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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.



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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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	3×10^{-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 _{1/2} = Stable	MRID 42743642; (pH 7)
Aqueous photolysis half-life	t _{1/2} = 23 days	MRID 43850114 (natural sunlight - maximum value)
Soil photolysis half-life	t _{1/2} = 5 days	MRID 43404302; (uncorrected for dark controls)
Aerobic soil metabolism half-life	t _{1/2} = 193 days	MRID 43404303; (sandy loam)
Anaerobic soil metabolism	t _{1/2} = 174 days	MRID 43850116
Anaerobic aquatic half-life	t _{1/2} = 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)

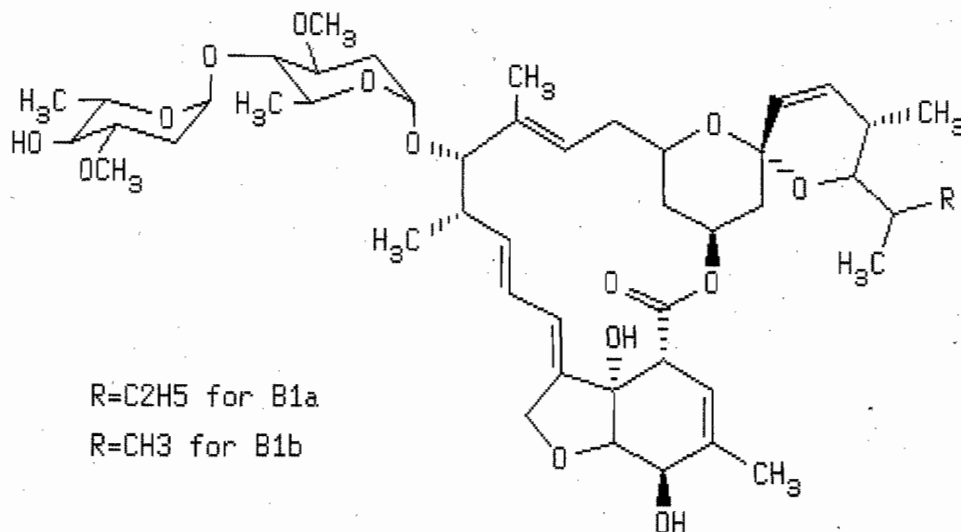


Figure 2.1. Structure of Emamectin Benzoate B1a and B1b

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 2002¹ and 2005², several Section 18 reviews³. 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.

¹DP barcode 279840 and 279841 (cole crops, leafy vegetables, cotton, and tobacco).

²DP 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 degrade 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.

