terrestrial invertebrates that forage on treated trees. Potential risks to birds, mammals, and terrestrial invertebrates also presumably exceed levels of concern, and potential risks to aquatic invertebrates could not be precluded.

Risk estimates were based on screening-level estimates of exposure. Submission of a study that measures the fate, uptake and translocation (magnitude of residues study) of

emamectin benzoate in trees after injection would allow for a refined estimate of exposure and would be of high value to this risk assessment. This type of study requires submission of a formal protocol prior to study initiation and should include an evaluation of the magnitude of residues in edible parts of treated trees, including leaves, nectar, fruit, seeds, and pollen. Without submission of a study to allow for a refined estimation of potential exposures and risks to non-target animals, evaluating the effectiveness of potential mitigation options is not possible. In addition, submission of an acute oral LD50 study in bees would be of high value to this assessment.

Data gaps noted in previous assessment (DP 309154) included the following (see the previous assessment for details):

- acute and chronic studies in sediment dwelling organisms (emamectin benzoate is expected to partition to and persist in sediment);
- acceptable life-cycle study in mysid shrimp;
- more sensitive analytical detection methodology;
- terrestrial plant toxicity data; and
- degradate toxicity data.

Neither studies nor acceptable data waivers have been submitted since the last assessment to satisfy these data gaps.

Label statements that restrict the timing of application of emamectin benzoate and the type of tree that may be treated may be effective in limiting potential risks to non-target organisms. Such label statements may be developed after submission of the magnitude of residues study and would need to be vetted through EFED, RD, and the pollinators team. Without submission of such a study, label statements similar to those recently developed for several neonicotinoid insecticides may be adapted.

The label was unclear with respect to application directions. For example, the label states that optimum control occurs if emamectin benzoate is applied at the base of the tree; however, application may also be made around the stem within 12 inches of the soil, in the trunk flare, or into tree roots. It is unclear, however, how the label directions can be followed for injection into the tree roots. Also, the amount of chemical to be added to each hole is not specified, and the label does not include any language to prevent or minimize spillage. If the holes drilled into the tree are filled until chemical spills out, then the potential for exposure to non-target organisms outside of the treated tree increases.

The label directions were also unclear with respect to application rates. Recommended application rates given on page 7 of the label were given in volume applied per tree. However, the label did not specify whether the application rate referred to volume of formulation or a.i. This assessment assumed that application rates referred to formulated product; however, the label should specify formulation or a.i.

United States Environmental Protection Agency

Office of Prevention, Pesticides, and Toxic Substances

Section 3 Request for a New Use of the Insecticide Emamectin Benzoate (PC Code 122806)

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January 13, 2009

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1. Executive Summary

An ecological risk assessment was conducted that evaluated the proposed use of emamectin benzoate to control arthropod pests in trees. The proposed uses include residential and commercial landscapes, parks, plantations, seed orchards, and forested sites. The label does not limit the type of tree that may be treated or the pest that may be controlled other than arthropods, although a number of target pests are included on the label. Also, the label indicates that pests may be controlled in multiple parts of trees including the seed, cone, bud, leaf, shoot, stem, trunk, and branch.

The proposed application method is tree injection at a rate of approximately 15 mL to 1060 mL of product per tree (approximately 600 mg to 42,000 mg a.i./tree) (see Table 2.2 in Section 2). The amount of chemical applied depends on the size of the tree.

After emamectin benzoate is injected into a tree, it is translocated throughout the tree by the sap. There is currently not an approved model or standard methodology that allows for an estimation of exposure to a pesticide resulting from tree injection. This assessment used screening level estimates of exposure to evaluate potential risks and the value of additional data to refine potential exposures and risks. Submission of a study that measures the fate, uptake and translocation (magnitude of residue study) of emamectin benzoate in trees after injection to allow for an estimation of exposure to terrestrial animals is of high value to this assessment. This type of study requires submission of a formal protocol prior to study initiation and should include data on the magnitude of residues in leaves, pollen, and nectar. Because such a study is currently not available, the risk estimates included in this assessment are screening level estimates of risk.

Risk estimates were derived that were based on (1) the total mass of emamectin benzoate applied to a tree, (2) estimated concentrations of emamectin benzoate in leaves assuming 100% translocation of the pesticide to the leaves, and (3) estimated concentration of emamectin benzoate in the whole tree assuming that the pesticide is evenly distributed throughout the tree. Each of these screens resulted in risk concern for birds, mammals, and terrestrial invertebrates.

In addition, if emamectin benzoate is translocated primarily to leaves, then the chemical could enter the soil and be available for runoff into aquatic environments when the leaves fall to the ground. The amount of chemical that could enter the soil and water is related to the number and type of trees that are treated in a given area and the amount of chemical in the leaves. Screening methods using conservative assumptions could not preclude potential risks to aquatic invertebrates resulting from emamectin benzoate entering aquatic systems resulting from tree injection as described in Section 5.

2. Problem Formulation

2.1. Proposed Action

The registrant is requesting a new use for emamectin benzoate as an insecticide for control of arthropod pests on ornamental trees. The proposed application method is injection in trees located in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites. The label does not limit the type of tree that may be treated or the pest that may be controlled other than arthropods, although a number of target pests are included on the label. Also, the label indicates that pests may be controlled in multiple parts of tree including the seed, cone, bud, leaf, shoot, stem, trunk, and branch.

2.2. Chemical Class and Mode of Action

Emamectin benzoate (Proclaim™) is an avermectin class insecticide developed for the control of lepidopteron insects. This class of pesticide consists of homologous semi-synthetic macrolides that are derived from the natural fermentation products of *Streptomyces* bacteria. It kills insects by disrupting neurotransmitters, causing irreversible paralysis. It is more effective when ingested, but it also somewhat effective on contact. Target pests are numerous. For the proposed use in tree injection, the target pests include mature and immature arthropod pests. It is lethal upon ingestion or direct contact.

When sprayed to foliage, emamectin benzoate penetrates the leaf tissue and forms a reservoir within treated leaves, which provides residual activity against foliage-feeding pests that ingest the substance when feeding. The proposed formulation is designed to translocate in the tree's vascular system when injected.

2.3. Pesticide Properties

The structure of emamectin benzoate is in Figure 2.1. Selected chemical and physical properties of emamectin benzoate are presented in Table 2.1. These data were obtained from a previous assessment (New Chemical Review, D226628), and studies from which these values were obtained were not re-evaluated. Emamectin benzoate consists of a mixture of at least 90% 4"-epi-methylamino-4"-deoxyavermectin B_{1a} and a maximum of 10% 4"-epi-methylamino-4"-deoxyavermectin B_{1b} benzoate. The available chemical properties and environmental fate data are primarily on the B_{1a} component; therefore, there is some uncertainty on the fate of the B_{1b} component. However, both components have very similar structures; therefore, their physicochemical properties, fate, and toxicity profiles are assumed to be similar. Some of emamectin benzoate's properties are pH dependent. For example, its water solubility is 320 mg/L at pH 5, 93 mg/L at pH 7, and 0.1 mg/L at pH 9. Similarly, its log Kow is 5.0 at pH 7 and 5.9 at pH 9. Therefore,

its properties may be altered by pH. Emamectin benzoate's low vapor pressure and Henry's law constant suggest that volatility from soil and water, respectively, will be low.

Table 2.1. Physical, Chemical, and Environmental Fate Properties of Emamectin Benzoate

Property	Value	Reference
Molecular Weight	964	New Chemical Review (D226628, 2000)
CAS number	148477-71-8	New Chemical Review (D226628, 2000)
Water solubility; (pH 7)	93 mg/L	Product Chemistry; MRID 44883704;
Vapor pressure	$3x10^{-8}$ Torr	New Chemical Review (D226628, 2000); (25°C)
pK_a	6.8	http://www.aoac.org/pubs/JOURNAL/2001/ab8403.htm
log K_{ow}	5.0 (pH 7)	New Chemical Review (D226628, 2000)
Henry's law constant	3.8×10^{-10} atm m^3/mol	Product Chemistry; MRID 44883705
Hydrolysis half-life	$t_{½}$ = Stable	MRID 42743642; (pH 7)
Aqueous photolysis half-life	$t_{½}$ = 23 days	MRID 43850114 (natural sunlight - maximum value)
Soil photolysis half-life	$t_{½}$ = 5 days	MRID 43404302; (uncorrected for dark controls)
Aerobic soil metabolism half-life	$t_{½}$ = 193 days	MRID 43404303; (sandy loam)
Anaerobic soil metabolism	$t_{½}$ = 174 days	MRID 43850116
Anaerobic aquatic half-life	$t_{½}$ = 427 days	MRID 43850116
Adsorption coefficient K_{oc}	265,687 (average)	MRID 428515-26; K_{oc}= 279,000 - 730,000 - 25,382 - 28,365)
Bioconcentration factor (BCF)	69	MRID 434930-05; (whole fish)

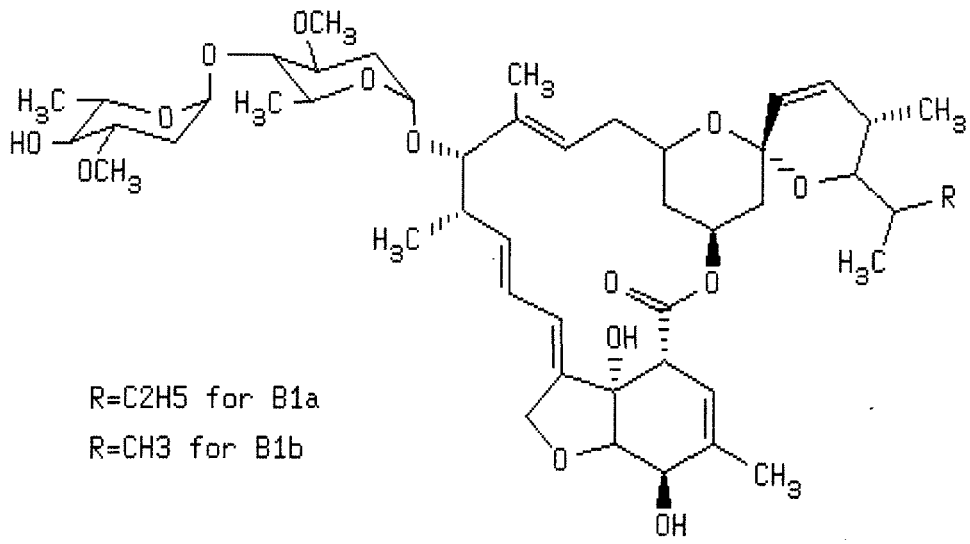

Figure 2.1. Structure of Emamectin Benzoate B1a and B1b

2.4. Approved Uses and Conclusions from Previous Assessments

Emamectin benzoate is currently registered for use on fruiting vegetables, brassica head and stem vegetables, leafy vegetables, and pome fruits. Current end use products include an emulsifiable concentrate (Proclaim 0.16 EC) and a water soluble concentrate (Proclaim 5 SG). It is applied by ground equipment or aerially as a foliar spray.

A number of risk assessments have been conducted for emamectin benzoate including a new chemical review in 2000 (D226628), new use reviews in 2002[1] and 2005[2], several Section 18 reviews[3]. However, none of the assessments included tree injection use. Primary risks identified in previous assessments included potential risks to aquatic and terrestrial invertebrates and mammals.

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[1]DP barcode 279840 and 279841 (cole crops, leafy vegetables, cotton, and tobacco).

[2]DP barcode 309154, Pome fruits

[3] DP barcodes include D223875, D223876, D239671, D239672; D255357, D279840, and D279841

2.5. Degradates of Concern

The Agency has identified four degradates of concern based on structural similarity to emamectin benzoate:

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB)

All of these degradation products form via photolysis of emamectin benzoate; the structures of these degradates are presented in Appendix A. For this assessment it is assumed that if these degradates form via tree injection, that they are as toxic to terrestrial animals as parent chemical. However, it is unknown if these degradates of concern form within injected trees.

2.6. Description of Proposed Use

The proposed new use of emamectin benzoate is a tree injection in ornamental trees. It is injected into active sapwood and is translocated in the tree's vascular system when injected.

It is applied by drilling a series of holes (5/8 to 2 inches deep past the bark) approximately 6 inches apart. Diameter of the holes is not specified on the label. The label states that optimum control occurs if application is made at the base of the tree; however, application may also be made around the stem within 12 inches of the soil, in the trunk flare, or into tree roots. It is unclear, however, how the labeled directions can be followed for injection into the tree roots. The amount of chemical to be added to each hole is not specified. If the holes drilled into the tree are filled until chemical spills out, then the potential for exposure to non-target organisms outside of the treated tree increases.

The amount of chemical injected depends on the size of the treated tree. The label indicates that up to approximately 50 mL per tree is applied to trees with a diameter of 4 to 6 inches and up to 1065 mL for trees with a diameter of 70 to 72 inches. The volumes presumably refer to mL of formulation and not mL of a.i. per tree; however, the label should specify mL product or mL a.i. Estimates of exposure assumed that the directions referred to mL of formulation product and were corrected for fraction of a.i. in the formulation. The amount of formulation that may be applied to various size trees as specified on the proposed label is summarized in Table 2.2.

Table 2.2. Summary of Application Rates for Various Tree Sizes			
Tree Diameter (DBH, Inches)	mL/tree applied[a]		Average No. of Injection Sites
	Low	High	
4 – 6	15	50	3
7 – 9	20	80	4
10 – 12	30	165	5
13 – 15	35	210	6
16 – 18	40	225	7
19 – 21	50	300	8
22 – 24	115	345	10
25 – 27	130	390	11
28 – 30	145	435	12
31 – 33	160	480	13
34 – 36	175	525	15
37 – 39	190	570	16
40 – 42	205	615	17
43 – 45	220	660	18
46 – 48	235	705	20
49 – 51	250	750	21
52 – 54	265	795	22
55 – 57	280	840	23
58 – 60	295	885	25
61 – 63	310	930	26
64 – 66	325	975	27
67 – 69	340	1020	28
70 – 72	355	1065	30

[a] These values presumably refer to mL of product and not mL of a.i. However, the label did not specify product or a.i. If the application rates refer to product, then this assessment would dramatically underestimate potential risks.

2.7. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

The conceptual model for emamectin benzoate provides a written description and visual representation of the predicted relationships between emamectin benzoate, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (USEPA 1998).

Based on the use pattern and mode of action, labeled use of emamectin benzoate may pose potential risks to non-target organisms. Because of the potential risk from direct effects to non-target organisms, potential concerns exist for indirect effects on listed animals that eat potentially affected non-target organisms, listed plants that require these taxa as pollinators or seed dispersers, and listed animals that require mammal burrows for shelter or breeding habitat. This forms the basis of the risk hypothesis and conceptual diagram discussed below.

2.8. Risk Hypothesis

A risk hypothesis describes the predicted relationship among the stressor, exposure, and assessment endpoint response along with the rationale for their selection. For emamectin benzoate, the risk hypothesis for this ecological risk assessment is as follows:

> *Emamectin benzoate has the potential to reduce survival, reproduction, and/or growth in non-target terrestrial and aquatic animals including vertebrates and invertebrates when used in accordance with the current label. These non-target organisms include Federally listed threatened and endangered species as well as non-listed species.*

2.9. Conceptual Diagram

The potential routes of exposure to terrestrial organisms is expected to be primarily through consumption of various parts of the tree after emamectin benzoate has been translocated throughout the tree after injection. It is assumed that the pesticide may enter foliage, fruit, seeds, and pollen, which can in turn be used as food items by other organisms. In addition, secondary exposure may occur for animals that consume invertebrates that have been exposed to the chemical. There are no data on the rate of translocation or decay of emamectin benzoate in trees nor has the presence of transformation products in trees been evaluated. Degradates of toxicological concern have been identified; however, they have only been shown to form via photolysis, and it is unknown whether they may form within a treated tree. Available microbial metabolism studies suggest that emamectin benzoate does not degradate rapidly via metabolism. Therefore, the focus of this assessment is on the parent with the assumption that it does not degrade rapidly in treated trees. However, this assumption may be re-evaluated if a magnitude of residues study in trees is submitted.

Given the specificity of the tree injection use pattern, the predominant transport mechanism consists of translocation/uptake to foliage, fruit, seeds, and pollen in treated trees. The transport mechanism (*i.e.*, source) is depicted in the conceptual model below **(Figure 2.2)** along with the receptors of concern and the potential attribute changes in the receptors due to exposures of emamectin benzoate. The conceptual model also depicts

the potential for emamectin benzoate residues in leaves, fruits, and seeds to enter adjacent water bodies.

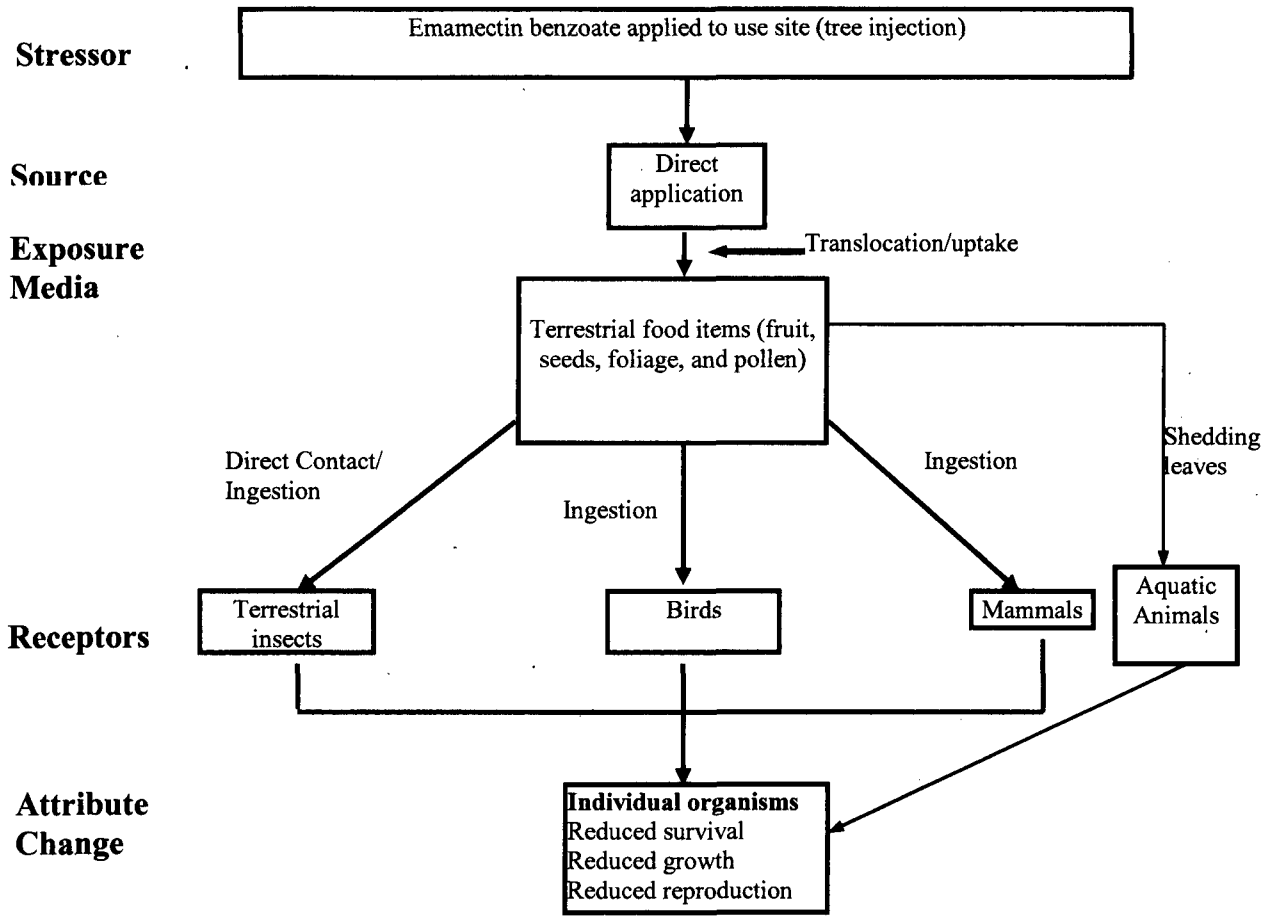


Figure 2.2. Conceptual Model for Emamectin Benzoate Application via Tree Injection

2.10. Assessment Endpoints

Assessment endpoints represent the actual environmental value that is to be protected, defined by an ecological entity (species, community, or other entity) and its attribute or characteristics (USEPA 1998). For the proposed use of emamectin benzoate, the ecological entities may include birds, mammals, and terrestrial insects that feed on translocated residues of emamectin benzoate in fruit, seeds, foliage, and pollen. The attributes for each of these entities may include growth, reproduction, and survival.

2.11. Environmental Fate and Transport

The environmental fate database has been discussed in depth in previous assessments (New Chemical Review, 2000; D226628) and is considered essentially complete. A brief summary of emamectin benzoate's environmental fate profile and a summary of

transformation/dissipation half-lives and BCF values are provided below. Previous reviews may be referenced for additional information.

Terrestrial Environments. Mobility studies conducted with emamectin benzoate indicate that the parent compound and its degradates would be expected to be relatively immobile in the environment due to a high degree of sorption to soil particles (K_d 219 to 2037). Therefore, most of the emamectin benzoate that enters the terrestrial environment is expected to remain at the site of application until it degrades or is transported via soil erosion. For this reason, high levels of parent and/or transformation products are not expected to enter surface water through runoff or to leach into ground water. The low emamectin benzoate vapor pressure suggests that volatilization from soil is expected to be minimal. Emamectin benzoate is resistant to microbial degradation (half-life 174 days) and hydrolysis (half-life 193 days), and is expected to be persistent when it is attenuated from light. The primary environmental dissipation pathway of emamectin benzoate is expected to be through photolysis on soil (half-life 5 days); however, degradation within injected trees has not been evaluated.

