



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

September 28, 2005 PC Code 044309 DP Barcodes: D313414, D314536 and D313415

MEMORANDUM

- SUBJECT: EFED Registration Chapter for **Clothianidin** for use on Potatoes and Grapes as a spray treatment and as a Seed Treatment for Sorghum and Cotton.
- FROM: N.E. Federoff, Wildlife Biologist/Team Leader M. Barrett, Senior Scientist/Water Modeler Environmental Risk Branch V Environmental Fate and Effects Division (7507C)
- THROUGH: Mah T. Shamim, Ph.D., Chief Environmental Risk Branch V Environmental Fate and Effects Division (7507C) 9/28/05

TO:

C. Rodia, Risk Manager Reviewer D. Kenny, Risk Manager 01 Registration Division (7505C)

This memo summarizes the Environmental Fate and Effects Division's (EFED) screening-level Environmental Risk Assessment for Clothianidin. The registrant, Arvesta Corporation, is submitting clothianidin to be used on potatoes, grapes and as a seed treatment for sorghum and cotton.

Clothianidin's major risk concern is to nontarget insects (that is, honey bees). EFED expects adverse effects to bees if clothianidin is allowed to be sprayed on blooming, pollen-shedding, or nectar producing parts of plants. Because of this, EFED is recommending bee precautionary labeling prohibiting such clothianidin applications.

Clothianidin is a neonicotinoid insecticide that is both persistent and systemic. Acute toxicity studies to honey bees show that clothianidin is highly toxic on both contact and oral basis. Although EFED does not conduct RQ based risk assessments on non target insects, information from standard tests and field studies, as well as incident reports involving other neonicotinoids insecticides (e.g., imidacloprid) suggest the potential for long term toxic risk to honey bees and other beneficial insects. Other neonicotinoid compounds like imidacloprid (e.g., sunflower seed



treatment) have resulted in incidents to honey bees. The product to be used for the proposed seed treatment for cotton is a mixture of clothianidin and imidacloprid. Since imidacloprid is systemic, and clothianidin appears to be also, there is a possibility of adverse effects to beneficial insects such as honey bees from products containing either compound.

Based on proposed application rates and uses, acute and chronic risks to small birds and mammals are unlikely, except for endangered mammals should exposure actually occur. In addition, considering the mode of agricultural practice of drilling seeds during planting, EFED believes that clothianidin seed treatment should result in minimal acute risk to these organisms.

A Tier II assessment for aquatic species (using the PRZM/EXAMS model) indicates that only the acute endangered species level of concern was exceeded for freshwater invertebrates (RQs 0.067 to 0.086) for the potato use, implying a possible level of risk should exposure actually occur.

Clothianidin does not appear to present risk to terrestrial plants (there were no significant effects in the studies submitted). In addition, it does not appear to present risk to aquatic vascular or nonvascular plants.

The available environmental fate data for clothianidin indicates that the chemical is persistent, mobile, and systemic. It is stable to hydrolysis at all pHs at environmental temperatures, has the potential to leach to groundwater, be transported via runoff to surface water bodies, and could accumulate in soils from year to year with repeated uses. The major route of dissipation for clothianidin would appear to be photolysis if exposure to sunlight occurs (e.g., the measured aqueous photolysis half-life was <1 day and aerobic half-lives were 148 to 1155 days). Major degradates include TMG, MNG, and TZNG.

Risk to Endangered Species

Based on available information, clothianidin may be of concern to endangered freshwater aquatic invertebrates (both single and multiple application to potatoes) and some small (15g) mammal species (potato and grape uses), should exposure actually occur. A probit slope response relationship was evaluated to calculate the chance of an individual event corresponding to the listed species acute LOCs. Analysis of raw data from the mammalian and aquatic acute toxicity studies for clothianidin estimated a slope of 7.61 and 4.24 for mammals and freshwater invertebrates, respectively. Based on these slopes, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 7.21 x 10^{13} for small mammals and 1 in 5.76 x 10^7 for freshwater invertebrates. Also, endangered beneficial insects may be at risk due to the toxicity profile for honeybees (clothianidin is toxic to honeybees, thus risk is assumed).