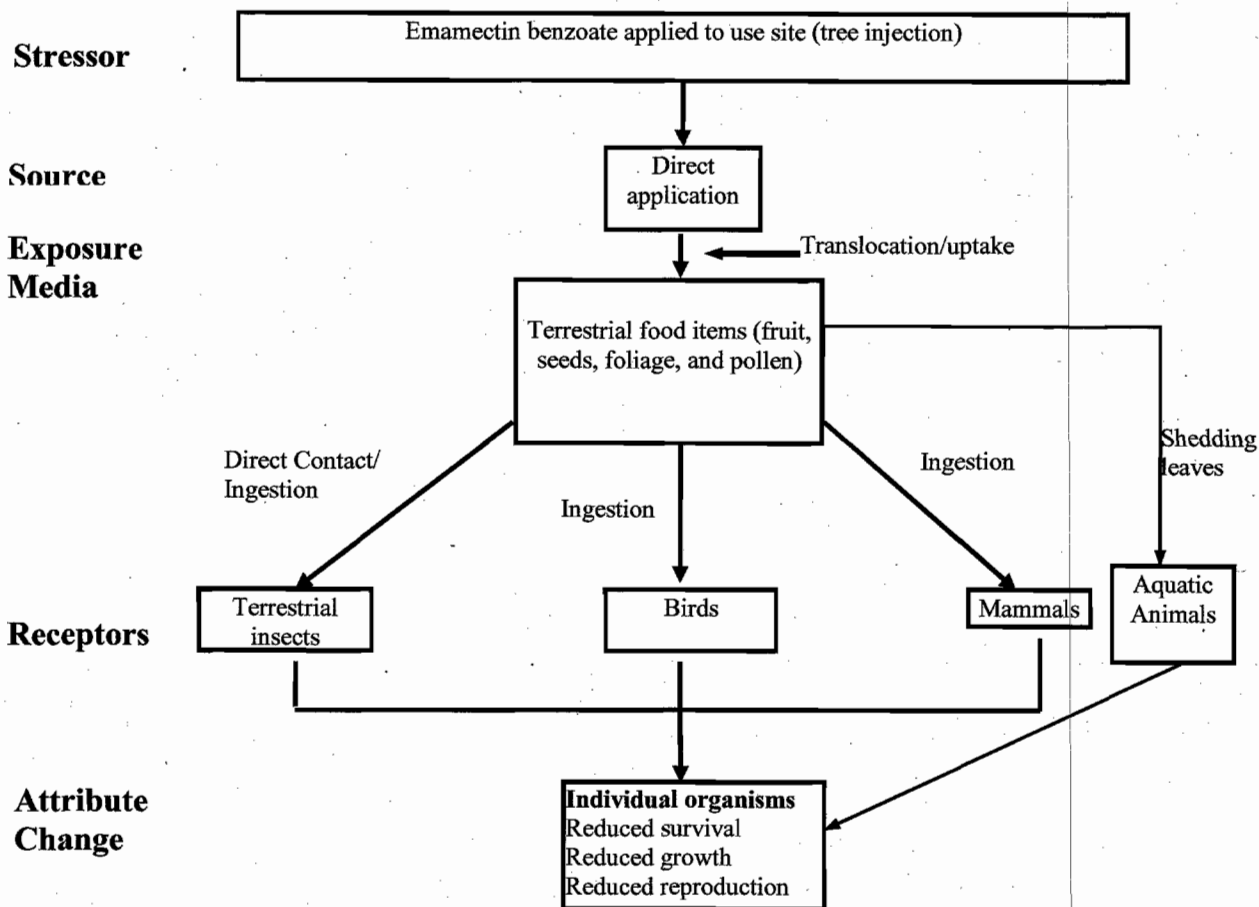


Figure 2.2. Conceptual Model for Emamectin Benzoate Application via Tree Injection

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 may 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 LD₅₀/sqft = (mg/sq ft) / (LD₅₀ * wt. of animal)

LD₅₀/day = (mg of toxicant consumed/day) / (LD₅₀ * 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.

^aProduct label specified volume of product applied to each tree. Mass was calculated using the following equations:

$$\text{mL product/tree (given on label)} \times 0.04 \text{ (4\% a.i. in formulation)} = \text{mL a.i./tree}$$

$$\text{mL a.i./tree} \times 1000 \text{ mg/mL (density of water; density of product not available)} = \text{mg a.i./tree}$$

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 = 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 (<i>Anas platyrhynchos</i>)	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 (<i>Mus musculus</i>)	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 (<i>Apis mellifera</i>)	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 (<i>Oncorhynchus mykiss</i>)	LC ₅₀ : 174 ug/L	7.0 (3.6-10)	Highly toxic	42851529	Acceptable study.
Waterflea (<i>Daphnia magna</i>) Flow-through	EC ₅₀ : 1.0 ug/L	4.7 (3.2-6.2)	Very highly toxic	42743603	Acceptable study.
Eastern oyster (<i>Crassostrea virginica</i>) (shell deposition or embryo-larvae) Flow-through	EC ₅₀ : 490 ug/L	4.9 (C.I. not reported)	Highly toxic	43393002	Acceptable study.
Mysid (<i>Americamysis bahia</i>) Flow-through	LC ₅₀ : 0.04 ug/L	8.1 (4.9 - 11.2)	Very highly toxic	43393001	Acceptable study.
Chronic Studies					
Mallard duck (<i>Anas platyrhynchos</i>)	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 (<i>Pimephales promelas</i>)	Early Life Stage NOAEC: 6.5 ug/L	Not applicable	Not applicable	43850107	Acceptable study.
Waterflea (<i>Daphnia magna</i>) Flow-through	NOAEC: 0.088 ug/L	Not applicable	Not applicable	43393004	Acceptable study.
Mysid (<i>Americamysis bahia</i>) Flow-through	NOAEC: 0.018 ug/L NOAEC: 0.0087 ug/L	Not applicable Not applicable	Not applicable Not applicable	44305601 45833001	Supplemental study. Supplemental study.
Aquatic Plant Studies					
Vascular Plant-Duckweed <i>Lemna gibba</i> Static	EC ₅₀ > 94 ug/L NOEC: 94 ug/L	Not applicable	Not applicable	43850109	Acceptable study.
Freshwater algae <i>Selenastrum capricornutum</i> 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			Risk Summary
Assumption	EEC	Birds	Mammals	Inverts.	
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 = 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