Aqueous Environments. Emamectin benzoate is expected to enter the water primarily through soil erosion. For the proposed use pattern, the pesticide could also enter the water directly via falling leaves or other tree parts. Once in an aquatic system, emamectin benzoate is likely to remain bound to sediment or suspended particles. It does not hydrolyze in water at pH 5 to 8, but slowly hydrolyzes at pH 9 (half-life 20 weeks). Its low Henry's Law constant suggests that volatilization from water is likely to be negligible. Although emamectin benzoate degrades rapidly through aqueous photolysis, other than in oligotrophic systems (clear, shallow water bodies with low in organic matter content), aqueous photolysis is not likely to significantly contribute to the degradation of emamectin benzoate. It is also not expected to bioconcentrate to any appreciable extent (whole fish BCF = 69).

2.12. Analysis Plan

2.12.1 Measures of Exposure

Evaluating exposure for this use pattern requires information on concentrations of the pesticide in animal food items after the chemical is translocated throughout the tree from the application site. This information is not available for emamectin benzoate. Therefore, exposure estimates used in this assessment are screening level estimates that are used to determine the value of additional data that may refine exposure estimates. This screen is based on the following assumptions:

(1) Total mass of chemical applied

a. **Terrestrial Assessment:** The total mass of chemical applied to the tree was compared to toxicity values of terrestrial animals; **EEC = total mass of chemical applied**

b. **Aquatic Assessment-1**: The total mass of chemical applied to the tree was assumed to enter a 20,000,000 L water body directly; **EEC = total mass of chemical / concentration of water**

c. **Aquatic Assessment-2**: The total mass of chemical applied to the tree was assumed to be available for runoff to a nearby water body; **EECs were estimated using GENEEC2 assuming that 100% of the chemical reached the soil.**

(2) Whole tree concentration

a. Whole tree concentration was estimated by assuming that the chemical was evenly distributed within the tree. Estimates of tree mass were based on information published by the University of Arkansas Cooperative Extension Service; **EEC = total mass of chemical applied / mass of tree.**

(3) Concentration of chemical in leaves

a. Leaf concentration was estimated by assuming that 100% of the chemical was translocated to the leaves. Leaf mass was estimated using allometric equations developed for blue oak trees presented by the USDA Forest Service (2002). **EEC = total mass of chemical applied / leaf mass on tree.**

2.12.2 Measures of Effects

Measures of ecological effects are obtained from a suite of registrant-submitted guideline studies conducted with a limited number of surrogate species. The test species are not intended to be representative of the most sensitive species but rather were selected based on their ability to thrive under laboratory conditions. Consistent with EPA test guidelines, a suite of ecological effects data on technical grade emamectin benzoate that complies with good laboratory testing requirements has been submitted. These data are summarized in Section 4.

2.12.3 Measures of Risk

The exposure and toxicity data are integrated in order to evaluate the potential risks of adverse ecological effects on non-target species. The risk quotient (RQ) method was used to compare exposure and toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs). Risk presumptions, along with the corresponding RQs and LOCs for terrestrial animals are summarized in Table 2.3. However, the exposure estimates used in this assessment are screening level estimates that inform the risk assessor of potential value of data to allow for refinements, and the RQs associated with LOCs in Table 2.2 my be interpreted differently than the RQs presented in this assessment.

Table 2.3. Risk Presumptions and LOCs

Risk Presumption	RQ	LOC
Birds[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5

Table 2.3. Risk Presumptions and LOCs		
Risk Presumption	**RQ**	**LOC**
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Mammals[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1

[1] LD_{50}/sqft = (mg/sq ft) / (LD_{50} * wt. of animal)
LD_{50}/day = (mg of toxicant consumed/day) / (LD_{50} * wt. of animal)

3. Exposure Analysis

Because the proposed use pattern is limited to tree injection, the major route of exposure to terrestrial organisms is expected to occur through uptake and translocation of the chemical to foliage, fruit, pollen, and seeds which can be used as food items. However, organisms could also be exposed to emamectin benzoate if it spills from the injection site or as a result of the chemical entering the terrestrial or aquatic environment via fallen leaves or other tree parts. Biodegradation data suggest that emamectin benzoate does not biodegrade fast.

In order to quantitatively assess exposure, data pertaining to the amount and rate of translocation and decay of emamectin benzoate in ornamental trees following application are needed. This type of data would facilitate estimation of potential residues in foliage/fruit/pollen which can be used as food items for terrestrial organisms. Currently, there are no data on the rate of translocation or decay of emamectin benzoate in trees after injection. Therefore, quantitative estimates of exposure are difficult. As a conservative screening approach, three exposure approaches were used to estimate exposures that were based on (1) total mass of emamectin benzoate applied to various sizes of trees (terrestrial and aquatic EECs), (2) estimated concentration in leaves assuming 100% of the chemical translocates to the leaves, and (3) estimated whole tree concentrations as further described in the following sections. In order to refine these exposure estimates, data that evaluate uptake, translocation, and degradation of emamectin benzoate *in situ* are needed.

3.1. Estimates of Exposure Based on Total Mass of Emamectin Benzoate Applied to Various Tree Sizes

3.1.1. Terrestrial EECs

A range of the total mass of emamectin benzoate that may be applied to trees is summarized in Table 3.1. These values were compared with terrestrial animal toxicity values to determine if there is a potential for LOC exceedances.

Table 3.1. Exposure Screen for Emamectin Benzoate for Tree Injection

Tree Size (diameter, in)	Amount of formulation injected (from proposed label)	
	mL formulation (from label)	mg a.i. (calculated assuming density of 1 g/mL)[a]
Small, 4 – 6 in.	15 to 50	600 to 2000 mg a.i.
Large, 70 – 72 in.	355 to 1065	14,000 to 42,600 mg a.i.

[a]Product label specified volume of product applied to each tree. Mass was calculated using the following equations:

mL product/tree (given on label) x 0.04 (4% a.i. in formulation) = mL a.i./tree

mL a.i./tree x 1000 mg/mL (density of water; density of product not available) = mg a.i./tree

3.1.2. Aquatic EECs

There is also potential for aquatic systems to be exposed to emamectin benzoate either directly from contaminated tree parts (e.g., leaves, sticks, flowers, pollen) entering the water or from tree parts falling onto land and subsequent runoff into aquatic systems. As a screen, the total amount of chemical applied to a tree was added to a 20,000,000 liter pond. The resulting water concentration would result in a conservative screen, but could be used to preclude risks to taxonomic groups if no LOCs are exceeded. The resulting pesticide concentrations range from 0.03 ug/L to 2 ug/L (600 ug/L to 42,600 ug / 20,000,000 L = 0.03 ug/L to 2.1 ug/L) depending on the amount of pesticide applied to the tree.

In addition, aquatic exposures could occur from the chemical entering soil environments and subsequently entering aquatic environments. This could occur if the chemical is translocated primarily to the leaves, and the leaves fall to the soil and decompose. As an initial screen, it was assumed that the total mass of the chemical applied to a tree via injection was applied directly to soil. Assuming 1 tree per acre is treated, the applied mass was used as an application rate (lbs a.i./Acre), and GENEEC2 was used to estimate potential aquatic concentrations. The application rate resulting from 600 mg (small tree) 42,600 mg (large tree) would be 0.001 lbs a.i./Acre to 0.094 lbs a.i./Acre (600 mg/tree to 42,600 mg/tree / 453592 mg/lb x 1 tree/acre = 0.001 lbs a.i./Acre to 0.094 lbs/Acre). The upper end of the range could represent application to one large tree or numerous smaller trees per acre.

Using these values as application rates and inputting the chemical properties for emamectin benzoate listed in Table 2.1 (page 7) results in peak EECs that range from

0.003 ug/L to 0.2 ug/L. Outputs from the modeling exercise are in Appendix B. These EECs are intended as screening level values that can be used to preclude potential risks to taxonomic groups if toxicity data indicate that effects are not likely to occur at these levels. If LOCs are exceeded based on these EECs, then additional refinements are needed to better characterize potential risks.

3.2. Estimates of Exposure Based on Estimated Whole Tree Concentrations and Leaf Concentrations

The tree injection formula of emamectin benzoate is designed to be distributed throughout the tree, and the fate of the chemical within a tree after injection is uncertain. Therefore, potential exposures to terrestrial organisms that feed on treated trees were estimated using estimated whole tree concentrations and leaf concentrations. These estimates were used to determine the value of a magnitude of residues study that measures potential exposures to organisms that may feed on treated trees.

Whole tree concentration estimates assume that the chemical is evenly distributed throughout the tree. Submission of a magnitude of residues study would reduce uncertainty in these estimates. Pesticide mass applied to trees was obtained from the proposed label. Tree weight estimates were obtained from the Cooperative Extension Service of the University of Arkansas, and they represent estimates for standing hardwood trees. The estimate was based on the merchantable portion of the tree (portion from a 1 foot stump to the top of a tree that is <4 inches in diameter). The estimate does not include tops, foliage, or limbs and, therefore, provides a conservative measure of whole-tree concentration. However, the estimates were within the range reported for above ground biomass for similar size trees reported by the U.S. Forest Service (1982). Therefore, the estimate was not further refined for this assessment.

The largest tree included in the publication was a 36 inch DBH tree. Therefore, estimates were only made for this assessment for trees that range from 12 to 36 DBH (inches). Whole-tree concentrations were compared with toxicity values to characterize potential risks to terrestrial organisms.

Table 3.2. Range of Whole Tree Concentration Estimates of Emamectin Benzoate

DBH	Tree Wt (kg)	Mass of pesticide injected in tree (mg)	Whole-tree pesticide concentration (mg/kg)
12 in	680	6600	9.8
36 in	7400	21000	2.8

Emamectin benzoate concentration was also estimated in leaves of treated trees. Estimated leaf concentrations resulting from tree injection assume that 100% of the chemical was translocated to the leaves and that the chemical was evenly distributed across the leaf mass. Submission of a magnitude of residues study would reduce uncertainty in these assumptions.

Pesticide mass applied to trees was obtained from the proposed label (Table 2.2). Estimated leaf mass was based on an allometric equation for oak trees published by the USDA Forest Service that relate tree size to estimated leaf mass (USDA Forest Service Gen. Tech. Rep. PSW-GTR-184. 2002):

$$\text{Leaf mass (g)} = 1.78x^2 - 12.4x - 108.5$$
$$x = \text{tree circumference at breast height (cm)}$$

Resulting estimates of leaf concentrations are summarized in Table 3.3. The resulting leaf concentration estimates were compared to toxicity values from terrestrial organisms to characterize potential risks.

Table 3.3. Range of Estimated Concentrations of Emamectin Benzoate in Leaves

DBH (in.)	Leaf mass (kg)	Pesticide mass (mg)	Pesticide concentration (mg/kg)
4	1.1	600	510
36	130	21,000	160
72	530	42600	80

4. Ecotoxicity Data

Toxicity reference values used in this assessment are presented in Table 4.1. Additional details are included in previous assessments. The effects database is relatively complete. Data gaps noted in the previous assessment (DP 309154) included the following (details are provided in DP 309154):

- Acute and chronic studies in sediment dwelling organisms (chemical is expected to partition to and persist in sediment);
- lack of an acceptable life-cycle study in mysid shrimp;
- more sensitive analytical detection methodology;
- terrestrial plant toxicity data;
- and degradate toxicity data.

In addition, submission of an acute oral study in bees would be valuable to this assessment.

Table 4.1. Summary of Toxicity Values Used in This Assessment					
Species	**Toxicity Value**	**Probit Slope (95% C.I.)**	**Toxicity Category**	**MRID No.**	**Comment**
Acute Studies					
Mallard duck *(Anas platyrhynchos)*	LD_{50}Adj: 23 mg/kg-bw	3.5 (1.9-5.2)	highly toxic	42743601	**Acceptable** study. Consumption of 0.46 mg would result in LD50 dose for a 20-gram bird (23 mg/kg-bw * 0.02 kg-bw = 0.46 mg)
Laboratory mouse *(Mus musculus)*	LD_{50}Adj: 24 mg/kg-bw	Not calculated	highly toxic	42743612	**Acceptable** study. Consumption of 0.36 mg would result in LD50 dose for a 15-gram mammal (24 mg/kg-bw * 0.015 kg-bw = 0.36 mg)
Honey bee *(Apis mellifera)*	LD_{50} 3.5 ng/bee	--	Highly Toxic	42851530	Acceptable study. Emamectin benzoate residues on foliage sprayed at 0.015 lbs ai/acre remain lethal to honeybees for 8 to 24 hours post-application (Palmer, 1994; MRID 43393006).
Rainbow trout *(Oncorhynchus mykiss)*	LC_{50}: 174 ug/L	7.0 (3.6-10)	Highly toxic	42851529	**Acceptable** study.
Waterflea *(Daphnia magna)* Flow-through	EC_{50}: 1.0 ug/L	4.7 (3.2-6.2)	Very highly toxic	42743603	**Acceptable** study.
Eastern oyster *(Crassostrea virginica)* (shell deposition or embryo-larvae) Flow-through	EC_{50}: 490 ug/L	4.9 (C.I. not reported)	Highly toxic	43393002	**Acceptable** study.
Mysid *(Americamysis bahia)* Flow-through	LC_{50}: 0.04 ug/L	8.1 (4.9 - 11.2)	Very highly toxic	43393001	**Acceptable** study.
Chronic Studies					
Mallard duck *(Anas platyrhynchos)*	NOEC: 40 mg/kg-diet	Not applicable	Not applicable	44007910	No adverse effects observed at any endpoint
870.3800	NOAEC: 0.6	Not	Not applicable	42851511	**LOAEL=1.8**

Reproductive Toxicity-Rat MK-0244	mg/kg-bw/day	applicable			**mg/kg/day** based on decreased fecundity and fertility indices and clinical signs (tremors and hind limb extension) in offspring of both generations.
Fathead Minnow (*Pimephales promelas)*	Early Life Stage NOAEC: 6.5 ug/L	Not applicable	Not applicable	43850107	**Acceptable** study.
Waterflea *(Daphnia magna)* Flow-through	NOAEC: 0.088 ug/L	Not applicable	Not applicable	43393004	**Acceptable** study.
Mysid *(Americamysis bahia)* Flow-through	NOAEC: 0.018 ug/L	Not applicable	Not applicable	44305601	**Supplemental** study.
	NOAEC: 0.0087 ug/L	Not applicable	Not applicable	45833001	**Supplemental** study.
Aquatic Plant Studies					
Vascular Plant-Duckweed *Lemna gibba* Static	EC_{50} > 94 ug/L NOEC: 94 ug/L	Not applicable	Not applicable	43850109	**Acceptable** study.
Freshwater algae *Selenastrum capricornutum* Static	EC_{50} > 3.9 ug/L NOEC < 3.9 ug/L	Not applicable	Not applicable	43850108	**Acceptable** study.

4.1. Incident Database Review

No incidents are included in the EIIS database.

5. Risk Characterization

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the use of emamectin benzoate as a tree injection fungicide and the likelihood of direct and indirect effects to non-target organisms in terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of emamectin benzoate risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's Levels of Concern (LOCs) (USEPA 2004). These criteria are used to indicate when emamectin benzoate's uses, as directed on the label, have the potential to cause adverse direct or indirect effects to non-target organisms. In addition, incident data from the EIIS will be considered as part of the risk characterization.

5.1. Risk Characterization

Potential risks to terrestrial organisms are described below. The lack of quantifiable exposure levels precludes derivation of refined RQs. Submission of a study that measures the fate, uptake and translocation (magnitude of residue study) of emamectin benzoate in ornamental trees to estimate exposure to honey bees, pollinators, and other terrestrial animals is of high value to this assessment. This type of study requires a formal protocol. Data on the magnitude of residues in leaves, pollen, and nectar are needed to derive reliable estimates of exposures. Because such a study is currently not available, the risk estimates included in this assessment are screening level estimates of risk.

5.1.1. Potential Risks to Terrestrial Animals

The adjusted LD50 for birds and mammals is approximately 20 mg/kg-bw, which corresponds to consumption of approximately 0.4 to 0.5 mg for a 15- to 20-gram animal. Therefore, consumption of 0.04 to 0.05 mg or more would result in exceedance of the endangered species LOC of 0.1.

Concentrations of emamectin benzoate of approximately 2, 10, and 20 mg/kg-food or higher in food items would result in EECs that exceed the endangered species LOC, acute LOC, and the LD50, respectively, for a 15 to 20-gram animal. As shown in Table 5.1, screening level EECs exceeded levels that may result in potential effects to terrestrial organisms.

Table 5.1. Risk Summary for Terrestrial Animals

Screening EEC		Toxicity Value			
Assumption	**EEC**	**Birds**	**Mammals**	**Inverts.**	**Risk Summary**
Total Mass	600 mg – 42,000 mg	0.46 mg	0.36 mg	3.5 ng/bee	Sufficient mass is available to potentially affect birds, mammals, and invertebrates
Whole-tree conc.	Birds: 3 – 11 mg/kg-bw[a] Mammals: 3 – 10 mg/kg-bw[a]	23 mg/kg-bw	24 mg/kg-bw	3.5 ng/bee	Estimated concentrations of emamectin benzoate are sufficient to result in potential risks to terrestrial animals.
Leaf Conc.	Birds: 91 – 570 mg/kg-bw[a] Mammal: 76 – 780 mg/kg-bw[a]	23 mg/kg-bw	24 mg/kg-bw	3.5 ng/bee	Estimated concentrations of emamectin benzoate are sufficient to result in potential risks to terrestrial animals.

[a] Pesticide concentration on leaves was converted to dose by assuming that birds and mammals consume 114% and 95% of their body weight daily. Estimated pesticide concentration was 80 – 500 mg/kg-leaf and 3 to 10 mg/kg-whole tree.

The total mass of emamectin benzoate applied to treated trees ranges from 600 mg to 42,000 mg. Therefore, there is sufficient mass applied to trees to potentially affect birds and mammals. The fraction of the mass of emamectin benzoate applied to a tree consumed by a 20-gram bird would need to be less than 0.0001 (0.01%) of the total mass applied for a small tree and <0.000001% (>0.0001%) of the total mass applied for a large tree to result in no LOC exceedances for birds.

Consideration of dilution within the tree did not reduce potential risks to levels that are below concern levels. Estimated leaf concentrations were sufficient to result in risk concerns for organisms that may eat leaves of treated trees. This evaluation assumed that 100% of the injected chemical was translocated to the leaves. However, even translocation of a relatively small fraction of emamectin benzoate to the leaves could result in potential effects to terrestrial organisms. Estimates of whole-tree pesticide concentrations assuming that the chemical is evenly distributed throughout the above ground biomass were also above levels that may be of concern to non-target terrestrial animals. Therefore, the available data suggest that potential risks to non-target terrestrial organisms are of concern. Submission of a magnitude of residues study that quantifies potential exposure levels after tree injection would be of high value to this risk assessment. Risks may be further quantified and refined if a magnitude of residues study in treated trees is submitted that evaluates concentrations of emamectin benzoate in edible parts of treated trees, including leaves, nectar, fruit, seeds, and pollen.

The above analysis only considered potential acute effects. However, there is also potential for repeated or prolonged exposures to terrestrial animals because emamectin benzoate is not expected to rapidly dissipate from trees after it is injected and translocated. Therefore, there is also potential risk to reproduction endpoints from the proposed tree injection use.

5.1.2. Potential Risks to Aquatic Organisms

There is also potential for aquatic systems to be exposed to emamectin benzoate either directly from contaminated tree parts (e.g., leaves, sticks, flowers, pollen) entering the water or from tree parts falling onto land and subsequent runoff into aquatic systems. As a screen, the total amount of chemical applied to a tree was added to a 20,000,000 liter pond. In addition, aquatic exposures could occur from the chemical entering soil environments and subsequently entering aquatic environments as described in Section 3. The resulting water concentration would result in a conservative screen, but could be used to preclude risks to taxonomic groups if no LOCs are exceeded. EECs and toxicity values are summarized in Table 5.2.

Table 5.2. Risk Summary for Aquatic Animals					
Screening EEC		**Toxicity Value (ug/L)**			**Risk Summary**
Assumption	**EEC**	**Fish**	**Invert**	**SW Invert**	
Direct Deposition	0.03 ug/L to 2 ug/L	LC50: 174 NOAEC: 6.5	EC50: 1 NOAEC: 0.09	LC50: 0.04 NOAEC: 0.009	Fish are not likely at risk of effects from the tree injection use of emamectin benzoate under the assumptions of this risk assessment. However, potential risks to aquatic invertebrates could not be precluded.
Runoff from Soil	0.003 ug/L to 0.2 ug/L				

This analysis indicates that potential risks to aquatic invertebrates cannot be precluded. However, potential risks to fish are not likely to exceed LOCs. Submission of a magnitude of residues study previously described would be of high value to this assessment and may allow for further refinement of the EECs included in table 5.2.

5.1.3. Summary

This analysis suggests that translocation of a small fraction of emamectin benzoate from the site of injection to edible portions of a tree may result in effects to birds, mammals, and non-target invertebrates. Potential risks to aquatic invertebrates could not be precluded. Additional data, including a magnitude of residues study in injected trees and an acute oral study in bees are needed to allow for refinements of potential risks.

5.2. Uncertainties and Data Gaps

There is currently no standard methodology for evaluating potential ecological risks from application of pesticides via tree injection. This assessment was based on conservative estimates of exposure, and a primary uncertainty in this assessment is that the screening level exposure estimates cannot be refined based on the currently available data. Screening level exposure values were used in this assessment that identified potential risks to non-target aquatic and terrestrial animals. However, these screening-level values were likely conservative, and submission of a magnitude of residues study that evaluates pesticide concentrations in various parts of the tree that may serve as food for birds, mammals, and invertebrates is necessary to allow for refinements of potential risks. This type of study requires submission of a formal protocol by the registrant.

The fate of the pesticide within the tree is also largely unknown. It was assumed that emamectin benzoate may leach from leaves or other parts of a tree after they have fallen to the ground. However, the fate of the chemical within the tree remains unknown. Also, degradates of toxicological concern were observed to form via photolysis. It is not known if degradates of concern form within a treated tree, and if they do form, to what extent non-target organisms may be exposed.

Estimates of exposure included estimations of pesticide concentrations in leaves and in the whole tree. Estimated pesticide concentrations in leaves were determined by assuming that 100% of the chemical is translocated to leaves. Leaf mass was estimated using the following allometric equation developed for blue oak trees presented by the USDA Forest Service (2002):

$$\text{Leaf mass (g)} = 1.78x^2 - 12.4x - 108.5$$
$$x = \text{tree circumference at breast height (cm)}$$

The regression was developed based on a study of 14 blue oak trees harvested in the Sierra Nevada foothills with an r^2 value of 0.98. The extent to which the equation estimates leaf mass for other types of trees or for blue oak trees in other locations has not been evaluated for this assessment.

Estimates of pesticide concentration in the whole tree assumed that the chemical was evenly distributed within the tree and required an estimate of tree mass. Estimates of tree mass were based on information published by the University of Arkansas Cooperative Extension Service and included only the merchantable portion of the tree (portion from a 1 foot stump to the top of a tree that is <4 inches in diameter). The estimate does not include tops, foliage, or limbs and is, therefore, provides a conservative measure of whole-tree concentration. However, the estimates were within the range reported for above ground biomass (dry weight) for similar size trees reported by the U.S. Forest Service (1982) when corrected for water content assuming a range of water content of 10% to 50% by weight. Therefore, the estimate was not further refined for this assessment. However, use of a whole tree concentration may not be conservative because the estimate assumes that the pesticide is evenly distributed throughout the tree, which could lead to an underestimation of exposure and risk if the chemical concentrates in an edible portion of the tree.

Aquatic exposure estimates assumed either that 100% of the chemical entered the soil and was available for runoff or that 100% of the chemical entered a water body directly. These are conservative estimates of exposure to aquatic organisms. Submission of a magnitude or residues study previously discussed may allow for refinement of potential aquatic exposures. Also, leaves and some other tree parts that enter the water could ultimately end up in the sediment. Exposure estimates for sediment organisms were not included in this assessment.

Also, given the high toxicity of emamectin benzoate to terrestrial invertebrates and that the dietary exposure route is likely to be an important exposure route due to the administration route of tree injection, an acute oral toxicity study in bees would also be of high value to this assessment. Submission of a magnitude of residues study previously described may reduce these uncertainties.

6. References

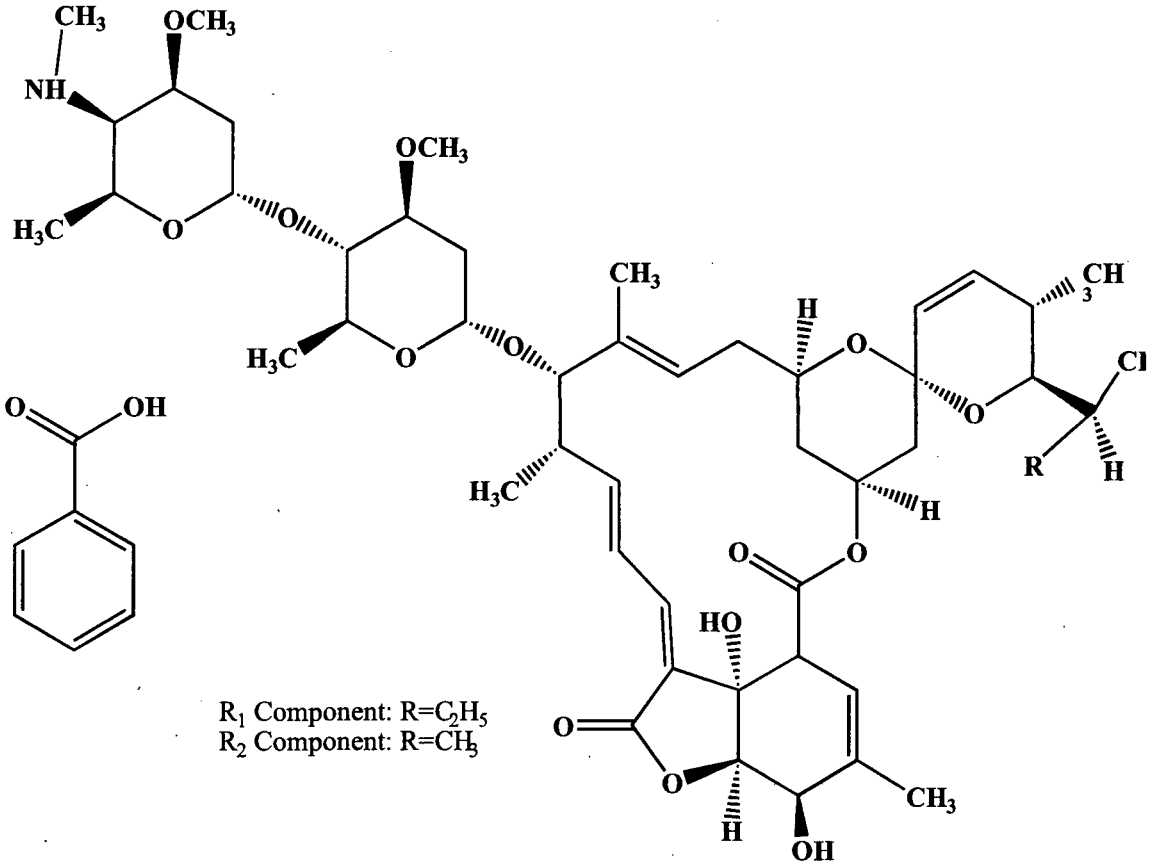
USDA Forest Service (John F. Karlik and Alistair H. McKay). 2002. Leaf area index, leaf mass density, and allometri relationships derived from harvest of blue oaks in California oak Savanna. USDA Forest Service Gen. Tech. Rep. PSW-GTR-184.2002.

USDA Forest Service (Louise M. Tritton and James W. Hornbeck). 1982. Biomass Equations for Major Tree Species of the Northeast. General Technical Report NE-69.

University of Arkansas Division of Agriculture (David W. Patterson). Undated. Landowner's guide to determining weight of standing hardwood trees. University of Arkansas Division of Agriculture, Cooperative Extension Service. FSA 5021.

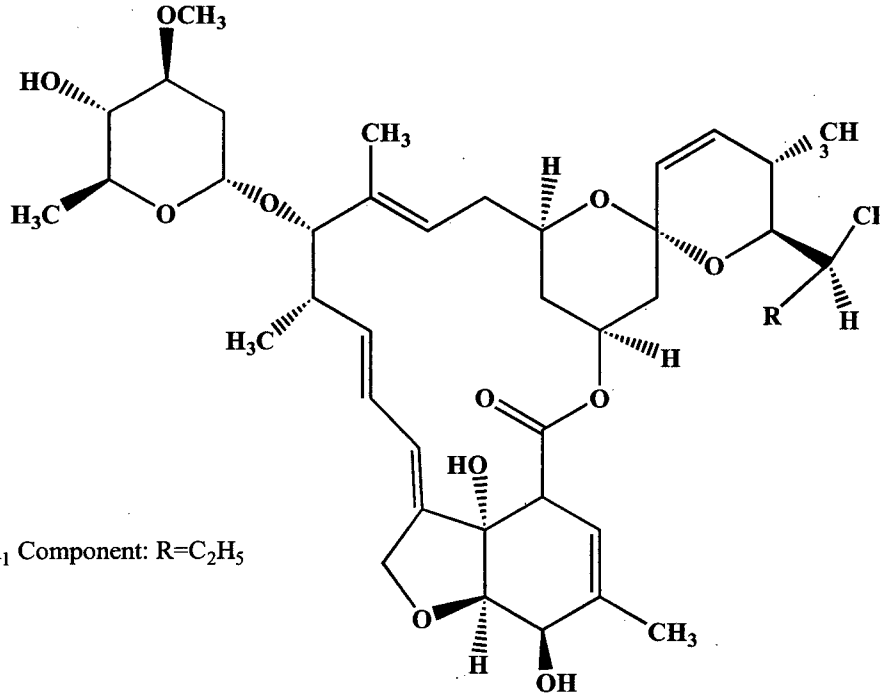
Appendix A. Structure of Degradates of Concern

Degradate 2: 8,9-Z MA ((8,9-Z)-4"-epimethylamino-4"-deoxy anermectin B1)

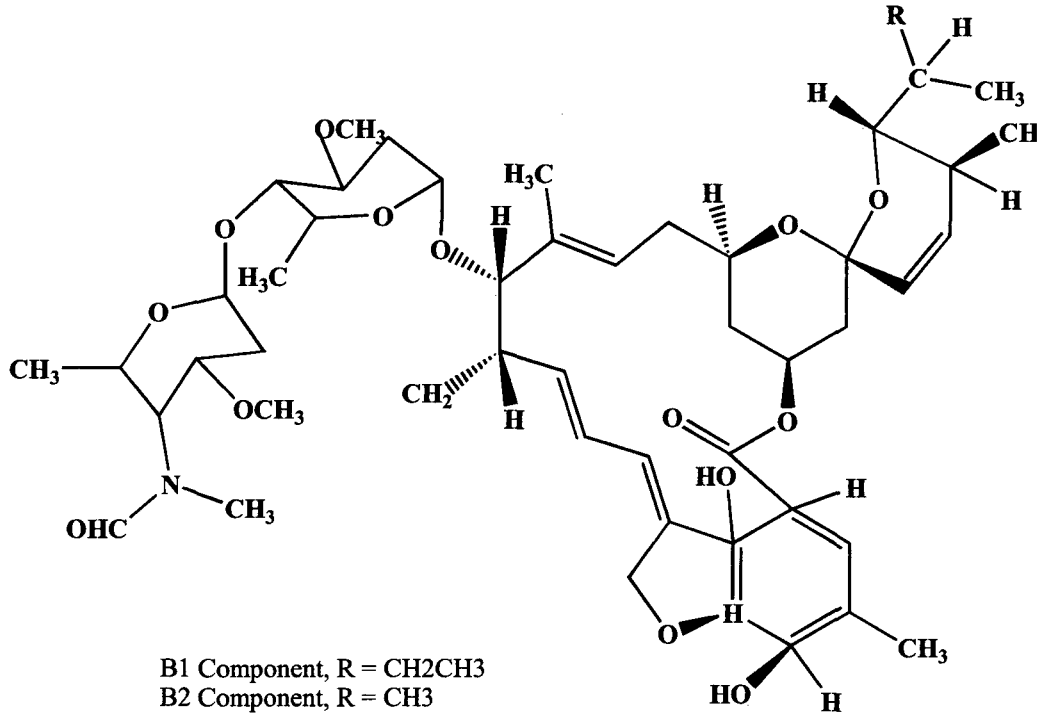


R_1 Component: R=C_2H_5
R_2 Component: R=CH_3

MAB1a (avermectin B1 monosaccharide)

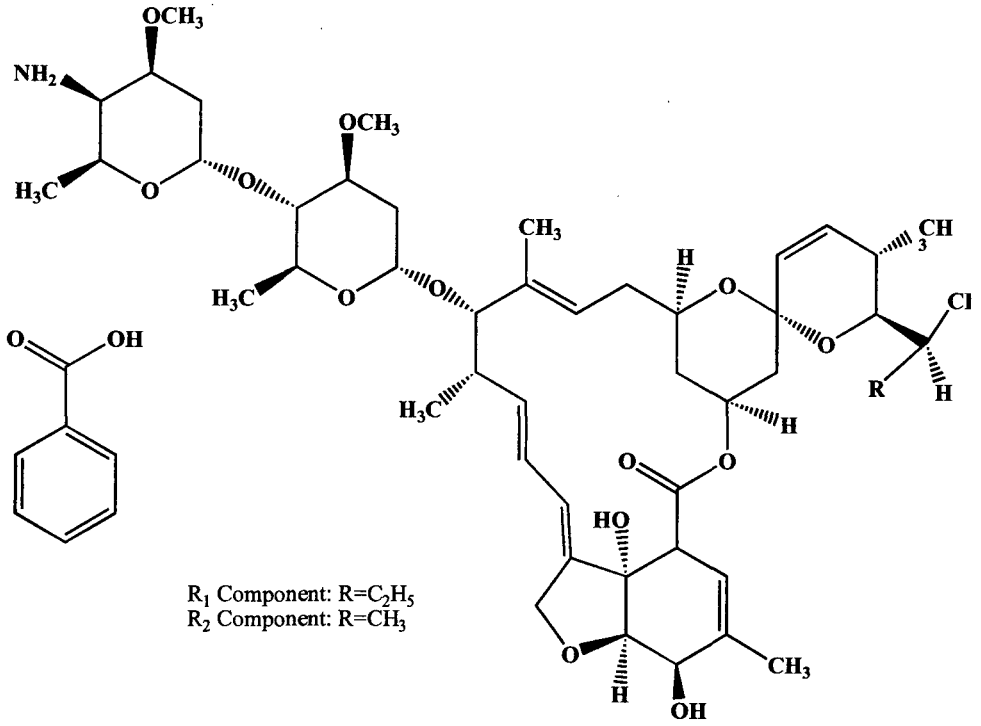


R_1 Component: R=C_2H_5



B1 Component, R = CH2CH3
B2 Component, R = CH3
FAB (4"-epi-(N-formyl)-4"-deoxyavermectin B1)

AB1a (4"-epiamino-4"-deoxyavermectin B1)



Emamectin Tree Injection: 100-RGNO / Treeage rev. 6/3/09				
division	topic	issues	data gaps	comments
RD / TRB	prod chem	CSF 12/13/07 ok	stor/stab 830.6317 corrosion 830.6320	added ai source on CSFs 2/14/08 - ok
RD / TRB	acute prod tox	oral III dermal IV inhale IV eye II skin IV derm sens negative signal WARNING		
RD / IRB	efficacy	- basic efficacy ok - 2-year data not sufficient		- numerous DFU label changes - drop 2-year claim
HED	ORE *(both EC tree inject and G tree nuts)*	-RUP due to eye I for end use prod -assumes no homeowner use (needs RUP) *** resolve I or II eye?; can it drive RUP?**		*FYI:* *-tech 100-902=eye I ; -tech 100-1270=eye III* *- with 100-904 reg replaced -902 with -1270 so lowered crop REI to 12 hr (except trees)* *- with 100-RGNO reg has CSFs with both -902 and -1270* ***- tech affects REI which is not relevant to -RGNO since injection***
EFED	eco (screening)	-need better label directions -potential risk to birds, mammals, invertebrates; possibly even aquatics due to leaf drop into water -bee risk possible; label should be conservative until more known	need data for risk via tree injection: -fate in tree/magnitude of residue (####.####) for tree injection (need protocol review first)	-new policy: if residual action > 1 year then label must state do not use on flowering trees - 6/3/09: policy still being worked out ; see neonicotinoids for model text

emamectin - Treeage tree injection: confirm need for RUP
Thomas Harris to: Jack Arthur 06/03/2009 01:52 PM
Cc: Paula Deschamp, John Hebert, Meredith Laws

Jack,

Thanks for agreeing to look at this since you know the ORE history on emamectin. I'll bring you a paper copy of this email and reviews (too hard to wrap your brain around all this on the screen - at least I couldn't).

outcome - JArthur confirm HED ORE is correct - needs to be RUP due to worker eye issue

QUESTION

- Should we require Treeage 100-RGNO tree injection to be a Restricted Use Pesticide? What exactly is reason? I'm fine with this but want us to be on solid ground with our reasoning.

- You might start by looking at 7/24/08 ORE memo, page 12.

BACKGROUND

- emamectin, Treeage 100-RGNO, **PRIA due date 7/15/09**

- Treeage is a 4.0% pour/mix/inject product (not pre-mixed capsules closed system). Ag crop foliar spray products are 2.0% and are RUP.

- Treeage intended audience is probably professional arborist given the equipment needed to do tree injection. However, only way to ensure arborist and not homeowner use is to make product RUP.

- Treeage was analyzed along with the new use on tree nuts and pistachios (7F7263). Tolerances were set on tree nuts 1/16/09.

- After tolerances were set we realized the HED risk assessment had an error regarding the REI. During the tree nut assessment, Syngenta registered a new technical. Old tech 100-902 had eye irritation I, new 100-1270 has eye irritation III. The 7/31/08 HED risk memo forgot to address this so a 1/28/09 addendum addressed changing REI from 48 to 12 hours (except for some tree activities).

- Treeage uses both old 100-902 and new 100-1270 technicals in CSFs (i.e. both eye I and eye III technicals).

- Treeage end-use product eye is II (other routes III, IV).

- HED 7/24/08 ORE memo says Treeage should be RUP based on eye irritation for end-use product (not technical) lasting > 7 days (page 12).

- Since Treeage is injected I wouldn't expect post app exposure to be an issue so REI not applicable. Risk is for mixer/loader/applicator.

- When I told Syngenta to make Treeage RUP they balked. I don't remember their arguments exactly but it had to do with the eye status. I said I would double check our work to make sure we're right (hence this email).

REVIEWS

6/3/08 RD acute tox

000100-0RGNO.20080603.acute prod tox.image.pdf

7/24/08 HED ORE

6.0.HED.ore.20080724.DP347923.mem.signed ocr.pdf

7/31/08 HED risk

7.0.HED.risk.20080731.Emamectin - tree nuts.risk assessment.DP345943.signed ocr.pdf

1/28/09 HED risk addendum on REI

6.1.HED.REI 48 to 12 with exceptions.20090128.DP360697 and DP360698.mem.signed ocr.pdf

100-RGNO status table

000100-0RGNO.20090603.issues.doc

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

ISSUE – during tree nut analysis a new technical was registered which dropped eye from I to III. 7/31/08 HED risk memo forgot to address this here this 1/28/09 memo

MEMORANDUM

Date: January 28, 2009

SUBJECT: **Revised.** Emamectin Benzoate; Change of WPS REI from 48 to 12 Hours. Review of Supporting Rationale.

PC Code: 122806
Decision No.: 389854 and 390649
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: D360697 and D360698
Registration No.: 100-903 and 100-904
Regulatory Action: Label Change
Case No.: NA
CAS No.: NA
40 CFR: NA

FROM: Jack Arthur, Environmental Scientist
Registration Action Branch 3 (RAB3)
Health Effects Division (7509P)

THROUGH: Paula Deschamp, Chief RAB3
Health Effects Division (7509P)

TO: Thomas Harris, Risk Manager
Insecticide Branch
Registration Division (7505P)

Introduction

This revised memorandum supersedes the previous version (DP#s: 350218 and 350219, May 7, 2008) in its entirety.

Two currently registered emamectin benzoate products, Denim® (EPA Reg. No. 100-903) and Proclaim® (EPA Reg. No. 100-904) are labeled with a Worker Protection Standard (WPS) Restricted Entry Interval (REI) of 48 hours based on a Category I for eye irritation resulting from the acute six-pack conducted on the technical product, Emamectin Benzoate Technical (EPA Reg. No. 100-902). In December of 2007, OPP registered a new technical emamectin benzoate, called Emamectin Benzoate Technical II (EPA Reg. No. 100-1207), which is produced by a new manufacturing company. The registrant is Syngenta Crop Protection Inc. The acute six-pack of tests performed on this new technical product resulted in new toxicity category assignments.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: 7/31/08

MEMORANDUM

SUBJECT: **Emamectin Benzoate.** Human Health Risk Assessment for Proposed Uses on Tree Nuts and Pistachios, and as an Injection Treatment for Ornamental/Nonbearing Trees.

PC Code: 122806
Decision No.: 384481
Petition No.: 7F7263
Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA
MRID No.: NA

DP Barcode: 345943
Registration Nos.: 100-904, 100-RGNO
Regulatory Action: Section 3 Registration
Case No.: NA

CAS No.: 155569-91-8
40 CFR: 180.505

FROM: Nancy Dodd, Chemist
Registration Action Branch 3
Health Effects Division (7509P)

and

for Kelly O'Rourke, Biologist
Whang Phang, Toxicologist
Registration Action Branch 3
Health Effects Division (7509P)

THROUGH: Jack Arthur, Environmental Health Scientist
Paula Deschamp, Branch Chief
Registration Action Branch 3
Health Effects Division (7509P)

TO: Thomas Harris/John Hebert, RM #6
Insecticide-Rodenticide Branch
Registration Division (7505P)

The Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The Registration Division (RD)

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: 24 July 2008

SUBJECT: Emamectin Benzoate; Occupational and Residential Risk Assessment for Proposed Use of Emamectin Benzoate on Tree Nuts and as a Tree Injection.

PC Code: 122806
Decision No.: 384481, 387891
Petition No.: NA
Assessment Type: Single Chemical/No Aggregate
TXR No.: NA
MRID No.: NA

DP Barcode: D347923, D354525
Registration No.: 100-904, 100-RGNO
Regulatory Action: Section 3
Case No.: NA
CAS No.: 155569-91-8
40 CFR: 180.505

FROM: Kelly O'Rourke, Biologist
Registration Action Branch 3
Health Effects Division (7509P)

THROUGH: Jack Arthur, ORE Assessment Team Leader
Registration Action Branch 3
Health Effects Division (7509P)

TO: John Hebert/Tom Harris, PM Team #07
Insecticide/Rodenticide Branch
Registration Division (7505P)

I. CONCLUSIONS

The TREE-äge™ label is not acceptable as written. This label needs to restrict use to application by certified applicators only, based on the acute primary eye toxicity of the product. In addition, the pounds of active ingredient per gallon need to be specified on the first page, and gloves need to be added to the personal protective equipment (PPE) section for handlers. The Proclaim® Insecticide label already specifies the necessary gloves and coveralls for airblast applicators. With these mitigation measures, occupational margins of exposure (MOEs) reach/exceed the levels of concern (LOC) of 300 and 1,000, and therefore, are not of concern.