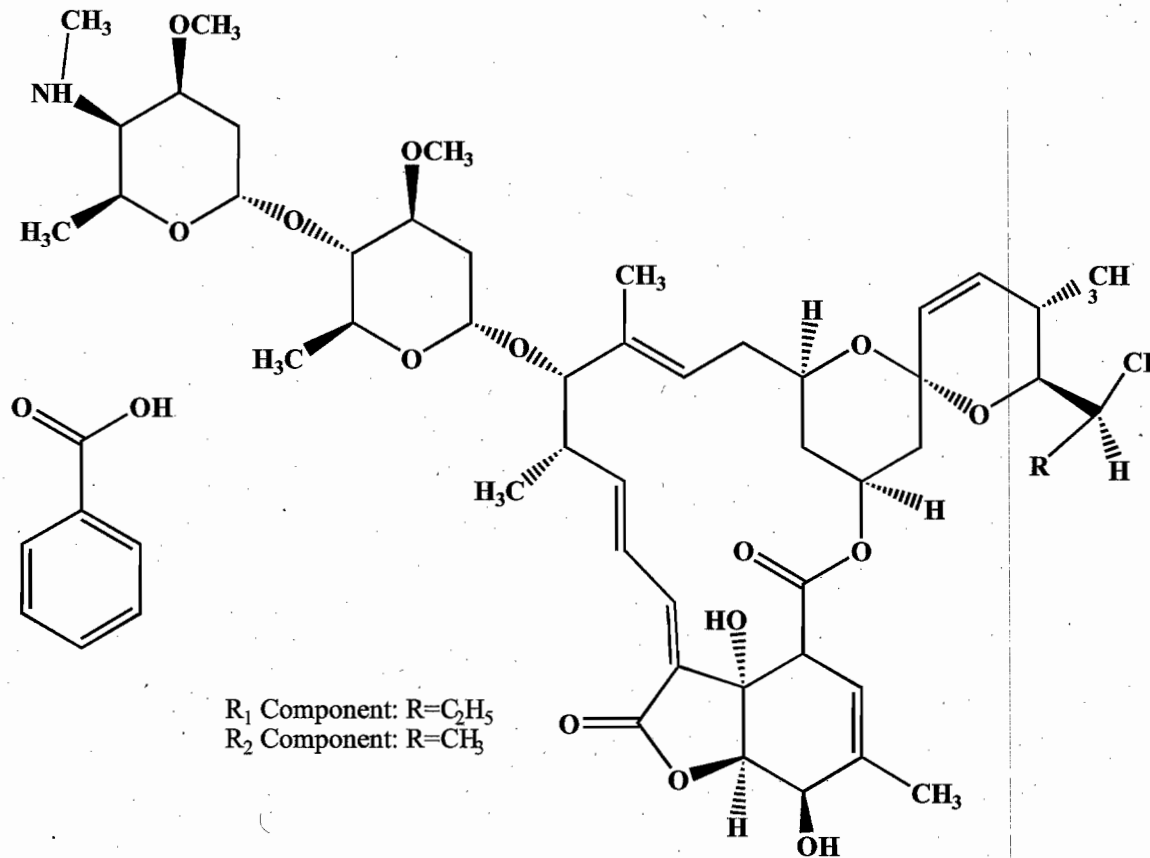
USDA Forest Service (John F. Karlik and Alistair H. McKay). 2002. Leaf area index, leaf mass density, and allometri relationships derived from harvest of blue oaks in California oak Savanna. USDA Forest Service Gen. Tech. Rep. PSW-GTR-184.2002.

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.

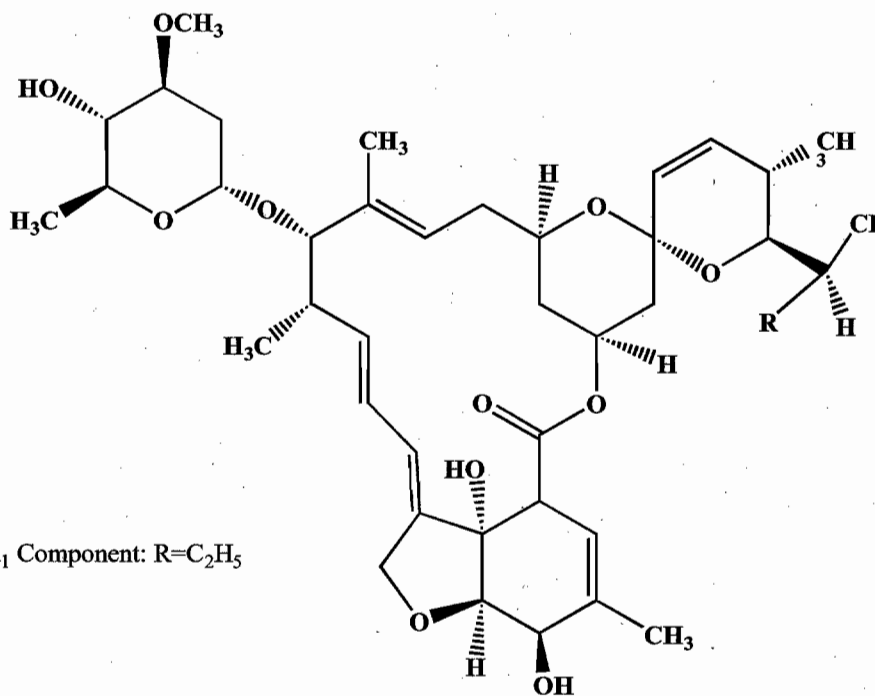
University of Arkansas Division of Agriculture (David W. Patterson). Undated. Landowner's guide to determining weight of standing hardwood trees. University of Arkansas Division of Agriculture, Cooperative Extension Service. FSA 5021.