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

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

03/JUN/2008

acute tox 100-RGNO end use

MEMORANDUM

Subject:	Name of Pesticide Product:	TREE-age
	EPA File Symbol:	100-RGNO
	DP Barcode:	D348524
	Decision No.:	387891
	Action Code:	R310
	PC Code:	128806 (emamectin benzoate)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew
Hasler 6-9-08

To: Thomas Harris, RM Team 07
Insecticide -Rodenticide Branch
Registration Division (7505P)

Applicant: Syngenta Crop Protection, Inc.
P. O. Box 18300
Greensboro, NC 27419

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Emamectin benzoate	4.0
Inert Ingredient(s):	96.0
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests review of acute toxicity data for 100-RGNO.

Treeage 100-RGNO - a) need revised label, b) 2-yr efficacy review
Thomas Harris to: tom.parshley 06/03/2009 12:16 PM

Tom,

Hope all is well at your end. Several things regarding Treeage 100-RNGO.

1) FYI, I received your email copy of the pollinator info for Treeage. I'll send it to EFED for review (although I need to wait for MRID paper copy to create the official DP).

2) Bo was able to review your 2-year efficacy data. The review is attached. He said it started out well but the later studies fell apart. We've denied the claim for now and stated what you need to provide. I assume you'll probably eventually be able to support this claim but for the moment leave it off the label.

000100-0RGNO.20090528.Tree-Age _2 year data_.pdf

3) I do have an action item for you: >>>> I need an updated version of the label reflecting the EPA changes outlined so far in the reviews (see my email to you 3/31/09). This won't be the final version; we still need to iron out the pollinator issue and the eye irritation issue. However, there were a number of straightforward revisions listed in the earlier reviews (especially the 11/6/08 efficacy review) and we need a starting point for further discussion. Since the PRIA deadline is 7/15/09 I could use this new label within the next week or so.

Thanks.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

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

March 4, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 02-MAR-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 845794

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: New Registration

Billable: Yes No

Company: 100 SYNGENTA CROP PROTECTION, INC.

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 100-RGNO Product Name: TREEAGE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 27-Feb-2009 OPP Rec'vd Date: 02-Mar-2009

Front End Date: 04-Mar-2009 Risk Manager Send Date: 04-Mar-2009

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content	Des
Study	

Fast Track: New Ingredient:

View/Edit

Receipt Description:

additional efficacy data

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Syngenta Crop Protection, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

476910-00

syngenta

FEDERAL EXPRESS

February 27, 2009

Document Processing Desk
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Attention: Mr. Thomas Harris

SUBJECT: SUBMISSION OF ADDITIONAL EFFICACY DATA TO SUPPORT TWO-YEAR RESIDUAL CONTROL FOR TREEÄGE, EPA FILE SYMBOL 100-RGNO

Dear Mr. Harris:

Enclosed please find three copies each of a transmittal document and a single data volume containing additional efficacy data on an extended control claim of 2 years for the quarantine pest Emerald Ash Borer. As we discussed back in December 2008, just after your office forwarded the initial efficacy review to Syngenta, this information was to be provided to EPA in February 2009 so that it could be reviewed in time for the registration decision. Syngenta is providing these data to address the length of control claim on the label. As we discussed, please allow these data to be considered in the support of a 2 year control claim for this product.

Fees for Service
This data is being submitted to support D-387891. In compliance with PRIA II, the fee for this action has been previously assessed and paid.

Please contact me at (336) 632-7207 if there are any questions concerning this submission or the pending registration action for TREEäge.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosures

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Submission of Additional Efficacy Data to Support Two-Year Residual Control For Treeage, EPA File Symbol 100-RGNO

3. Transmittal Date

02/27/2009

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
47691001	2 OF 2	Addendum - Emamectin Benzoate ME (A16297A) - Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees (Multiple Year Performance Data for Emerald Ash Borer) (EPA MRID No. 47465501), T004223-07, (A16297A_1000000)	810.1000

COMPANY OFFICIAL: TOM PARSHLEY **(NAME)** Thomas J Parshley **(SIGNATURE)**

COMPANY NAME: SYNGENTA CROP PROTECTION

COMPANY CONTACT: TOM PARSHLEY **(NAME)** (336) 632-7207 **(PHONE)**

Please read instructions on reverse before completing form.

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
100-RGNO	Mr. Thomas Harris	[X] None [ ] Restricted
4. Company/Product (Name) TREEäge	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated ____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated ____

[ ] "Me Too" Application.

[x] Other - Explain below. New Product-nonfood use

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

Enclosed is efficacy data on an extended control claim of 2 years for the quarantine pest Emerald Ash Borer. This information was to be provided to EPA in February 2009 so that it could be reviewed in time for the registration decision.

Fees for Service

This data is being submitted to support D-387891. In compliance with PRIA II, the fee for this action has been previously assessed and paid.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) Plastic tube ____
***Certification must**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued for tubes [ ] Stenciled [ ] Outer box is preprinted ____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J. Parshley	Sr. Regulatory Product Manager	336-632-7207

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.

2. Signature	3. Title	6. Date Application Received (Stamped)
Thomas J Parshley	Senior Regulatory Product Manager	
4. Typed Name Thomas J. Parshley	5. Date February 27, 2009	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Treeage reviews 2 of 2
Thomas Harris to: tom.parshley
Cc: John Hebert

03/31/2009 03:36 PM

more reviews for 100-RGNO

000100-00RGNO.20080724.HED ORE.image.pdf

000100-00RGNO.20090113.EFED eco.image.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Fw: Treeage 100-RGNO reviews and label revisions
Thomas Harris to: tom.parshley 03/31/2009 03:35 PM
Cc: John Hebert

Let's try this again with the right Tom!

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides
----- Forwarded by Thomas Harris/DC/USEPA/US on 03/31/2009 03:34 PM -----

From:	Thomas Harris/DC/USEPA/US
To:	Thomas Harris/DC/USEPA/US@EPA
Cc:	John Hebert/DC/USEPA/US@EPA
Date:	03/31/2009 03:34 PM
Subject:	Treeage 100-RGNO reviews and label revisions

1 of 2

Tom,

Attached please find a scan (image) of the reviews for 100-RGNO: prod chem, acute tox, efficacy, HED ORE, EFED eco. I will split into two emails to get through all. BTW, the additional CSFs are ok (came in after data sent for review but simply change in ai source so I can approve on my own). I will try to get you a text .pdf for the final official copies of the reviews but the images will do for now.

Regarding label revisions, please make the following:

1) Below the ingredient statement, add text stating lbs a.i./gal.

2) Directions for use: In general, you need to be more specific on the directions and watch some of the adjectives. The efficacy review gives a detailed description of changes.

3) Directions for use: Given the current attention to pollinators, OPP has come up with a new policy that any product with residual activity of more than one year needs to include the restriction: "Do not use on flowering trees." This is a broad statement to address the concerns we've been discussing. The additional information you will be providing may allow us to refine that statement. Also, given that emamectin is used for some quarantine pests we may want to allow exceptions for some specific pest/host situations. Keep this restriction in mind as a starting point when you submit the additional bee/flowering tree information you are preparing.

4) RUP: Note that the HED review states that the end-use is acute eye category I while the acute tox review states acute eye II. I need to resolve this at my end.

>>>> Please revise the label and email me a text .pdf of the next version for discussion. If there are still pending issues just make a note on the label to that effect. I'd mainly like to see refined application directions (see efficacy review) before we finalize the RUP and bee issues.

000100-00RGNO.20080402.prod chem.image.pdf

000100-00RGNO.20080603.acute prod tox.image.pdf

000100-00RGNO.20081106.efficacy.image.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

RE: TREEage Efficacy data
Thomas Harris to: tom.parshley 03/11/2009 02:09 PM
Cc: John Hebert, Meredith Laws

Tom,

No, it's not upstairs yet but I see it was received and checked in downstairs 3/2/09. It's still in in-processing.

However, there is a snag.

As per OPP's policy, all data associated with an action need to be submitted up front. It is too late at this point to be submitting new data to associate with this current action. FYI, while the PRIA date for this action is 7/15/09, OPP is actually targeting 3/31/09 for completion. The policy applies, however, even with the 7/09 due date. I even checked with the reviewers to see if this data would be a quick review that we could slip in and they said no; it involves six studies and will take a while.

If we were to code this new data now we'd have to bill you for a new use (R230, $21,740) since the initial application is still pending. I don't think you want to do that!

If you wait until I stamp the label at the end of this month then submit the data it will be a R340, $3444, four months. Practically speaking, I think we could probably get it done within a couple of months.

It's up to you, but I suggest you send me an email withdrawing this action for now. Once the label is stamped, you can submit a new cover letter, application form, and label asking us to review this efficacy data. Since your study is getting an MRID assigned as we speak you do not need to resubmit the study, just reference the MRID that we will already have on file.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Tom: Just checking to see if you received the pa... 03/09/2009 02:43:32 PM

From: <tom.parshley@syngenta.com>
To: Thomas Harris/DC/USEPA/US@EPA
Date: 03/09/2009 02:43 PM
Subject: RE: FW: Cover letter for TREEage Efficacy data

Tom: Just checking to see if you received the paper version of the submission noted below. Let me know if there is anything else I can provide or if there are any questions. Thanks

Tom

-----Original Message-----
From: harris.thomas@epamail.epa.gov
[mailto:harris.thomas@epamail.epa.gov]
Sent: Monday, March 02, 2009 5:50 PM
To: Parshley Tom USGR
Subject: Re: FW: Cover letter for TREEage Efficacy data

Thanks for the head's up, Tom. I put a note on my calendar to check in a couple of weeks if I've gotten the hardcopy w/ MRID yet. If not, I'll use the e-copy to get the efficacy review going.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

From: <tom.parshley@syngenta.com>

To: Thomas Harris/DC/USEPA/US@EPA

Date: 02/27/2009 12:56 PM

Subject: FW: Cover letter for TREEage Efficacy data

Tom: Attached is a courtesy electronic copy of a cover letter and single data volume that were filed today by courier mail for TREEage. This is the recently available data on 2 year extended control claim for Emerald Ash Borer. We discussed this back in December 2008 and it was determined then that the data would need to be available in February 2009 for consideration in the initial registration decision. Thanks for your kind consideration of this information. Please contact me with any questions. I hope you have a great weekend.

Best regards,

Tom

From: Strader Cherilyn USGR
Sent: Friday, February 27, 2009 12:06 PM
To: Parshley Tom USGR
Subject: RE: Cover letter for TREEage Efficacy data

Total is under 2 MB.
-CS

From: Parshley Tom USGR
Sent: Thursday, February 26, 2009 12:51 PM
To: Strader Cherilyn USGR,
Subject: Cover letter for TREEage Efficacy data

This is cover letter for efficacy study being prepared. Please look over and edit as necessary. I would like to e-mail the letter to Tom Harris along with a PDF of the study. Will it exceed 4MB? If so, it will need to be zipped. Can you do a Zip file for me if it is too large?

Tom

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.[attachment "2-27-09 Treeage Efficacy data.pdf" deleted by Thomas Harris/DC/USEPA/US] [attachment "T004223-07.pdf" deleted by Thomas Harris/DC/USEPA/US]

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

<tom.parshley@syngenta.com>

01/19/2009 04:03 PM

To Thomas Harris/DC/USEPA/US@EPA

cc Venus Eagle/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, Kable

bcc

Subject RE: Treeage: ArborJet still has false claims on website

History: This message has been replied to.

Tom: Thanks for the follow up note on the Arborjet website issues with TREEage. Attached is my e-mail to them of last week and their response. I have checked the web site and links and everything now seems to be in order. I am sorry that it took a couple of rounds to get everything fixed. Syngenta appreciates your patience.

On a related note we are in the process of pulling together the additional efficacy research on TREEage to support a multi-year control claim. These data will be submitted in February as we discussed.

Best regards,

Tom Parshley

-----Original Message-----
From: harris.thomas@epamail.epa.gov
[mailto:harris.thomas@epamail.epa.gov]
Sent: Tuesday, January 13, 2009 5:20 PM
To: Parshley Tom USGR
Cc: Eagle.Venus@epamail.epa.gov; Hebert.John@epamail.epa.gov;
Laws.Meredith@epamail.epa.gov; Davis.Kable@epamail.epa.gov;
Chao.Julie@epamail.epa.gov; Metzger.Autumn@epamail.epa.gov
Subject: Treeage: ArborJet still has false claims on website

Tom,

I was checking back on ArborJet's website concerning Emerald Ash Borer control with Treeage (emamectin) and discovered that they still have the same false/misleading claims we noted in our initial discussions via email on the same subject on 10/29/08 and 11/21/08.

ArborJet needs to remove all references to multi-year control from emamectin. In addition (I did not mention this last time), they also need to replace claims for "100% control" with a qualitative statement like simply "controls" or maybe "excellent control". In general, we don't allow percentage claims. Specifically, we realize that nothing is perfect so we definitely do not allow claims for 100% control. I've listed several URLs below although I would request that you and ArborJet scour the entire site to find all instances of these problem claims.

I think the problem here is more than just a hyperactive marketing team. It sounds like there may actually be data showing multi-year efficacy but the company doesn't seem to realize that to make claims for the product they not only need to have data but also need to have the data submitted to and approved by EPA. They need to stop jumping the gun and posting statements that haven't been approved by EPA.

Please talk to them about this again and let me know when the website is corrected. I don't think they'll want us to turn this over to Enforcement. I'll check the website myself next week, as well. Thanks

main EAB page [delete 100% control]
http://www.arborjet.com/problems-solutions/emerald-ash-borer.htm

EAB Pest Info - PDF [a document dated 7/17/08; delete multi-year control claims]
http://www.arborjet.com/problems-solutions/emerald-ash-borer.pdf

EAB facts [basically same as PDF above; delete multi-year control claims]

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TREE-age Video [delete multi-year control claims]
http://arborjet.com/videos/tree-age-intro-eab.htm

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----- Message from <tom.parshley@syngenta.com> on Thu, 15 Jan 2009 17:49:18 -0500 -----

To: <russdavis@arborjet.com>, <ericbristol@arborjet.com>, <peterwild@arborjet.com> <bert.wagemans@syngenta.com>, <joan.tao@syngenta.com>, <vince.alventosa@syngenta.com>, <j

cc: <steve.spain@syngenta.com>, <larry.zang@syngenta.com>, <fred.pearson@syngenta.com>, <dan.st <scott.reasons@syngenta.com>

Subject: RE: Arborjet website

Dear Russ and Peter:

Attached is an e-mail received by Syngenta from EPA concerning false and misleading claims appearing on Arborjet's web pages for TREEage. These claims have been discussed between Arborjet and Syngenta on several occasions, the most recent being November 19, 2008. I believe also, Bert Wagemans sent an e-mail to you on December 10, 2008 asking for verification that these claims had been removed; I am unaware if a response was received from Arborjet. At the November 19 meeting, Syngenta staff pointed out a number of such claims for TREEage that needed to be removed from the web pages in order to avoid EPA taking enforcement action against Arborjet. This included removal of any claims for multi-year control and claims for 100% control of Emerald Ash Borers. Our staff spent considerable time reviewing the content on these web pages and provided page by page review and comment regarding

these claims. Arborjet staff provided assurances in that meeting with Syngenta that all of the false and misleading claims would be removed from its web pages. However, this obviously has not taken place. Let me assure you that Syngenta considers this matter as very serious. As you will note, EPA is poised to take immediate enforcement action against Arborjet on this matter. Since Tom Harris of EPA has indicated he will be checking your various web pages early next week, you are therefore instructed to remove any and all such claims from the web site by no later than close of business on Friday, January 16, 2009. We will expect an immediate response to this message from Arborjet acknowledging your understanding and agreement to remedy the situation, as well as confirmation to Syngenta when all false and misleading information has actually been removed from the web pages noted below.

Sincerely,

Tom Parshley

Senior Regulatory Product Manager

----- Message from <harris.thomas@epamail.epa.gov> on Tue, 13 Jan 2009 17:20:29 -0500 -----

To: <tom.parshley@syngenta.com>

cc: <Eagle.Venus@epamail.epa.gov>, <Hebert.John@epamail.epa.gov>, <Laws.Meredith@epamail.epa <Davis.Kable@epamail.epa.gov>, <Chao.Julie@epamail.epa.gov>, <Metzger.Autumn@epamail.epa

Subject: Treeage: ArborJet still has false claims on website

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Please talk to them about this again and let me know when the website is corrected. I don't think they'll want us to turn this over to Enforcement. I'll check the website myself next week, as well. Thanks

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----- Message from <russdavis@arborjet.com> on Mon, 19 Jan 2009 10:14:56 -0500 -----

To: <tom.parshley@syngenta.com>

cc: <dan.steltz@syngenta.com>

Subject: RE: Arborjet website

Tom

Sorry for taking more of your time on this. Apparently, even though we removed the links from our website you could still get there if you saved the link and went back to it. The links have been removed completely now. We also addressed the new points. I will send you the e-mails I sent to Margaret, Dan and Bert after our meeting. Again sorry for taking your time and any loss of goodwill with your friends at the EPA. This certainly was not our intention.

Russ

From: tom.parshley@syngenta.com [mailto:tom.parshley@syngenta.com]
Sent: Thursday, January 15, 2009 5:49 PM
To: russdavis@arborjet.com; ericbristol@arborjet.com; peterwild@arborjet.com
Cc: bert.wagemans@syngenta.com; joan.tao@syngenta.com; vince.alventosa@syngenta.com; janis.mcfarland@syngenta.com; steve.spain@syngenta.com; larry.zang@syngenta.com;

fred.pearson@syngenta.com; dan.steltz@syngenta.com;
scott.reasons@syngenta.com
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Thomas Harris/DC/USEPA/US
01/13/2009 05:20 PM

To <tom.parshley@syngenta.com>
cc Venus Eagle/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, Kable
bcc
Subject Treeage: ArborJet still has false claims on website

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Emerald Ash Borer

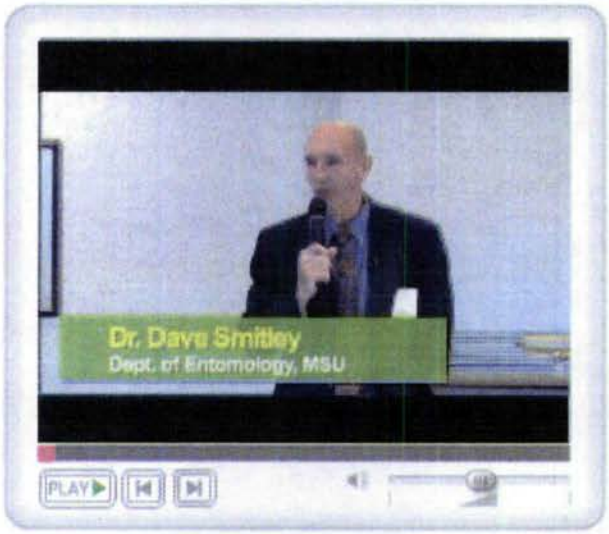
The Emerald Ash Borer (EAB) is an invasive pest introduced from Asia that attacks ash trees. This metallic wood boring beetle was found in Detroit, Michigan in 2002.

The Effects of EAB

EAB has killed moire than 40 million ash trees in Michigan and tens of millions more in Ohio, Illinois, Indiana, Pennsylvania, West Virginia, Missouri, Wisconsin and Virginia. >More

Treatment and Control

Arborjet products for Emerald Ash Borer are rated #1 in University studies. Our world class equipment and formulations have protected over 10,000 ash trees. Don't delay, be proactive.



Dr. Dave Smitleys EAB Presentation at the Illinois ArboristShow 2008

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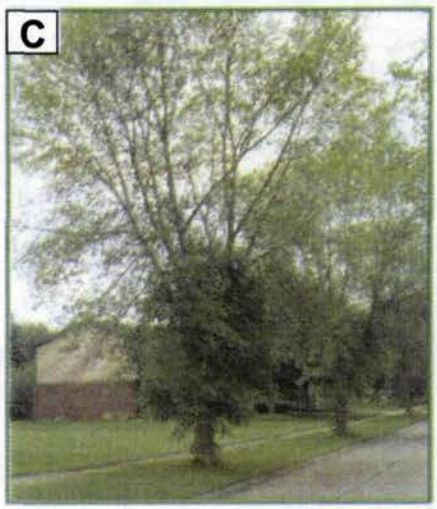
ARBORJET
A Revolutionary Plant Injection System

Emerald Ash Borer

(Agrilus planipennis)

The Emerald Ash Borer (EAB) is an invasive pest introduced from Asia that attacks ash trees (*Fraxinus* spp.) This metallic wood boring beetle was found in Detroit, Michigan and Ontario, Canada in 2002, and has now been identified in Ohio, Illinois, Indiana, Virginia, Pennsylvania, and Maryland. The larvae live under the bark of the tree and feed in the vascular cambium on the nutrient rich conductive tissues. The adult beetles leave a "D" shaped exit hole ~1/8 inch wide when they emerge from the bark in June.

SYMPTOMS:
Dieback of the canopy above the site of infestation. As many as one half of the branches may die back in one year of infestation. The tree will try to compensate by sprouting new epicormic growth below the level of infestation. The bark may begin to split. Under the bark, larval trails will meander through the vascular cambium. Trees can die within only two years of the onset of symptoms.



PHOTOS: **A:** EAB Adult beetle, **B:** EAB Larval stage, **C:** EAB infested Ash tree *Photos taken by Dave Cappaert and Arborjet, Inc.*

WHAT TO DO:

Arborjet recommends a trunk micro-infusion or microinjection with either IMA-jet (imidacloprid) or TREE-äge (emamectin benzoate) using either the Tree I.V. system or the QUIK-jet device. The large vessel transport system in ash trees will rapidly take up injected IMA-jet. TREE-äge is more viscous and will take slightly longer to inject but will provide a longer residual effect. TREE-äge and IMA-jet will kill the EAB larvae inside the tree. IMA-jet can be mixed with MICRO-jet Mixable to provide the tree with insecticide and fertilization in one treatment. See the IMA-jet and TREE-äge labels for dosage rate based on tree size.

WHEN TO DO IT:

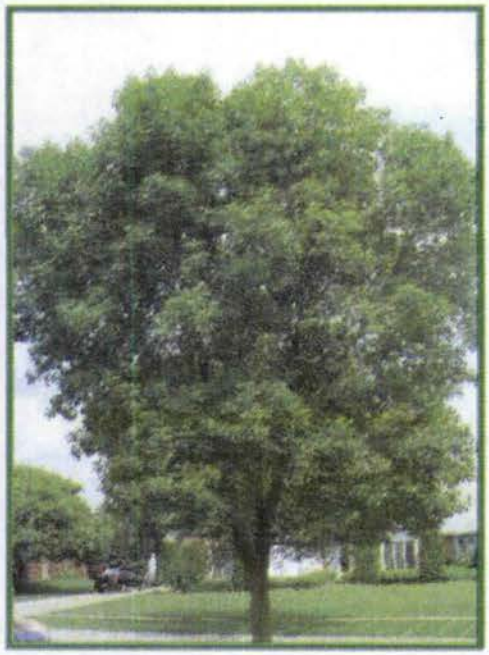
Treat ash if EAB is reported in your area. Do not wait for visible dieback in the canopy. There is a significant delay between damage to the vascular cambium and dieback in the canopy. Delaying treatment will result in canopy dieback or tree loss. There are 2 treatment windows for EAB in a given year. Treatment in the spring will prevent the adult beetles from feeding and laying eggs in the tree. Injecting in the summer will kill the larval stage of EAB feeding under the bark. Uptake of formulation is fastest when trees are actively transpiring. Morning applications are best, especially during summer weather. When air temperatures are high or when soil conditions are dry, it is best to postpone injection for better environmental conditions.

downloaded 1/13/09 from Arbor Jet website

Revised 7/17/08

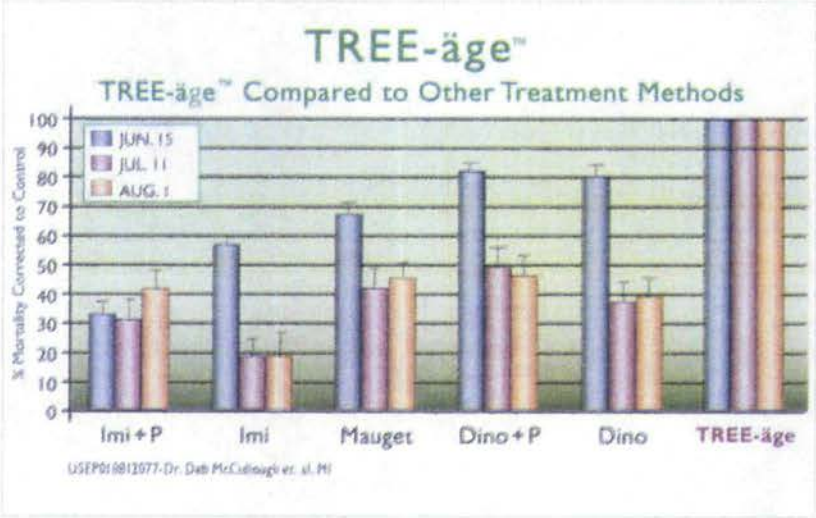
WHAT WILL HAPPEN:

IMA-jet will kill the EAB larvae under the bark and deter adult feeding on the treated tree. TREE-äge will kill the EAB larvae under the bark as well as any adult beetles that feed on the tree. Depending upon the overall health of the tree, IMA-jet will protect a tree from EAB for up to 2 years and TREE-äge will protect a tree from EAB for a potential 3 years. Tree recovery from an established infestation is relative to the severity of the infestation at the time of treatment as well as other environmental factors. Do not treat trees more than once annually.



PHOTOS: **Left:** EAB Larval Galleries **Right:** IMA-jet Treated Ash Tree

"I only wish we had started using the Arborjet system a couple years ago. There would certainly be a larger number of mature ash trees still alive in our community. Such a shame." Guerin Wilkinson, Green Street Tree Care, Ann Arbor, MI



1-866-ARBORJT or 1-866-272-6758 www.Arborjet.com

downloaded 1/13/09 from Arborjet website

ed 7/17/08

Thomas Harris/DC/USEPA/US
01/12/2009 06:08 PM

To Venus Eagle/DC/USEPA/US@EPA
cc Kable Davis/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA
bcc
Subject Re: Fw: Competitor 2-year claims

Important: It took me about 5 minutes to realize there are two different companies here: ArborJet (website with false claims) and ArborSystems (company represented by lawyer below who is complaining about false claims on competitors site).

Background: There was previously an issue with the Arborjet website concerning claims for emerald ash borer (EAB) control using Treeage, the pending emamectin product (100-RGNO). I learned of this from Bo who learned of it from another registrant.

Problem: Arborjet website for Treeage (emamectin) included claims for a) three years control of EAB, b) directions to apply every other year, and c) 100% control of EAB,

Solution: Before starting any legal action we decided to contact Syngenta on 10/29/08 to see if they could exert pressure on ArborJet. Syngenta will hold the registration but Arborjet will be the sales agent. I asked Sygenta to have Arborjet remove the 3 year and treat every other year text*. I found that the text was still present on the website on 11/3/08. However, in telephone conversations Tom Parshley of Syngenta informed me that Arborjet was correcting the website. I did not do a print of the revised website so I don't know exactly when the correction was made.

** Note: I did not mention the 100% control text. Actually, Bo's 11/6/08 review subsequently noted that 100% control of EAB was seen in some tests. If we ask them to change this text on the label it will be because we might consider this to be misleading to state that a product always has perfect results. I'm not sure of that yet, however.*

Current: The Arborjet website currently shows multiyear claims for Imajet (imidicloprid) but the Treeage (emamectin) text is ok [except for unresolved 100% issue]. The website even mentions that Treeage is not for homeowner use. That isn't an issue at the moment since the product is only available via SLNs. We'll probably wind up making the Sec 3 an RUP. I'm sure the registrant will object.

>>>>>>> We should make a consistent decision on RUP status for both imidicloprid and emamectin.

Tom Harris
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voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Venus Eagle | Hi Tom, I am following up with Mr. Chen's note b... | 01/12/2009 05:12:09 PM

Venus Eagle/DC/USEPA/US
01/12/2009 05:12 PM

To Thomas Harris/DC/USEPA/US@EPA
cc Kable Davis/DC/USEPA/US@EPA
Subject Fw: Competitor 2-year claims

Hi Tom,

I am following up with Mr. Chen's note below (lawyer for Abor Systems and friend of Kim Davis). Before Bo begins with these claims I wanted to make sure that you haven't already contacted this company as they do have claims regarding emamectin as well.

Thanks,

Venus

Venus Eagle
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division
(703) 308-8045

----- Forwarded by Venus Eagle/DC/USEPA/US on 01/12/2009 05:08 PM -----

"Chen, James"
<JChen@crowell.com>
12/31/2008 02:55 PM

To Venus Eagle/DC/USEPA/US@EPA
cc
Subject Competitor 2-year claims

Venus - on behalf of ArborSystems, I wanted to thank you for your prior e-mail regarding the extension for submission of the one-year data and label clarifications/corrections. I appreciate your working with us on this issue.

On a related note, you recommended that I continue to keep you posted should competitors to ArborSystems continue to make claims that EPA has determined to be violative (i.e., 2 year efficacy claims for Imidaclorprid where EPA has approved none). The attached links will take you to ArborJet's website where they are clearly advertising 2-year efficacy for their IMA-Jet product - an injectable Imidaclorprid solution for use in trees against EAB and Asian Long Horned beetles (among other pests). This sounds a lot like the ArborSystems Pointer product for which we are being asked to produce data.

I hope you can understand my client's continued skepticism about the value of cooperating with the Agency when their competitors are taking advantage of illegal claims. I have convinced them that this is the right path, however, with these types of claims continuing from competitors, please understand that it won't be long before ArborSystems feels it is forced to take some alternative action.

Let's talk when you get a chance - many thanks again.

Jim Chen

http://www.arborjet.com/videos/smitley.htm
http://www.arborjet.com/products/ima-jet.htm

James C. Chen
Crowell & Moring LLP
1001 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

(202) 624-2570 (direct dial)
(202) 628-5116 (fax)
jchen@crowell.com
www.crowell.com

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Clips from Dr. Dave Smitley's EAB Presentation at the Illinois Arbor

Introduction - Ash Trees Can Be Saved (35 sec.)

IMA-jet provides at least 2 years of control (40 sec.)

TREE-äge Shows 100% Control (2 min.)

Cities and Municipalities Should Treat (1 min. 15 sec.)

Click one of the C buttons on the l play the Vide

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EAB Facts
EAB Research
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TREE-age 24c Labels

IMA-jet

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Emerald Ash Borer

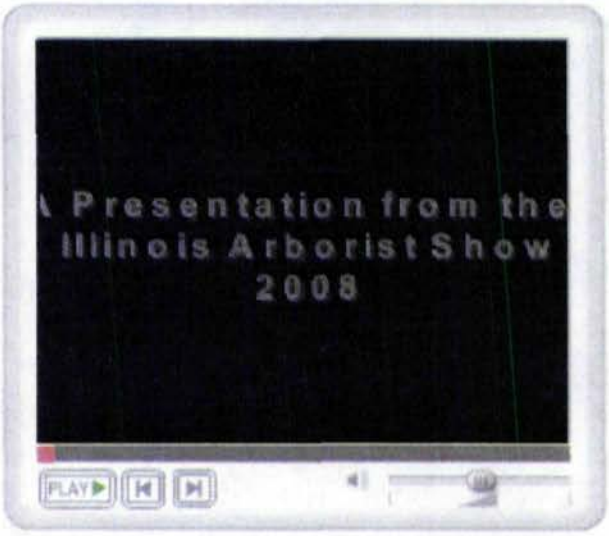
The Emerald Ash Borer (EAB) is an invasive pest introduced from Asia that attacks ash trees. This metallic wood boring beetle was found in Detroit, Michigan in 2002.

The Effects of EAB

EAB has killed moire than 40 million ash trees in Michigan and tens of millions more in Ohio, Illinois, Indiana, Pennsylvania, West Virginia, Missouri, Wisconsin and Virginia. >More

Treatment and Control

Arborjet products for Emerald Ash Borer are rated #1 in University studies. Our world class equipment and formulations have protected over 10,000 ash trees. Don't delay, be proactive.



Dr. Dave Smitleys EAB Presentation at the Illinois ArboristShow 2008

**World Class Tree Inje
Formulations**

TREE-äge
**Up to 100% control!
For use in selected state**

IMA-iet
**Proven to save your ash.
For use in most states.**

**Research
See resul
university**

**Emerald A
Find out w**

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Effective Treatment For:

Emerald Ash Borer

FOR SALE ONLY IN THESE STATES - Emergency Use Registration in **IL, IN, MI, MN, MO,OH, VI,WV,WI**

TREE-äge is not intended for homeowner use.

TREE-age 24c Labels

- Illinois
- Indiana
- Michigan
- Minnesota
- Missouri
- Ohio
- Pennsylvania
- Virginia
- West Virginia
- Wisconsin

ACTIVE INGREDIENTS:
Emmamectin Benzoate.....
OTHER INGREDIENTS.....
TOTAL.....1

PRICING:
For information on pricing and av
1-866-ARBORJT

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ARBORJET METHODOLOGY

The Arborjet Methodology represents the cutting edge in trunk injection technology. It is precise, efficient, highly effective and easy to do.

Arborjet has ranked #1 in every head to head university study.

No other system compares to Arborjet. The method is so safe and simple to use, you can start treating trees immediately!

1. DRILL
2. PLUG
3. INJECT

- Fastest product delivery times
- No risk of cambial injection
- Closed injection site
- Lowest wound profile
- Fastest wound closure
- No risk of bark separation
- No product "Blow-Back"
- No bark cracking

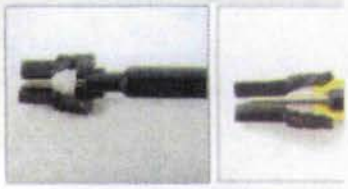
#4 Arborplugs 3/8" for conifer and medium to large trees
Pack of 100 $65.00
Pack of 25 $20.00

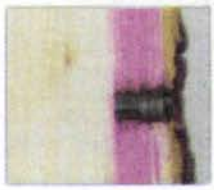
#3 Arborplugs 9/32" for small to medium deciduous trees
Pack of 100 $75.00

The patent pending Arborplug advancement in trunk injection

ADVANTAGES OF THE ARBORPLUG

- Facilitates high volumes of medic xylem tissue of the tree.
- Arborplug's tight seal in the tree throughout injection process, ma
- The self sealing surgical septum product "blow back."
- Prevents lost or wasted product.
- Minimizes the number of injectio
- "Closed" injection site limits wou decay or infection from entering becoming vector for insects





Arborplug e product del xylem tissu

Order Online

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OK

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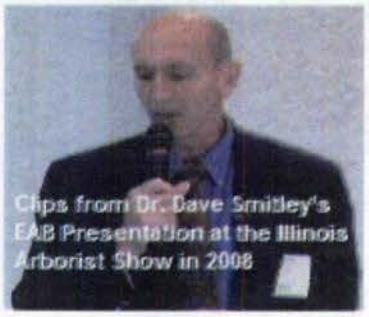


Arborjet Gets Effecitve Results

Arborjet is proud to display the effective results we achieve with our devices and formulations on a number of pests threatening our urban and natural forests. These results are a combination of Arborjet in-house research, collaborative research, and independent research results. We recommend you also review our research reports, presentations, pest info pages, product pages for more research results.

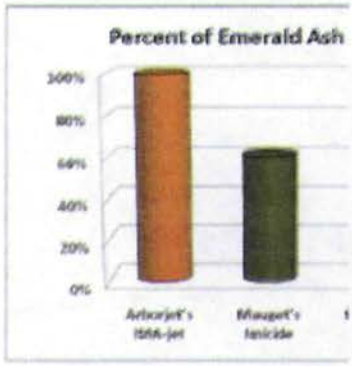
Emerald Ash Borer
Hemlock Woolly Adelgid
Pine Bark Beetle
Erythrina Gall Wasp
Leaf Chewing Caterpillars
Anthracnose
Iron Deficiencies
Manganese Deficiencies

ARBORJET INJECTION SYSTEMS

Arborjet's formulations are applied using the Tree I.V. or QUIK-jet device. The QUIK-jet user rapidly injects formulations through a single needle at 1-5mL per trigger push. The Tree I.V. user has several one liter Tree I.V. bottle with 4-8 needles allowing high volume multiple injection site uptake while treating several trees simultaneously.

Emerald Ash Borer

Extensive university research stu
(imidacloprid) as the #1 most effe
for EAB control! IMA-jet is injecte
system of the tree, and the speci
translocates the active imidaclop
adults and larvae



Reference: www.emeraldashborer.inf
Results, D.R. Smitley et. al., Michigan

IMA-jet is highly effective against Em
multiple years of efficacy. IMA-jet sh
of EAB in the 2004 and 2005 stud
State University.

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OK

Thomas Harris/DC/USEPA/US
11/21/2008 06:00 PM

To <tom.parshley@syngenta.com>
cc
bcc
Subject Treeage - efficacy review; label changes needed

Tom,

Here's an advance copy of the efficacy review of your latest data for Treeage 100-RGNO. There are a number of label changes specified. Please use this to revise the label and email me a text .pdf. Thanks.

BTW, there's no action needed based on the prod chem and acute tox reviews. Only thing of interest is that eye irritation is II but you've already got the correct text and PPE for this on the draft label.

[I'll include the official copy of efficacy review at the end with all other reviews.]

000100-0RGNO.20081106.efficacy review.image.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Thomas Harris/DC/USEPA/US
11/21/2008 09:45 AM

To <tom.parshley@syngenta.com>
cc John Hebert/DC/USEPA/US@EPA, Venus Eagle/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA
bcc
Subject more on Treeage claims

Tom,

About a month ago we brought to your attention some false/misleading claims on the Arborjet website regarding Treeage (specifically, claims for 2 years of control from one application). I was just given a copy of the May/June 2008 Buckeye Arborist (OH arborist newsletter). It, too, included the two year control claim for emamectin even though one of the articles mentioned that only one year's research had been done by a researcher in MI mentioned in the article. Obviously, the newsletter was prepared early last Spring and that issue is now out of date.

The point, however, is to be sure to have Arborjet retract the 2-year claim in ALL outlets (website, print, radio/tv, etc). I suspect you did this when you talked with Arborjet early this month but just wanted to remind you to keep on eye on all their media statements.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

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TREE-äge now registered in IL, IN, MI, MN, OH, and WV

- **> FAQ'S About TREE-äge**
- **> 24C Special Local Need Label for IL**
- **> 24C Special Local Need Label for IN**
- **> 24C Special Local Need Label for MI**
- **> 24C Special Local Need Label for MN**
- **> 24C Special Local Need Label for OH**
- **> 24C Special Local Need Label for WV**
- **> TREE-äge Material Safety Data Sheet:**
- **> How to Apply TREE-äge with the Tree I.V.**
- **> How to Apply TREE-äge with the QUIK-jet**
- **> TREE-äge is not intended for homeowner use.**

TREE-

SYSTEMIC INSECT CON

Broad spectrum insect contr
activity for micro-injection
application through Arborjet
äge is used to control speci
and landscape ornamentals
emamectin benzoate, eliminat
insect pests and provides mul
new infestations. TREE-äge i
vascular tissue to assure rapid
results. It is has been proven
be highly effective against Em

"This is as close to ... a silver bullet as possible."

– Jim Bowes, spokesman for Michigan's emerald ash borer programs.

ACTIVE INGREDIENT:

Emmamectin Benzoate.....

OTHER INGREDIENTS.....

TOTAL.....

USE

TREE-äge (emamectin benzoate) has proven in independent university studies and field trials to be highly effe
control of Emerald Ash Borer. In certain trials, it has demonstrated three years of protection against insect da
one injection. TREE-äge is uniquely formulated to move quickly through the xylem of trees without adversely im
normal cell function of the vascular tissue. While highly toxic to insect pests, it is non-toxic to the tree. TREE
particular effectiveness against many of today's most destructive insect pests such as Emerald Ash Borer. TREE
only insect control product on the market to consistently deliver 100% control for Emerald Ash Borer.

ACTIVE INGREDIENT

The active ingredient in TREE-âge is emamectin benzoate. Utilizing an innovative proprietary technology, ingredient molecules are held in a micro-encapsulated emulsion making them miscible in water and able to flow in the tree's vascular system without the use of any harmful solvents.

PEST MANAGEMENT

In trials, TREE-âge has demonstrated excellent control and long residual activity. It offers up to three years for Emerald Ash Borer.

RESEARCH AND DATA

Independent University Studies have proven TREE-âge to be the only insecticide on the market to deliver 100% Emerald Ash Borer. Below are representative samples of TREE-âge efficacy data taken from independent resea For complete reports, go to www.Arborjet.com/reseach/reports.htm

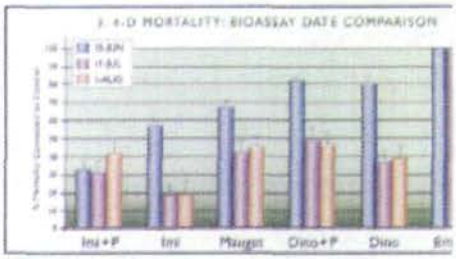
EAB Larva Control at Multiple Rates of Active

TREATMENT DATES	STUDY	gm A.I./DBH	LARVAE/ m2 F 2005	LARVAE/ m2 F 2006
5 2005	Therapeutic	0.1	0.0a	0.0a
		0.2	0.0a	0.0a
		0.4	0.0a	0.0a
		0.6	0.0a	0.0a
	Controls	0.0	59.2b	X*

[illegible]
[illegible]

In the independent university study referenced above, TREE-âge demonstrated 100% control of emerald ash borer larvae at even very low rates of active ingredient per inch of tree diameter. With one application in 2005, TREE-âge continued to show 100% control in the second year at every application rate.

TREE-âge vs. Competitive Products



[illegible]

In an independent efficacy study, TREE-âge (EmBen) was cor imidacloprid sprayed on the bark (Imi+P), soil applied imidaclo Mauget's imicide caps (Mauget). Safari bark application (Din Safari soil application and TREE-âge was the only product t 100% control with no loss of efficacy over time.

TREE-äge™

Frequently Asked Questions

Q. What is TREE-äge?

A. TREE-äge is a broad spectrum insecticide with multi-season control, specially formulated to be injected into the vascular system of trees. The active ingredient is emamectin benzoate.

Q. How is TREE-äge applied?

A. TREE-äge was specifically designed for trunk injection into the water & nutrient transport tissue, or xylem, of the tree. It should be applied using either the Arborjet Tree I.V. micro-infusion system, or the Arborjet QUIK-jet microinjection system. It cannot be applied as a spray, soil application, or cambial injection.