Appendix A. Structure of Degradates of Concern

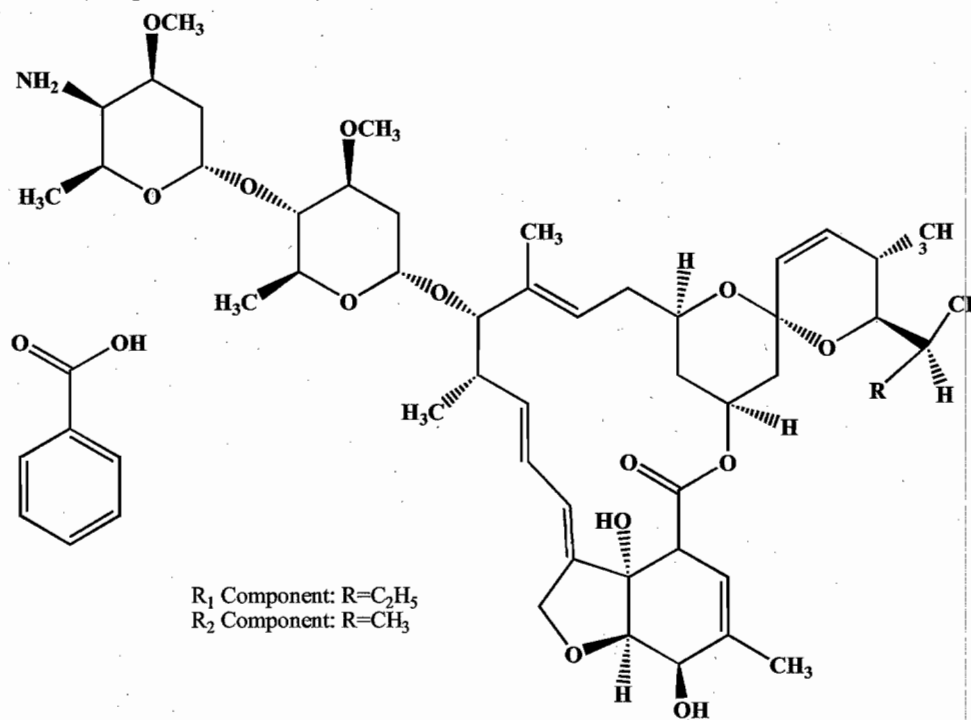
Degradate 2: 8,9-Z MA ((8,9-Z)-4"-epimethylamino-4"-deoxy anermectin B1)



MAB1a (avermectin B1 monosaccharide)



AB1a (4"-epiamino-4"-deoxyavermectin B1)



Appendix B. GENEEC2 Output

RATE (#/AC) ONE(MULT)		No.APPS & INTERVAL		SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY (FT)	INCRP (IN)
.093(.093)		1	1	265687.0	93.0	GRANUL(.0)	.0 .0
FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)								

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF		HYDROLYSIS (POND)		PHOTOLYSIS (POND-EFF)		METABOLIC (POND)	COMBINED (POND)

193.00	2		N/A		23.00-	2852.00	386.00	339.99
GENERIC EECs (IN NANOGRAMS/LITER (PPT _r))						Version 2.0 Aug 1, 2001		

PEAK GEEC	MAX 4 DAY AVG GEEC		MAX 21 DAY AVG GEEC		MAX 60 DAY AVG GEEC		MAX 90 DAY AVG GEEC	

225.42	141.80		35.39		4		8.41	

RUN No. 12 FOR Emamectin Benzoa ON Trees						* INPUT VALUES *		

RATE (#/AC) ONE(MULT)		No.APPS & INTERVAL		SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY (FT)	INCRP (IN)
.001(.001)		1	1	265687.0	93.0	GRANUL(.0)	.0 .0
FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)								

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF		HYDROLYSIS (POND)		PHOTOLYSIS (POND-EFF)		METABOLIC (POND)	COMBINED (POND)

193.00	2		N/A		23.00-	2852.00	386.00	339.99
GENERIC EECs (IN NANOGRAMS/LITER (PPT _r))						Version 2.0 Aug 1, 2001		

PEAK GEEC	MAX 4 DAY AVG GEEC		MAX 21 DAY AVG GEEC		MAX 60 DAY AVG GEEC		MAX 90 DAY AVG GEEC	

3.15	1.98		.49		.18		.12	