Q. Who makes TREE-äge?

A. TREE-äge is formulated and patented by Arborjet. It is the result of 5 years of laboratory research and field trials refining and developing the active ingredient emamectin benzoate into a tree-friendly, trunk injectable formulation. The emamectin benzoate molecule is owned by Syngenta Crop Science.

Q. Where can I purchase TREE-äge or find an applicator?

A. Go to the "Contact Us" tab on our homepage where you will find listings of Distributors and Service Providers. At this time, to purchase direct from Arborjet requires a *minimum* purchase of an 8 liter case.

Q. How effective is TREE-äge against emerald ash borer?

A. In field trials, TREE-äge is consistently proving it is the most effective product available to treat emerald ash borer.

Q. How often does TREE-äge need to be applied?

A. Using the medium dosage rate as outlined on the emergency use label, the product should be applied every other year but can be applied annually.

Q. How much does it cost to treat a tree?

A. Pricing can vary depending upon a number of factors including how many trees you have to treat and how large those trees are. Your local service provider or distributor can give you an estimate of what the treatment cost will be for your particular trees or you can contact Arborjet directly and speak to a customer service representative.

Thomas
Harris/DC/USEPA/US
10/29/2008 09:35 AM

To <tom.parshley@syngenta.com>
cc John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, Kable Davis/DC/USEPA/US@EPA
bcc
Subject emamectin/Treeage - false, misleading claims

Tom,

re: http://www.arborjet.com/treeage.htm

It was just brought to our attention that the above website by Arborjet (company number 74578) includes false and misleading claims concerning Treeage, your pending new Sec 3 emamectin tree injection product for control of arthropod pests. Specifically, the website claims multi-year control of the Emerald Ash Borer in ash trees and states that treatments can be made every other year. These claims are not supported by the efficacy data submitted by Syngenta.

I am also surprised to see the website state that Treeage is "formulated and patented" by Arborjet although they do state that the molecule is "owned" by Syngenta. The pending Sec 3 registration is from Sygnenta (100-RGNO). There are no pending actions from Arborjet for emamectin.

>>>>> We are looking into taking enforcement action based on the current website and any related marketing material. However, we thought you might be able to exert some influence to get this website corrected quickly. Please let me know what you are able to find out and if/when any changes are made to the website and any other advertising material.

Note: Registration of the Section 3 product is currently pending (due 7/09). However, there are already a number of Section 24(c) state registrations (IN, IL, OH, MI, MN, WV) for the control of Emeral Ash Borer in ash trees given the destructive nature of this quarantine pest and the good control demonstrated by emamectin in field trials. Unlike typical Sec 24(c) registrations, these state labels are self-contained and do not reference a Sec 3 product at this time.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

EFFICACY REVIEW

PRODUCT: Tree-Age

FILE SYMBOL: 100-RGNO

DATE: November 6, 2008

GLP: No

BARCODE: D358155

DECISION: 387891

CHEMICAL: Emamectin benzoate (4%)

CHEMICAL NUMBER: 122806

PURPOSE: Review data to support product registration.

MRIDS: 47465501. Cox, D.; Cosky, S. (2008) Emamectin Benzoate (A 16297A)- Product Performance Data Supporting the Conrol of Emerald Ash Borer, *Agrilus planipennis* and Asian Longhorn Borer, *Anoplophora glabripennis* Following Trunk Injection in Trees: Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection. 84 p.

TEAM REVIEWER: Tom Harris

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist 11-6-08

SECONDARY EFFICACY REVIEWER: Joanne Edwards, M.S., Entomologist Joanne L Edwards 11/6/08

BACKGROUND:

Tree-Age (EPA File Symbol 100-RGNO) is an injected insecticide intended for the control of numerous tree pests, including emerald ash borers and Asian longhorn beetles. The dosage varies depending upon tree diameter (see Table 1). The proposed label references the following website: www.syngenta-us.com.

Currently, there are already two Tree-Age SLN products registered (WV080002; OH080002) for the control of emerald ash borers. The registrations of both products were supported by the submission of efficacy data (see Agency Review dated April 18, 2008; D351729; D351728). The submission was comprised of adult mortality, larval

density and canopy dieback data and was conducted by Michigan State University (multiple geographic locations).

Table 1. Tree-Age; Directions for Use[1]

Tree Diameter	Low (ml/tree)	Medium (ml/tree)	Medium-High (ml/tree)	High (ml/tree)	Injection Sites
4 – 6	15	25	50	-	3
7 – 9	20	40	80	-	4
10 – 12	30	55	110	165	5
13 – 15	35	70	140	210	6
16 – 18	40	75	150	225	7
19 – 21	50	100	200	300	8
22 – 24	-	115	230	345	10
25 – 27	-	130	260	390	11
28 – 30	-	145	290	435	12
31 – 33	-	160	320	480	13
34 – 36	-	175	350	525	15
37 – 39	-	190	380	570	16
40 – 42	-	205	410	615	17
43 – 45	-	220	440	660	18
46 – 48	-	235	470	705	20
49 – 51	-	250	500	750	21
52 – 54	-	265	530	795	22
55 – 57	-	280	560	840	23
58 – 60	-	295	590	885	25
61 – 63	-	310	620	930	26
64 – 66	-	325	650	975	27
67 – 69	-	340	680	1020	28
70 – 72	-	355	710	1065	30

[1] *Higher rates tend to provide longer residual and control of more difficult insects*

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

47465501. Cox, D.; Cosky, S. (2008) Emamectin Benzoate (A 16297A)- Product Performance Data Supporting the Conrol of Emerald Ash Borer, Agrilus planipennis and Asian Longhorn Borer, Anoplophora glabripennis Following Trunk Injection in Trees: Final Report. Project Number: T004223/07. Unpublished study prepared by Syngenta Crop Protection. 84 p.

EMERALD ASH BORER DATA

The objective of this study was to determine the effective dose rates of Tree-Age when applied via tree injections. Additionally, the duration of control from a single application was examined. This submission is comprised of data from multiple test sites

located within Michigan and Ohio. Depending upon the site, product performance was evaluated through observations on canopy dieback, adult mortality and larval density.

Site 1- Troy, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of 10 trees per dosage. Trees injected with emamectin benzoate were treated with the following rates: 0.1 g ai/inch DBH, 0.2 g ai/inch DBG, 0.4 g ai/inch DBH, 0.5 g ai/inch DBH and 0.6 ai/inch DBH. All trees were between 12 and 26 years old and ranged in diameter from 7 to 24 inches (DBH). The initiation of the study was May/June 2005. To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in ~1 month after treatment in 2005 and again in summer 2006.

Results-

Table 2. Results; Troy, Michigan

Treatment	Rate (g ai/inch DBH)	2005		2006	
		Larval Density (per m^2)	% Die-back	Larval Density (per m^2)	% Die-back
Control	-	59.2	19	All Control Trees Dead	
Emamectin Benzoate	0.1	0	17	0	17
Emamectin Benzoate	0.2	0	25	0	27
Emamectin Benzoate	0.4	0	31	0	28
Emamectin Benzoate	0.5	0	27	0	21
Emamectin Benzoate	0.6	0	42	0	34

The percent canopy dieback for trees treated with emamectin benzoate (all doses) remained approximately the same between 2005 and 2006 or improved. There was no larval activity found in any of the trees treated with emamectin benzoate in either 2005 or 2006.

Site 2- East Lansing, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of approximately 10 trees per dosage. Trees injected with emamectin benzoate were treated with the following rates: 0.1 g ai/inch DBH, 0.2 g ai/inch DBG, and 0.4 g ai/inch DBH. All trees were between 14 and 28 years old and ranged in diameter from 10 to 24 inches (DBH). To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in summer 2006 and 2007.

Results-

Table 3. Results; East Lansing, Michigan

Treatment	Dose	Treatment Date	% Canopy Die-Back	
			2006 Die-back	2007 Die-back
Emamectin Benzoate	0.4 g ai/inch DBH	Sept. 2005	7.3	12.9
Emamectin Benzoate	0.4 g ai/inch DBH	Sept. 2005	12.5	9.9
Emamectin Benzoate	0.2 g ai/inch DBH	May 2007	20.3	17.4
Emamectin Benzoate	0.1 g ai/inch DBH	May 2007	18.5	23.1
Control	-	-	16.0	28.8

The percent canopy die-back in 2007 for trees treated with emamectin benzoate ranged from 9.9% (0.4 g ai/inch DBH; Sept. 2005) to 23.1% (0.1 g ai/inch DBH; May 2007), while the percent canopy die-back from control trees was 28.8%.

In 2007, there was no larval activity found in any of the trees treated with emamectin benzoate in 2006 or 2007, while there were approximately 19.2 larvae per m^2 found in the control trees.

Site 3- Adrian, Michigan

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of approximately trees 10 per dosage. Trees injected with emamectin benzoate were treated at a rate of 0.4 g ai/inch DBH in June 2006. All trees were between 14 and 28 years old and ranged in diameter from 6 to 26 inches (DBH). To determine the level of efficacy, the percent canopy dieback (0% = healthy; 100% = dead) and larval densities were observed in summer 2007.

Results-

Table 4. Results; Adrian, Michigan

Treatment	Rate	Percent Canopy Die-back		Larvae (per m^2)
		2006 Die-back	2007 Die-back	
Emamectin Benzoate	0.4 g ai/inch DBH	7.3	5.5	2.4
Control	-	9.0	16.0	6.3

The percent canopy die-back from trees treated with 0.4 g/ai inch DBH emamectin benzoate was 5.5% in 2007, as compared to 16% in the control trees. There were 2.4 larvae per m^2 in the treatment trees as compared to 6.3 larvae per m^2 in the control trees.

Sites 4 & 5- Toledo, Ohio

Archwood Study

The experimental design consisted of treating a total of 12 trees with 0.4 g/ai inch DBH emamectin benzoate in June 2006. In 2007, observations on canopy die-back and larval density (number exit holes) were compared to control trees and recorded.

Blackthorn Study

The experimental design consisted of treating trees with the following rates of emamectin benzoate: 0.1 g ai/inch DBH, 0.2 g ai/DBH, 0.4 g ai/inch DBH and 0.8 g ai/inch DBH. There were a total of 4 trees per dosage. In 2007, observations on canopy die-back and larval density (number exit holes) were compared to control trees and recorded.

Results-

Table 5. Results; Archwood Study (Toledo, Ohio)

Treatment	Dosage	# Exit Holes	% Die-back
Emamectin Benzoate	0.4 g ai/inch DBH	0.67	0
Control	-	3.92	7.5

The percent die-back of trees treated with 0.4 g ai/inch DBH emamectin benzoate was 0%, as compared to 7.5% in the controls. There were a mean total of 0.67 exit holes found in the treatment trees, as compared to 3.92 in the controls.

Table 6. Results; Blackthorn Study (Toledo, Ohio)

Treatment	Dosage	# Exit Holes	% Die-back
Emamectin Benzoate	0.1 g ai/inch DBH	0.25	0
Emamectin Benzoate	0.2 g ai/inch DBH	0.50	0
Emamectin Benzoate	0.4 g ai/inch DBH	0.25	0
Emamectin Benzoate	0.8 g ai/inch DBH	0	0
Control	-	2.75	7.5

The percent die-back of trees treated with emamectin benzoate ranged from 0 (0.8 g ai/inch DBH) to 0.50 (0.2 g ai/inch DBH), as compared 2.75 holes found in the control trees. The percent canopy die-back from trees treated with emamectin benzoate was 0% for all dosages, as compared to 7.5% in the controls.

Site 6- Wolverine Campgrounds (Michigan)

The experimental design consisted of treating trees with a variety of different pesticides at different dose rates. There were a total of 30 trees per treatments. All trees ranged in diameter from 6.6 to 13.2 inches. Trees injected with emamectin benzoate were treated with the following rates: 0.1 g for DBH $\leq$ 6.5 inches, 0.15 g for DBH 6.5 to

10 inches and 0.2 g for DBH ≥ 10 inches. All trees were treated in May, 2007. Bioassays were conducted in mid-June, early July and late July to assess the percent survival of adult emerald ash borers caged with leaves taken from treated trees for 4 days.

Results-

There were 100% mortality of adult beetles caged with leaves taken from trees treated with emamectin benzoate for all three dates, as compared to ~18% (July) to ~57% (June) mortality of adult beetles caged with leaves taken from trees injected with imidacloprid.

Site 7- Strongsville, Ohio

The experimental design consisted of treating trees with a variety of different pesticides. Trees injected with emamectin benzoate were treated with 0.4 g ai/inch DBH and averaged in diameter of 4.3 to 8.0 inches. Trees were inspected for signs of emerald ash borer infestation 42 – 43 DAT and 145 – 146 DAT.

Results-

There were no signs of emerald ash borer infestation on any of the trees.

ASIAN LONGHORN BEETLE DATA

2000 Field Experiment

The experimental design consisted of treating elm, popular and willow trees with one of three insecticides (12 trees per treatment). For the purpose of this review, only emamectin trees will be discussed. All trees were between 8 to 10 years old. Emamectin benzoate was injected at a rate of 0.2 g/cm up to 15 cm DBH with an additional 0.6 g/cm for each 5 cm increment in DBH. All injections were made from June 11-14, 2000. On September 2, 2000, the numbers of dead adult beetles around the base (within 5 m of the trunk) of all elm and popular trees were collected and tallied. Due to a disturbance, beetles were not collected around the willow trees. On October 25-30, 2000, 6 trees from each treatment group were cut down to inspect for larval density.

Results-

Table 7. Chinese Data; Adult Mortality

Treatment	Mean # of Dead Adults		
	Elm	Popular	Willow[1]
Emamectin Benzoate	0.3	4.7	-
Control	1.2	0.2	-

[1] *Dead adults not collected due to disturbance*

The mean number of adult Asian longhorn beetles found under trees treated with emamectin benzoate ranged from 0.3 (elm) to 4.7 (popular).

Table 8. Chinese Data; Larval Density

Treatment	Larvae Per m^2		
	Elm	Popular	Willow
4 Month Post-Injection-			
Emamectin Benzoate	3.4	33.6	6.4
Control	11.7	39.9	21.9
12 Month Post-Injection-			
Emamectin Benzoate	4.8	21.2	4.0
Control	11.5	24.2	19.1

The number of larvae per m^2 of trees treated with emamectin benzoate after 12 months ranged from 4.0 (willow) to 21.2 (popular), while the number of larvae per m^2 in control trees ranged from 11.5 (elm) to 24.2 (popular).

RECOMMENDATIONS:

The submitted data support the registration of Tree-Age (EPA File Symbol 100-RGNO) and the addition of claims for the control of Emerald Ash Borers for up to one year. The following recommendations apply:

1. On the first page of the label, revise the claim "*Injected insecticide for the control for arthropod pest in trees*" to read "*Injected insecticide for the control of listed arthropod pests in trees*".

2. The first page of the label includes the statement "*See additional precautionary statements and directions for use on label [in booklet]*". Has the referenced "booklet" been submitted for review? Does it contain additional directions for use that are not on the label?

3. Delete the words "*optimal*" and "*optimally*" throughout the label. The use of these words can be found within the following label sections: **APPLICATION TO TREES** (page 5), **GENERAL DIRECTIONS** (page 5), **ENVIRONMENTAL CONDITIONS** (page 6), **MONITOR TREE HEALTH and PEST INFESTATIONS** (page 6) and **APPLICATION IN TREES** (page 8). In addition, make the following changes:

    a. Within the **APPLICATION TO TREES** (page 5) section of the label, revise "*To assure optimum effectiveness, this product must be placed into active sapwood.*" to read "*This product must be placed into active sapwood.*"

b. Within the **GENERAL DIRECTIONS** (page 5) section of the label, revise "***Placement of Application/Injection Sites:*** *for optimum distribution, inject at the base of the tree.*" to read "***Placement of Application/Injections Sites:*** *inject at the base of the tree.*"

4. On page 6 of the label, revise the sentence "*Tree-age may also be effective as a curative treatment against some pests, such as...*" to read "*Tree-age may also be effective as a remedial treatment against some pests, such as...*"

5. Within the **USE RATE TABLE** section of the label, delete the sentence "*Higher rates tend to provide longer residual and control of more difficult to control pests.*" This statement is unclear as to what is meant by "*...longer residual....*" and "*....control of more difficult to control pests.*"

6. Within the **USE RATE TABLE** section of the label, make the following changes concerning injection sites:

   a. Revise "***Average No. Injection Sites***" to read "***No. Injection Sites***".

   b. The footnote "*The number of injection sites listed is a guide for approximately how many are needed per size of tree.*" is too vague and must be deleted.

   c. Revise the footnote "*For optimal control, it is recommended to be with ± 1 injection site of this number per tree.*" to read "*For control, be within ± 1 injection site of this number per tree.*"

7. Recommended rates (ranging from low to high) per pest are outlined on page 8 of the label. These directions do not adequately describe when it is appropriate to apply each rate. These directions must be expanded upon.

   For example: The label states that the recommend rates for emerald ash borers are from "*low*" to "*high*". However, it doesn't explain when it is appropriate to apply the "*low*" rate and when it is appropriate to apply the "*high*" rate.

8. Page 8 of the label includes the sentence "*For optimal control apply at least 2-3 weeks before economic threshold is predicted.*" How is an applicator to know when economic threshold is predicted? To retain this statement, the label must include information on how to predict economic threshold or advice on who to contact to find out.

9. The label does not adequately state the reapplication interval. The label must be revised to clearly address this.

10. The submitted data are not adequate to support the addition of Asian longhorn beetles to the label (see comments below). All references to this pest must be deleted from the label.

    a. The submitted study only had data for one test site. To have this pest added on in the future, there must be acceptable data from at least three geographically separated areas.

    b. The submitted data for adult beetle mortality were inadequate. In addition to willow trees being removed from the trials due to a "disturbance", there were more dead beetles collected from the control elm trees than from elm trees treated with emamectin benzoate. To have this pest added back on in the future, additional data showing that this product kills both immature and adult beetles must be submitted.

11. The **GENERAL DIRECTIONS** on page 5 of the label are extremely vague on how to determine DBH. The label language "*Often the diameter is determined from measuring the...*" is not strong enough. The label must be revised to clearly state how to determine DBH.

    In addition, this section of the label contains multiple typographical errors. Throughout this section of the label, delete the quotation mark following DBH.

12. Within the **WHEN TO TREAT** section of the label, delete the sentence "Foliar pests may be controlled within 1-2 weeks after treatment under ideal conditions." This statement must be supported by data.

13. Within the **WHEN TO TREAT** section of the label, the sentence "*The primary route of toxicity is through ingestion, but may also be lethal upon contact.*" must be deleted or revised. What is meant by "*...but may also be lethal upon contact*"? Is this referring to direct contact of the pesticide and the pest, contact of a treated trees bark and the pest or contact of the treated trees leaves and the pest? In addition, is there data to support this?

14. The **WHEN TO TREAT** section of the label contains the following sentences: "*Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Watering the trees prior to injection may enhance the uptake of Tree-Age.*" If this is truly the case, then the **DIRECTIONS FOR USE** must include a statement similar to the following: "*Applications to drought or heat stressed trees require watering prior to injection.*"

15. Within the **APPLICATION TO TREES** section of the label, revise the sentence "*Tree-Age is for control of mature and immature arthropod pests of trees...*" to read "*Tree-Age is for control of listed mature and immature arthropod pests of trees...*"

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

July 8, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 02-JUL-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 831921

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: Miscellaneous Receipt

Billable: Yes No

Company: 100 SYNGENTA CROP PROTECTION, INC.

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 100-RGNO Product Name: TREEAGE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 01-Jul-2008 OPP Rec'vd Date: 02-Jul-2008

Front End Date: 02-Jul-2008 Risk Manager Send Date: 02-Jul-2008

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

Fast Track: New Ingredient:

Receipt Description:

efficacy data

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

Syngenta Crop Pro[illegible]n, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

FEDERAL EXPRESS

July 1, 2008

Document Processing Desk **(DATA)**
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Mr. Thomas Harris

SUBJECT: SUBMISSION OF EFFICACY DATA FOR TREEÄGE, EPA FILE SYMBOL 100-RGNO

Dear Mr. Harris:

Enclosed please find three copies each of a transmittal document and a single data volume containing efficacy data on two of the insect pests claimed on the proposed label for the subject product. This information was requested in a Certified Mail letter from your office dated April 18, 2008 and is being provided at this time, in accordance with the time schedule in this notice (copy enclosed for reference).

The efficacy data is being provided for two USDA quarantine pests, Emerald Ash Borer and Asian Longhorn Borer. Our understanding is that due to a recent policy change, EPA now requires efficacy data for USDA quarantine pests. Previous to receipt of the April 18 letter, Syngenta was not aware of this requirement; hence that is why efficacy for these pests was not included in the original application for registration.

Please contact me at (336) 632-7207 if there are any questions concerning this submission or the pending registration action for TREEäge.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data volume and attachment to letter

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 18, 2008

CERTIFIED MAIL
Article Number: 7006 2150 0002 6305 7217

Thomas Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: application to add new use (ornamental trees) for emamectin
EPA Registration Number: Treeage, 100-RGNO
Application Dates: 12/20/2007, PRIA category changed 4/10/2008
Associated Pesticide Petition: none (non-food)

Dear Mr. Parshley:

Pursuant to 40 CFR §152.105, the application cited above has been determined to be insufficient and cannot be processed at this time.

Problem
The following deficiencies have been identified with this request:

- Control is claimed for USDA quarantine pests Emerald Ash Borer and Asian Longhorn Borer. However, efficacy data were not presented to support these claims.

Action required

- **Submit or cite efficacy data for Emerald Ash Borer and Asian Longhorn Borer using this product.**

Deadline and consequences

- **Response is due 75 days from date of this letter, i.e. July 2, 2008.**

If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on this application and will treat the application as if it had been withdrawn by the applicant. Any subsequent submissions relating to this withdrawn application must then be submitted as a new application and will by subject to PRIA.

APR 25 2008 R
336

If you choose to submit the requested information, EPA may require a renegotiated PRIA due date that will allow the Agency sufficient time to complete the review process for these products.

Please contact me if you have any questions.

Sincerely,

Thomas C. Harris
Biologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

Phone: 703 308-9423
Fax: 703 308-0029
E-mail: harris.thomas@epa.gov

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Submission of Efficacy Data for Treeäge, EPA File Symbol 100-RGNO

3. Transmittal Date

7/1/2008

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal document	NA
47465501	2 OF 2	Emamectin Benzoate ME (A16297A) - Product Performance Data Supporting the Control of Emerald Ash Borer, Agrilus Planipennis and Asian Longhorn Borer, Anoplophora Glabripennis Following Trunk Injection in Trees; (T004223-07), (09003aeb8029e22c), (466993)	810.1000

COMPANY OFFICIAL: THOMAS PARSHLEY (NAME) — Thomas Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION, INC.

COMPANY CONTACT: THOMAS PARSHLEY (NAME) — (336) 632-7207 (PHONE)

Thomas
Harris/DC/USEPA/US
10/29/2008 09:35 AM

To <tom.parshley@syngenta.com>
cc John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA, Kable Davis/DC/USEPA/US@EPA
bcc
Subject emamectin/Treeage - false, misleading claims

Tom,

re: http://www.arborjet.com/treeage.htm

It was just brought to our attention that the above website by Arborjet (company number 74578) includes false and misleading claims concerning Treeage, your pending new Sec 3 emamectin tree injection product for control of arthropod pests. Specifically, the website claims multi-year control of the Emerald Ash Borer in ash trees and states that treatments can be made every other year. These claims are not supported by the efficacy data submitted by Syngenta.

I am also surprised to see the website state that Treeage is "formulated and patented" by Arborjet although they do state that the molecule is "owned" by Syngenta. The pending Sec 3 registration is from Sygnenta (100-RGNO). There are no pending actions from Arborjet for emamectin.

>>>>> We are looking into taking enforcement action based on the current website and any related marketing material. However, we thought you might be able to exert some influence to get this website corrected quickly. Please let me know what you are able to find out and if/when any changes are made to the website and any other advertising material.

Note: Registration of the Section 3 product is currently pending (due 7/09). However, there are already a number of Section 24(c) state registrations (IN, IL, OH, MI, MN, WV) for the control of Emeral Ash Borer in ash trees given the destructive nature of this quarantine pest and the good control demonstrated by emamectin in field trials. Unlike typical Sec 24(c) registrations, these state labels are self-contained and do not reference a Sec 3 product at this time.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Occupational exposure assessment for TREEage, EPA File Symbol 100-RGNO

tom.parshley to: John Hebert, Thomas Harris 05/08/2008 11:12 AM

John/Tom: Attached to this message is a PDF that contains a courtesy copy of Syngenta's assessment of worker exposure potential from mixing/loading of TREEage, our currently pending tree injection system product containing emamectin benzoate. Also provided is a copy of the cover letter, which provides further details on assumptions for the assessment. The formal paper submission is also being provided by courier mail service as a normal data submission and you should receive it in a couple of days.

The purpose of this document, as we discussed, is to allow EPA staff in HED to have a comfort level that the proposed product and use pattern will have acceptable margins of exposure (MOE). Syngenta is hopeful that the Agency will be able to utilize this document to establish HED work priorities for this project that would allow this new product and use pattern to be assessed as part of ongoing reviews for agricultural uses of emamectin benzoate for tree nuts for which a January 2009 completion date is expected.

I also am including as an attachment to this e-mail, a revised label for TREEage (two copies one highlighted, the other clean) in which the personal protective equipment (PPE) recommendations have been revised to include a glove statement. From our review of this assessment, gloves will be a necessary PPE recommendation for this product and use and should have been on the original labeling.

On a separate, but related matter, please note that Syngenta will also be revising all of the 24c registration labeling to add the glove statement as well, so you should begin seeing the revised labeling from the states in the next couple of weeks.

Thank you for your efforts, advice and recommendations on this project.

Best regards,

Tom Parshley
NAFTA Senior Regulatory Product Manager
tele: (336) 632-7207
cell: (336) 509-0512
email: tom.parshley@syngenta.com

<<T001352-08.pdf>> <<5-7-08 EPA Treeage assessment.doc>>
<<000100-xxxxx.20071220b.treeage.pdf>> <<TREE-age xxxxA-M_draft-b_marked lg- 5-7-08.pdf>>

T001352-08.pdf 5-7-08 EPA Treeage assessment.doc 000100-xxxxx.20071220b.treeage.pdf

TREE-age xxxxA-M_draft-b_marked lg- 5-7-08.pdf

(Master label)

TREE-äge™

Injected insecticide for the control for arthropod pests in trees

Active Ingredient:

Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-xxxxx

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP xxxxxA-M(draft-b TREE-äge)

_____
Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- shoes and socks
- protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product 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 because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. To assure optimum effectiveness, this product must be placed into active sapwood.

GENERAL DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Breast height is a standardized distance of 54" from the ground. Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: for optimum distribution, inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Avoid injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion, but may also be lethal upon contact.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For optimal uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Watering the trees prior to injection may enhance the uptake of TREE-äge.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a curative treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Foliar pests may be controlled within 1- 2 weeks after treatment under ideal conditions. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml./tree	Medium ml./tree	Medium - High ml./tree	High ml./tree	Average No. Injection Sites*
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

* The number of injection sites listed is a guide for approximately how many are needed per size of tree.
For optimal control, it is recommended to be with ± 1 injection site of this number per tree. Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Recommended Rate	Comments
Seed and Cone	Pine Cone Worm (Dioryctria spp)	Medium to High	For optimal control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	For optimal control apply at least 2-3 weeks before economic threshold is predicted.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For optimal control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Asian, Eucalyptus, Pine Sawyer) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTIONS

- Do not apply to trees that may yield food consumed by humans or used in animal feed.
- Avoid treating trees that are moisture stressed or suffering from herbicide damage.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Disposal

Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

TREE- äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2008 Syngenta

For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
www.syngenta-us.com

SCP xxxxxA-M(draft-b TREE-äge)

TREE-age xxxxxA-M(draft-b)-lg-5-7-08 000100-xxxxx.20071220b.treeage.pdf

100-RGNO
IRB-PM7
JGM 5/12/08
CA 5/16/08

Memorandum

Date: 05/12/08

To: PM 07, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Tom - It looks like this is already in OPPIN (he electronically sent in earlier), but the ~~data~~ assessment has not been routed to HED. That is the plan, right?

JM 5/30/08

ACCEPTED
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
EPA. Reg. No:

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

May 9, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 08-MAY-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Syngenta Crop Protection, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

474196-00

syngenta

FEDERAL EXPRESS

May 7, 2008

Document Processing Desk
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Mr. John Hebert, PM Team 4B

SUBJECT: SUBMISSION OF OCCUPATIONAL EXPOSURE ASSESSMENT TREEAGE, EPA FILE SYMBOL 100-RGNO

Dear Mr. Hebert,

Enclosed please find three copies each of a transmittal document and a single data volume containing an occupational exposure assessment in support of the subject action.

Recently we had a discussion about the PRIA category for this action being reclassified to a R230 with a timeline of 15 months. Because the Agency reviewers and staff may find it useful for purposes of determining HED work priorities, it was decided that Syngenta would submit a formal worker assessment to cover the mixing and loading scenarios for the tree injection use of this product as a way to assist the timely completion of this action. As we discussed, there is a pending tolerance petition for tree fruits for emamectin benzoate which could be combined with this new product and use into one exposure assessment. The crop use assessment is scheduled for completion in January 2009 and you indicated that it would be more efficient if both were assessed at the same time. Syngenta believes this is a sound approach and the enclosed worker assessment for mixing/loading scenarios of this product is for that purpose.

The following provides some additional clarification regarding the assessment document inputs.

- In 2007 the EPA approved Syngenta's new source of technical emamectin benzoate, Emamectin Benzoate Technical II, EPA Reg. No. 100-1270, which will replace Syngenta's previous source of technical emamectin benzoate, Emamectin Benzoate Technical, EPA Reg. No. 100-902. Although the acute toxicity of the two technicals differed (see next comment), the EPA concluded that the two technicals are toxicologically equivalent; the subchronic and chronic toxicity studies that supported the registration of the previous technical also support the registration of the new source, so the endpoints identified in the assessment are appropriate.

- The acute toxicity of the new source of technical emamectin benzoate is featured below:
  Acute oral – Category II
  Acute dermal – Category II
  Acute inhalation – Category II
  Primary Eye Irritation – Category III
  Primary Dermal Irritation – Category IV
  Dermal Sensitization – Negative

syngenta

The enclosed assessment document referred to the old source of technical, which is no longer being used, so Syngenta is noting here the new acute toxicity information. While several of the toxicity ratings are changed, the eye irritation category change is of particular note, as the technical material is no longer severely irritating to the eye.

- Regarding the assessment assumptions, for determining the amount of product that a worker is exposed to during mixing/loading, it was assumed that mixing and loading of material would occur at each tree to be treated. Also, because the application itself is accomplished through a closed system (injection), exposure during application would be limited to mixing/loading material only.

Also, please note that an e-mailed electronic version of this document is being concurrently submitted to you as a courtesy to facilitate the internal process. Included in that e-mail is an electronic revised version of the proposed product label for TREEäge in which gloves has been added to the Personal Protective Equipment (PPE) precautions.

Finally, we are in receipt of a certified mail letter from Tom Harris of EPA dated April 18, 2008, indicating efficacy data are being requested for this product to support claims for Emerald Ash Borer and Asian Longhorn Borer. These data are due to EPA on or before July 2, 2008. Syngenta will be providing the requested data as requested.

Please contact me at (336) 632-7207 if there are any questions concerning the submission or the pending registration.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosures

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Submission of Occupational Exposure Assessment, Treeage, EPA File Symbol 100-RGNO

3. Transmittal Date

5/7/2008

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal document	NA
47419601	2 OF 2	Emamectin Benzoate -Occupational Exposure and Risk Assessment for Tree Injection Applications of Emamectin Benzoate 4% Insecticide; (T001352-08), (09003aeb802911f6), (465577)	NA

COMPANY OFFICIAL: THOMAS PARSHLEY (NAME) — Thomas D Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION, INC.

COMPANY CONTACT: THOMAS PARSHLEY (NAME) — (336) 632-7207 (PHONE)

Please read instructions on reverse before completing form.

EPA	United States **Environmental Protection Agency** Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 100-RGNO	2. EPA Product Manager John Hebert	3. Proposed Classification [X] None [ ] Restricted
4. Company/Product (Name) TREEäge	PM# 4	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____

[ ] "Me Too" Application.

[x] Other - Explain below. New Product-nonfood use

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).
Syngenta is respectfully submitting an Occupational Exposure Assessment for the product TREEäge, EPA Reg. No. 100-RGNO with the active ingredient emamectin benzoate. This submission is linked to another PRIA II action and therefore does not require a category & fee assignment.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) Plastic tube _____
***Certification must**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information [ ] Label [ ] Container	4. Size(s) Retail Container	5. Location of Label Directions [ ] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
[ ] Lithograph
[ ] Paper glued for tubes
[ ] Stenciled
[ ] Outer box is preprinted _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J. Parshley	Senior Reg. Product Manager	336-632-7207

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.

2. Signature Thomas J Parshley	3. Title Senior Regulatory Product Manager	6. Date Application Received **(Stamped)**
4. Typed Name Thomas J. Parshley	5. Date May 7, 2008	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

EPA-FRM [G - CA-DOC - REGAFFRS] 6/5/97 - bb

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 18, 2008

CERTIFIED MAIL
Article Number: 7006 2150 0002 6305 7217

Thomas Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: application to add new use (ornamental trees) for emamectin
EPA Registration Number: Treeage, 100-RGNO
Application Dates: 12/20/2007, PRIA category changed 4/10/2008
Associated Pesticide Petition: none (non-food)

Dear Mr. Parshley:

Pursuant to 40 CFR §152.105, the application cited above has been determined to be insufficient and cannot be processed at this time.

Problem
The following deficiencies have been identified with this request:

- Control is claimed for USDA quarantine pests Emerald Ash Borer and Asian Longhorn Borer. However, efficacy data were not presented to support these claims.

Action required

- **Submit or cite efficacy data for Emerald Ash Borer and Asian Longhorn Borer using this product.**

Deadline and consequences

- **Response is due 75 days from date of this letter, i.e. July 2, 2008.**

If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on this application and will treat the application as if it had been withdrawn by the applicant. Any subsequent submissions relating to this withdrawn application must then be submitted as a new application and will by subject to PRIA.

If you choose to submit the requested information, EPA may require a renegotiated PRIA due date that will allow the Agency sufficient time to complete the review process for these products.

Please contact me if you have any questions.

Sincerely,

/S/

Thomas C. Harris
Biologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

Phone: 703 308-9423
Fax: 703 308-0029
E-mail: harris.thomas@epa.gov

7006 2150 0002 6305 7217

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Sent To Tom Parshley
Street, Apt. No.; or PO Box No. Syngenta, PO Box 18300
City, State, ZIP+4 Greensboro, NC 27419

PS Form 3800, August 2006 See Reverse for Instructions

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Thomas Parshley
Syngenta Crop Protection
PO Box 18300
Greensboro, NC 27419

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X Wanda D. Jonette ☐ Agent ☐ Addressee

B. Received by (Printed Name) Wanda D. Jonette

C. Date of Delivery 4/25

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7006 2150 0002 6305 7217

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

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Tom Harris
US EPA-OPP (7502P)
1200 Pennsylvania Ave, NW
Washington, DC 20460

Thomas Harris/DC/USEPA/US
04/10/2008 12:14 PM

To <tom.parshley@syngenta.com>
cc John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA
bcc
Subject treeage 100-RGNO

Tom,

This email documents our phone conversations this morning.

As a result of receiving a number of SLNs yesterday for your pending 100-RGNO emamectin tree injection product, we looked over your original application for the Sec 3 to see if the SLN labels were in the right ballpark. In reviewing your application we realized two things:

1) The application is not for just a new application method as implied in your cover letter but actually for a new, non-food use. As such, the PRIA coding has been changed from R310 to R230. This increases the fee and changes the PRIA time frame from 6 months to 15 months. A revised bill was issued today and sent to Bunnie Konat in Regulatory Affairs at Syngenta in Greensboro.

2) While registrants are always required to have efficacy data for their products in their files, the Agency usually does not require submission of this data except for certain situations such as public health pests. Given the APHIS quarantine status of emerald ash borer (and Asian longhorned beetle), OPP is now requiring that efficacy data be submitted to support label claims for these pests. The data does not need to be a GLP study. Public literature is usually sufficient. The SLNs usually reference (and some include) efficacy results. You can collect all such data you have and bundle them together into one MRID submission. Please submit efficacy data for this product to control emerald ash borer ASAP.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

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

File Copy

April 10, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-387891
EPA File Symbol or Registration Number: 100-RGNO
Product Name: TREEAGE
EPA Receipt Date: 21-Dec-2007
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, INC.

BUNNIE KONAT
SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee - Revised

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has previously identified as R310 has been reclassified as Action Code: R230

NEW USE;OUTDOOR;NON-FOOD;

The fee associated with this action is $21,740. Payment in the amount of $4,360 has been received. Please remit additional payment in the amount of $ 17,380 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

John Hebert/DC/USEPA/US
04/09/2008 04:27 PM

To John Jamula/DC/USEPA/US@EPA
cc Thomas Harris/DC/USEPA/US@EPA, Linda Arrington/DC/USEPA/US@EPA
bcc
Subject Change in PRIA code

JJ - can you please change the following PRIA code from R310 to **R230** for the following:

100-RGNO
D - 387891

The reason for the change is that during screening the registrant did not identify this product(tree injection) as a "new-use." They said that, "...there are already outdoor use patterns registered for emamectin benzoate..." While that is true, these registered uses are only for food crops and do not use injection as the method of application. Please let me know if you have any questions.

Regards,
John

John Hebert/DC/USEPA/US
04/09/2008 04:27 PM

To John Jamula/DC/USEPA/US@EPA
cc Thomas Harris/DC/USEPA/US@EPA, Linda Arrington/DC/USEPA/US@EPA
bcc
Subject Change in PRIA code

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Regards,
John

Syngenta Crop Protection, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

FEDERAL EXPRESS

March 19, 2008

Document Processing Desk
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

ATTN: Mr. John Hebert, PM Team 4B

SUBJECT: TREE-äge, EPA Reg. No. 100-RGNO
Addition to December 21, 2007 Submission (D-387891)
Two Alternate Confidential Statement of Formulas

Dear Mr. Hebert,

Syngenta Crop Protection, Inc., herein submits two alternate Confidential Statement of Formulas (CSFs) for the product TREE-äge (EPA Reg. No. 100-RGNO), which is currently pending registration. These CSFs are meant to be used in addition to the basic CSF originally submitted with the registration package on December 21, 2007. The purpose of this submission is to recognize a new source of the active ingredient Emamectin Benzoate (EPA Reg. No. 100-1270).

PRIA II
As the CSFs being submitted are to be included in the submission D-387891, the PRIA II fee has already been appropriately invoiced and paid.

Enclosed with this submission please find the following:

- Original & copy of Alternate CSF 690/2
- Original & copy of Alternate CSF 692/1

Syngenta appreciates the EPA's review of the Tree-äge submission. Should questions arise, please contact me at 336.632.7207, email Thomas.parshley@syngenta.com or fax 336.632.5688.

Sincerely,

Thomas Parshley

Thomas Parshley
Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosures

Completion of 21-Day Content Screen

PM- 07

EPA Reg. #(File Symbol) 100 - RGNO

Decision # D 387891

Data package delivered to you on 1/3/08.
(date)

Jacket/Mini-jacket will be transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

IRB

Memorandum

Date: 1 / 2 / 08

To: PM 07, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

NEW APPLICATIONS

DATE: DEC 21 2007

FILE NUMBER: 100- RGNO

FEP (OPPIN ENTRY) LV 12/26/07
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: KC 12/31/07
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ ASSIGN TO PM 7 (NO DATA)

____ JACKET TO SHELF (DATA)

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: DEC 21 2007	EPA Reg. Number: 100 - RGNO			
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?			
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package?	X		
8	Are **Data** Included in the Submission Package?	X		
9	**Is the Submission an Amendment?**		X	

PRIA – 21 Day Content Screening Checklist

IRB

Experts In-Processing Signature: [redacted] ~~11/19/07~~ Miller [redacted] Fee Paid: Yes ✓ No __

EPA Reg. Number: 100-RGNO	EPA Receipt Date: 12-21-07

	Check List Item	Yes	No	NA
1	**Application Form** (EPA Form 8570-1) –signed & complete including package type?	✓		
2	**Confidential Statement of Formula** (EPA Form 8570-29)	✓		
	a) Is the CSF completely filled out (Boxes 1-21)? Does it add up to 100%	✓		
	b) After the inerts list is on the web, are all inerts cleared for food and non food proposed uses?	✓		
	c) CAS # provided?			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34)? [Applicable, if submission is not a 100% repack]	✓		
4	**Formulator's Exemption Statement** (EPA Form 8570-27)?			✓
	a) Formulator's Exemption Statement was not addressed because registrant owns/formulates the source of active ingredient in product formulation,			✓
	b) if so, was a generic data matrix included?			
5	**Data Matrix** (EPA Form 8570-35) [Applicable, if submission is not a 100% repack]	✓		
	a) Selective Method?	✓		
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay	✓		
	c) Public copy of Matrix provided? See PR Notice 98-5	✓		
6	**Is Label Included? (5 copies)**	✓		
7	**Letter of Authorization for exclusive use only?**			✓
8	**Required Data and or data waivers submitted?**			
	a) Which study(s) is missing? List them below			
9	**CRP Certification Statement**			
10	**86-5 Rejection List?**			
11	**Notice of Filing included with petitions?**			
	Comments:			

PRIA fee has been pre-paid.

Copy of check/pay.gov receipt enclosed.

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

December 31, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 21-DEC-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 821819

Resubmission: Yes No

Regulatory Type: Product Registration - Section 3

Fee For Service: Yes No

Application Type: New Registration

Billable: Yes No

Company: 100 SYNGENTA CROP PROTECTION, INC.

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 100-RGHO Product Name: TREEAGE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 20-Dec-2007 OPP Rec'vd Date: 21-Dec-2007

Front End Date: 26-Dec-2007 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content: Study

Fast Track: New Ingredient:

Receipt Description:

Application for registration of a new product.

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

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

December 27, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-387891
EPA File Symbol or Registration Number: 100-RGNO
Product Name: TREEAGE
EPA Receipt Date: 21-Dec-2007
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, INC.

G. THOMAS GALE, JR.
SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

Strader Cherilyn USGR

From: paygovadmin@mail.doc.twai.gov
Sent: Thursday, December 20, 2007 9:38 AM
To: Strader Cherilyn USGR
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24UFHP06
Payment Agency Tracking ID: 74037388295

Cardholder Name: Janis McFarland
Cardholder Address: P.O. Box 18300
Cardholder City: Greensboro
Cardholder State: NC
Cardholder Country: USA
Cardholder Zip Code: 27419
Card Type: Visa
Payment Amount: $4,360.00
Transaction Date: Dec 20, 2007 9:38:06 AM

Decision Number:
Registration Number:

Fee for Service

{821819>~

This package includes the following

- New Registration
  Amendment

✓ Studies? ✓ Fee Waiver?

volpay % Reduction: ___

for Division

- AD
- BPPD
- RD

Risk Mgr. 7

Receipt No. S-	821819
EPA File Symbol/Reg. No.	100-RGNO
Pin-Punch Date:	12/21/2007

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: $ 4,360.00

Parent/Child Decisions:

X Inert Cleared for non-food use only. (KM) 1/2/08

Uncleared Inert in Product

Reviewer: J. Miller

Date: 12/27/07

Remarks:

– product appears to be non-food use, therefore Inert review was for non-food use. (KM) 1/2/08

Syngenta Crop Pr[illegible]on, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

473093-00

syngenta

FEDERAL EXPRESS

December 20, 2007

Document Processing Desk **(APPL)**
Office of Pesticide Programs **(7505P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: John Hebert, PM Team 4B

SUBJECT: APPLICATION FOR REGISTRATION OF NEW PRODUCT REQUIRING LIMITED DATA REVIEW WITHIN RD: TREEÄGE, EPA REG. NO. 100-XXXX

RGNO

Dear Mr. Hebert,

Enclosed please find the following information, which is being provided in support of a request for registration of a new non-food outdoor product containing emamectin benzoate:

- Receipt of PRIA II prepayment
- Application for Registration, EPA Form 8570-1
- Confidential Statement of Formula, EPA Form 8570-4
- Data matrices for active ingredient and end-use product
- Certification with Respect to Citation of Data, EPA Form 8570-34
- Three copies (3) each of a transmittal document and eight (8) data volumes containing product chemistry and acute toxicity data for the formulation
- Five (5) copies of draft product labeling and a (CD) with a pdf of the label
- Certification with Respect to Label Integrity form

This product is to be used only in tree-injection systems for control of wood-boring insect pests of various coniferous and deciduous tree species in forest and ornamental settings.

Because of the product's proposed use pattern as a tree injection, Syngenta asserts that environmental exposure to this active ingredient outside the treated tree will be minimal. Further, exposure to workers handling this product will be extremely limited given the delivery system, which does not possess much potential for significant human exposure. Studies have shown that emamectin benzoate, injected into the phloem of a tree, is able to maintain excellent efficacy for extended periods of time, with little or no chemical expected to leave the target tree(s). This unique combination of traits makes this compound and product ideal for control of wood-boring pests such as the Emerald Ash Borer, an economically significant pest, which is responsible for destruction of large tracts of Ash trees in Michigan and other Midwest states. Presently there is a federal government quarantine in effect because of the seriousness of the Emerald Ash Borer outbreak in the US.

syngenta

Mr. Hebert
December 20, 2007
Page 2

Therefore, because of the unique characteristics of this compound and application technique, coupled with the near crisis situation with respect to the Emerald Ash Borer outbreak in the Midwest, Syngenta believes that there is a very significant and urgent need for such a product. Syngenta would be happy to present further information on the type of application/use of this product in a meeting sometime in late January 2008. Because the Agency reviewers and staff may find it useful for this meeting prior to the start of the formal review process, please contact me at (336) 632-7207 at your earliest convenience to arrange for such a discussion, and/or if there are any questions concerning the submission itself.

Since there are already outdoor use patterns registered for emamectin benzoate (Proclaim® and Denim®), and given the low exposure potential of the use being proposed, Syngenta suggests that the appropriate **PRIA II fee category for this action is proposed as a R-310**, with a fee of $4,360 and a processing timeline of 6 months. Attached is the receipt of payment for this amount.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosures

VOLUME 1 OF 9 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Application For Registration of New Product Requiring Limited Data Review Within RD: Treeäge, EPA Reg. No. 100-XXXX

3. Transmittal Date

12/20/2007

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 9	Transmittal document	NA
47309301	2 OF 9	A16297A -Manufacturing Process Description and Supporting Data for Emamectin Benzoate ME (042.9) (A16297A); (PC-07-084), (09003aeb80273dda), (462236)	830.1550, 830.1600, 830.1650, 830.1670, 830.1750, 830.1800
47309302	3 OF 9	A16297A -Physical and Chemical Properties of Emamectin Benzoate ME (042.9) (A16297A); (PC-07-085), (09003aeb80273dda), (462237)	830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.6319, , 830.7000, 830.7100, 830.7300
47309303	4 OF 9	Emamectin Benzoate ME (042.9) (A16297A) -Acute Oral Toxicity Up-and-Down Procedure in Rats; (T007407-06), (09003aeb80273dda), (462221)	870.1100

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
47309304	5 OF 9	Emamectin Benzoate ME (042.9) (A16297A) -Acute Dermal Toxicity in Rats; (T007408-06), (09003aeb80273dda), (462223)	870.1200
47309305	6 OF 9	Emamectin Benzoate ME (042.9) (A16297A) -Acute Inhalation Toxicity in Rats; (T007412-06), (09003aeb80273dda), (462231)	870.1300
47309306	7 OF 9	Emamectin Benzoate ME (042.9) (A16297A) -Primary Eye Irritation in Rabbits; (T007410-06), (09003aeb80273dda), (462227)	870.2400
47309307	8 OF 9	Emamectin Benzoate ME (042.9) (A16297A) -Primary Skin Irritation in Rabbits; (T007409-06), (09003aeb80273dda), (462225)	870.2500
47309308	9 OF 9	Emamectin Benzoate ME (042.9) (A16297A) -Dermal Sensitization Test - Buehler Method; (T007411-06), (09003aeb80273dda), (462229)	870.2600

COMPANY OFFICIAL: THOMAS PARSHLEY (NAME) — Thomas Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION, INC.

COMPANY CONTACT: THOMAS PARSHLEY (NAME) — (336) 632-7207 (PHONE)

Please read instructions on reverse before completing form.

EPA	United States Environmental Protection Agency Washington, DC 20460	[X] Registration [ ] Amendment [ ] Other	OPP Identifier Number

819

Application for Pesticide - Section I

1. Company/Product Number 100-~~XXXX~~ RGNO	2. EPA Product Manager John Hebert	3. Proposed Classification [ ] None [ ] Restricted
4. Company/Product (Name) Treeäge	PM# 4B	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419 [ ] *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

[ ] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____

[ ] "Me Too" Application.

[X] Other - Explain below.

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

Syngenta Crop Protection, Inc., herein submits an application for registration of a new product containing the active ingredient emamectin benzoate. This product is to be used only in tree-injection systems for control of wood-boring insect pests of various coniferous and deciduous tree species in forest and ornamental settings. Since there are already outdoor use patterns registered for emamectin benzoate (Proclaim® and Denim®), and given the low exposure potential of the use being proposed, Syngenta suggests that the appropriate **PRIA II fee category for this action is proposed as a R-310**, with a fee of $4,360 and a processing timeline of 6 months.

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[X] Yes* [ ] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1 pint – 55 gallons	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [X] Paper glued [ ] Stenciled [ ] Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas Parshley	Regulatory Product Manager	336-632-7207

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
Thomas Parshley	Regulatory Product Manager
4. Typed Name	**5. Date**
Thomas Parshley	December 20, 2007

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Syngenta Crop Protection,Inc. Box18300 Greensboro NC	EPA Registration Number/File Symbol 100-XXXX
Active Ingredient(s) and/or representative test compound(s) Emamectin Benzoate	Date December 19, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Outdoor, non-food	Product Name TREE-äge

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it 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.

Signature	Date	Typed or Printed Name and Title
Thomas Parshley	December 19, 2007	Thomas Parshley, Regulatory Product Manager

[G:CA-DOC.Regaffrs]Epa-frm 8570-34:bpt:9/24/98

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this co of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC Do not send the form to this address.

DATA MATRIX

Date: 12/12/2007	Reg. No: 100-XXXX	Page 1 of 1
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: TREEAGE (submitted w/ Registration Application)	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.0000	Product identity and composition	Submitting	SYNGENTA	OWN	
870.1100	Acute oral toxicity	Submitting	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	Submitting	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	Submitting	SYNGENTA	OWN	
870.2400	Acute eye irritation	Submitting	SYNGENTA	OWN	
870.2500	Acute dermal irritation	Submitting	SYNGENTA	OWN	
870.2600	Skin sensitization	Submitting	SYNGENTA	OWN	

Thomas J. Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 12/12/2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this co of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC *Do not send the form to this address.*

DATA MATRIX

Date: 12/12/2007	Reg. No: 100-XXXX	Page 1 of 1
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: TREEAGE (submitted w/ Registration Application)	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 12/12/2007

385

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this co of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC Do not send the form to this address.

DATA MATRIX

Date: 12/12/2007 | Reg. No: 100-902 |

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: EMAMECTIN BENZOATE TECHNICAL

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
Cite-All	Cite-All	Cite-All (AHE	AGRICULTURAL HAN	PER	
Cite-All	Cite-All	Cite-All (ART	AGRICULTURAL REE	PER	
Cite-All	Cite-All	Cite-All (FES	FIFRA ENDANGERED	PER	
Cite-All	Cite-All	Cite-All (ORE	OUTDOOR RESIDENT	PER	
Cite-All	Cite-All	Cite-All (REJ	RESIDENTIAL EXPOS	PER	
Cite-All	Cite-All	Cite-All (SDT	SPRAY DRIFT TF	PER	
Cite-All	Cite-All	Cite-All (Syng	SYNGENTA	OWN	
830.0000	Product identity and composition	42743644	MERCK & CO., INC.	OWN	
830.0000	Product identity and composition	42743645	MERCK & CO., INC.	OWN	
830.0000	Product identity and composition	42743646	MERCK & CO., INC.	OWN	
830.0000	Product identity and composition	42743647	MERCK & CO., INC.	OWN	
830.0000	Product identity and composition	42743649	MERCK & CO., INC.	OWN	

Thomas J Parshley Thomas J. Parshley, Senior Regulatory Manager

Date: 12/12/2007

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DATA MATRIX

Date: 12/12/2007 | Reg. No: 100-902 |

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: EMAMECTIN BENZOATE TECHNICAL

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.0000	Product identity and composition	42743651	MERCK & CO., INC.	OWN	
830.0000	Product identity and composition	43824002	MERCK & CO., INC.	OWN	
830.0000	Product identity and composition	44883705	SYNGENTA	OWN	
830.0000	Product identity and composition	45420801	SYNGENTA	OWN	
830.1550	Product identity and compostition	45420801	SYNGENTA	OWN	
830.1550	Product identity and compostition	46044901	SYNGENTA	OWN	
830.1550	Product identity and compostition	47153904	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	44883701	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	45420801	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	47153904	SYNGENTA	OWN	
830.1620	Description of production process	44883701	SYNGENTA	OWN	
830.1620	Description of production process	45420801	SYNGENTA	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.1650	Description of Formulation process	44883701	SYNGENTA	OWN	
830.1650	Description of Formulation process	47153904	SYNGENTA	OWN	
830.1670	Discussion of formation of impurities	43393010	MERCK & CO., INC.	OWN	
830.1670	Discussion of formation of impurities	45420801	SYNGENTA	OWN	
830.1670	Discussion of formation of impurities	47153904	SYNGENTA	OWN	
830.1700	Preliminary analysis	46044901	SYNGENTA	OWN	
830.1700	Preliminary analysis	47153904	SYNGENTA	OWN	
830.1750	Certified limits	46044901	SYNGENTA	OWN	
830.1750	Certified limits	47153904	SYNGENTA	OWN	
830.1800	Enforcement analytical method	44007908	MERCK & CO., INC.	OWN	
830.1800	Enforcement analytical method	44007909	MERCK & CO., INC.	OWN	
830.1800	Enforcement analytical method	46044901	SYNGENTA	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.1800	Enforcement analytical method	47153904	SYNGENTA	OWN	
830.6302	Color	47153905	SYNGENTA	OWN	
830.6303	Physical state	47153905	SYNGENTA	OWN	
830.6304	Odor	47153905	SYNGENTA	OWN	
830.6313	Stability to normal and elevated temperatures, metals,	42743648	MERCK & CO., INC.	OWN	
830.6313	Stability to normal and elevated temperatures, metals,	43850103	MERCK & CO., INC.	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	47153905	SYNGENTA	OWN	
830.6315	Flammability	47153905	SYNGENTA	OWN	
830.6316	Explodability	47153905	SYNGENTA	OWN	
830.6317	Storage Stability	42743646	MERCK & CO., INC.	OWN	
830.6317	Storage Stability	42743650	MERCK & CO., INC.	OWN	
830.6317	Storage Stability	47153905	SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.6320	Corrosion characteristics	42743646	MERCK & CO., INC.	OWN	
830.6320	Corrosion characteristics	42743649	MERCK & CO., INC.	OWN	
830.6320	Corrosion characteristics	47153905	SYNGENTA	OWN	
830.7000	pH	44883702	SYNGENTA	OWN	
830.7000	pH	47153905	SYNGENTA	OWN	
830.7200	Melting point/melting range	42794202	MERCK & CO., INC.	OWN	
830.7300	Density/relative density/bulk density	42794202	MERCK & CO., INC.	OWN	
830.7300	Density/relative density/bulk density	47153905	SYNGENTA	OWN	
830.7370	Dissociation constants in water	42794202	MERCK & CO., INC.	OWN	
830.7550	Partition coefficient (n-octanol/water), shake falsk metl	42794202	MERCK & CO., INC.	OWN	
830.7550	Partition coefficient (n-octanol/water), shake falsk metl	44883703	SYNGENTA	OWN	
830.7560	Partition coefficient (n-octanol/water), generator colum	42794202	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.7560	Partition coefficient (n-octanol/water), generator colum	44883703	SYNGENTA	OWN	
830.7570	Partition coefficient (n-octanol/water), estimation by liq	42794202	MERCK & CO., INC.	OWN	
830.7570	Partition coefficient (n-octanol/water), estimation by liq	44883703	SYNGENTA	OWN	
830.7840	Water salubility: column elution method, shake flask m	42794202	MERCK & CO., INC.	OWN	
830.7840	Water salubility: column elution method, shake flask m	43850102	MERCK & CO., INC.	OWN	
830.7840	Water salubility: column elution method, shake flask m	44883704	SYNGENTA	OWN	
830.7860	Water solubility: generator column method	42794202	MERCK & CO., INC.	OWN	
830.7860	Water solubility: generator column method	43850102	MERCK & CO., INC.	OWN	
830.7860	Water solubility: generator column method	44883704	SYNGENTA	OWN	
830.7950	Water solubility, Vapor pressure	42794202	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42743613	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42851518	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.1100	Acute oral toxicity	42851519	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	43824003	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	44007915	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	47153906	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47153907	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	43824004	MERCK & CO., INC.	OWN	
870.1200	Acute dermal toxicity	43869401	MERCK & CO., INC.	OWN	
870.1200	Acute dermal toxicity	47153907	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47153908	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	43868101	MERCK & CO., INC.	OWN	
870.1300	Acute inhalation toxicity	43868102	MERCK & CO., INC.	OWN	
870.1300	Acute inhalation toxicity	47153907	SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.2400	Acute eye irritation	43824005	MERCK & CO., INC.	OWN	
870.2400	Acute eye irritation	43850112	MERCK & CO., INC.	OWN	
870.2400	Acute eye irritation	47153907	SYNGENTA	OWN	
870.2400	Acute eye irritation	47153909	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47153907	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47153910	SYNGENTA	OWN	
870.2600	Skin sensitization	42743609	MERCK & CO., INC.	OWN	
870.2600	Skin sensitization	42743610	MERCK & CO., INC.	OWN	
870.2600	Skin sensitization	42743617	MERCK & CO., INC.	OWN	
870.2600	Skin sensitization	47153907	SYNGENTA	OWN	
870.2600	Skin sensitization	47153911	SYNGENTA	OWN	
870.3100	90-Day oral toxicity	43868103	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3150	Subchronic nonrodent oral toxicity - 90-day	43868103	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	42743625	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	44007902	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42851511	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42743624	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42851510	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42868902	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868105	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851512	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851513	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	42743624	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743628	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851505	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851508	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851509	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851510	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42868902	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	43868104	MERCK & CO., INC.	OWN	
870.7600	Dermal penetration	43850113	MERCK & CO., INC.	OWN	
810.1000	Overview, Definitions, and General Considerations	47153901	SYNGENTA	OWN	
810.1000	Overview, Definitions, and General Considerations	47153902	SYNGENTA	OWN	
810.3000	General Considerations for Efficacy of Invertebrate Co	47153901	SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
810.3000	General Considerations for Efficacy of Invertebrate Co	47153902	SYNGENTA	OWN	
810.3500	Premise Treatments	47153901	SYNGENTA	OWN	
810.3500	Premise Treatments	47153902	SYNGENTA	OWN	
810.3500	Premise Treatments	47153903	SYNGENTA	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and	43850108	MERCK & CO., INC.	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and	43850109	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850108	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850109	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43943301	MERCK & CO., INC.	OWN	
875.2600	Biological Monitoring	43943301	MERCK & CO., INC.	OWN	
850.3020	Honey bee acute contact toxicity	42851530	MERCK & CO., INC.	OWN	
161-1	Hydrolysis - laboratory	42743642	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
161-2	Photodegradation in water - laboratory	43404301	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43850114	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	43404302	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	42743643	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	43850117	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43404304	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43850118	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater daph	42743603	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater daph	44007901	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393001	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393002	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393003	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1025	Oyster acute toxicity test (shell deposition)	44007912	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007913	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007914	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393003	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1045	Penaeid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393001	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393002	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393003	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007912	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007913	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007914	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42743602	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42851529	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393001	MERCK & CO., INC.	OWN	

Thomas J. Parshley, Senior Regulatory Manager

Date: 12/12/2007

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1075	Fish acute toxicity test, freshwater and marine	43393002	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393003	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43850106	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007912	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007913	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007914	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1350	Mysid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1350	Mysid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1400	Fish early-life stage toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	45833001	SYNGENTA	OWN	
850.1710	Oyster BCF	43393005	MERCK & CO., INC.	OWN	
850.1730	Accumulation in fish -- waiver	43393005	MERCK & CO., INC.	OWN	
850.1850	Aquatic organism accumulation	43393005	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42743601	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42868905	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851527	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.2200	Avian dietary toxicity test	42851528	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850104	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850105	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007910	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007911	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 | Product: EMAMECTIN BENZOATE TECHNICAL

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			AGRICULTURAL HAN	PER	
			AGRICULTURAL REE	PER	
			FIFRA ENDANGERED	PER	
			OUTDOOR RESIDENT	PER	
			RESIDENTIAL EXPOS	PER	
			SPRAY DRIFT TF	PER	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]	[redacted]	[redacted]	MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]	[redacted]	[redacted]	MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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DATA MATRIX

Date: 12/12/2007	Reg. No: 100-902	Page 14 of 17
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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Thomas J Parshley Jr

Thomas J. Parshley, Senior Regulatory Manager

Date: 12/12/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

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			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
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Thomas J Parshley Thomas J. Parshley, Senior Regulatory Manager

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Thomas J Parshley

Thomas J. Parshley, Senior Regulatory Manager

Date: 12/12/2007

Certification with Respect to Label Integrity

Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-xxxxx	December 20, 2007	000100-xxxxx.20071220.treeage.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Thomas J Parshley
Signature

December 20, 2007
Date

Thomas J Parshley
Name (typed)

Sr. Regulatory Product Manager
Title

E-LABEL Notice

The electronic copy of the label (PDF on a CD) submitted with this application has been removed by the In-processing Team for entry into the Electronic Label Library* (ELL) to make it available to OPP staff.

You should be using this e-label to conduct your label review.

Note: If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the In-processing Team.

If the e-label is not found in the ELL, contact Tom Harris, RD (308-9423), Willie Abney, AD (308-1689) or Jim Downing, BPPD (308-9071) for further information and assistance.

* A Lotus Notes database

(Master label)

Mark up

TREE-äge™

Injected insecticide for the control for arthropod pest in trees

Active Ingredient:	
Emmamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8

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. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-xxxxx

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP xxxxxA-M(draft TREE-äge)

_____
Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•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.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- shoes and socks
- protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, 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. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

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

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

TREE-äge is for control of mature and immature arthropod pests of trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). TREE-äge contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. To assure optimum effectiveness, this product must be placed into active sapwood.

GENERAL DIRECTIONS

TREE-äge is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Breast height is a standardized distance of 54" from the ground. Often the diameter is determined from measuring the circumference of the tree at this height, and dividing circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: for optimum distribution, inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Avoid injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

TREE-äge contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion, but may also be lethal upon contact.

ENVIRONMENTAL CONDITIONS: Uptake of TREE-äge is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For optimal uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Watering the trees prior to injection may enhance the uptake of TREE-äge.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of TREE-äge may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of TREE-äge in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

TREE-äge may also be effective as a ~~curative~~ remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to TREE-äge. Foliar pests may be controlled within 1- 2 weeks after treatment under ideal conditions. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on TREE-äge treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml./tree	Medium ml./tree	Medium - High ml./tree	High ml./tree	Average No. Injection Sites*
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

* The number of injection sites listed is a guide for approximately how many are needed per size of tree.
For optimal control, it is recommended to be with ± 1 injection site of this number per tree.
Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

explain when to use which esp if low-high

Applications in Trees

Tree Tissue	Target Pest	Recommended Rate	Comments
Seed and Cone	Pine Cone Worm (Dioryctria spp)	Medium to High	For optimal control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	For optimal control apply at least 2-3 weeks before economic threshold is predicted.
	Mites: Eryiophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For optimal control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers- (Roundhead borers including Asian, Eucalyptus, Pine Sawyer) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

Compatibility

Do not mix TREE-äge before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTIONS

- Do not apply to trees that may yield food consumed by humans or used in animal feed.
- Avoid treating trees that are moisture stressed or suffering from herbicide damage.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

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

Container Disposal

Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

TREE- äge is a registered trademark of Arborjet, Inc.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
www.syngenta-us.com

SCP xxxxxA-M(draft TREE-äge)

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