EPA's Interim Policy for Potential Endocrine Disruptors

EPA is required under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator

may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, clothianidin may be subjected to additional screening and or testing to better characterize effects related to endocrine disruption.

Data suggests that clothianidin could be a candidate for additional screening and/or testing to better characterize effects related to endocrine disruption. Effects in avian species included significant decreases in eggshell thickness. Effects in mammalian reproduction studies included decreased body weight gains and delayed sexual maturation (males only), decreased absolute thymus weight in F1 pups (both sexes), increased stillbirths (F1 and F2 litters), decreased sperm mobility and increased number of sperm with detacched heads (F1 and F2 litters).

Outstanding Data Requirements

Environmental Fate:

<u>162-4 Aerobic Aquatic metabolism Study</u>. Based on the additional information submitted by the registrant, EFED agreed to change the previously-reviewed aerobic aquatic metabolism study (MRID 45422324) from "unacceptable" to "supplemental". However, the aerobic aquatic metabolism data requirements are still not fulfilled, the registrant must submit a new aerobic aquatic metabolism study. Reasons are presented below:

1. The potential for clothianidin to move from the treated area to the nearby surface water body has been increased significantly since 2003 because the registrant has recently added new uses on the labels. According to the review completed on 2/20/2003 (Title - "EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola", the Agency required the registrant to conduct a new aerobic aquatic metabolism study (162-4). This risk assessment was based on the maximum application rate for the seed treatment at 0.1 lb ai/A. However, according to the new uses reviewed by EFED (Turfgrass, Tobacco, Apples, Pears, and Ornamentals), this chemical can be directly applied to the soil surface/foliage at much higher application rate (0.4 lbs ai/A). As a result, the potential for clothianidin to move from the treated area to the nearby surface water body under the new uses is much greater than the use as a seed treatment. Therefore, there is a need for a better understanding of the fate of clothionidin in the aerobic aquatic environment.

2. The fate of the thiazolyl ring was not monitored in the previously-reviewed aerobic aquatic metabolism study (MRID 45422324) because the test substance was labeled on the nitroimino side chain. Therefore, the fate of the thiazolyl ring remains unknown. The fate guidelines

recommend to use the ring-labeled test substance.

3. A well-designed new aerobic aquatic metabolism study is deemed critical for EPA to fully assess the risk of clothionidin in the aquatic environment.

<u>166-1 Small-Scale Prospective Groundwater Monitoring Study</u>. Due to direct soil and foliar applications of clothianidin and concerns about the chemical leaching into ground water (see below), the Agency will request the registrant to submit a small-scale prospective groundwater monitoring study.

Source: EPA review "EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola" dated February 20, 2003 (page 3):

"Clothianidin has the properties of a chemical which could lead to widespread groundwater contamination, but no ground-water monitoring studies have been conducted to date. Should the registrant request field uses involving direct application of clothianidin to the land surface, Prospective Ground-Water Monitoring Studies may be needed to evaluate fully the potential impact of such uses." Due to the extreme mobility and persistence of clothianidin in the environment, a small-scale prospective groundwater monitoring study will provide additional fate information on the better understanding of this chemical in the environment and improve the certainty of the risk assessment.

Ecological Effects:

The database available for clothianidin to support the assessment was largely complete. EFED received and reviewed a honey bee residue on foliage (141-2). EFED also received a honey bee field testing for pollinators (141-5) protocol from Bayer CropScience's (BCS's) [Clothianidin (044309), D295318]. The protocol title is: An Investigation of the Potential Long-Term Impact of Clothianidin Seed Treated Canola on Honey Bees, *Apis mellifera* L. The study was due in may 2005 but the registrant has requested an extension.

EFED and Canada's Pest Management Regulatory Agency (PMRA) completed a joint review of BCS's proposed field study at the end of March, 2004. EFED has not received any response from BCS since the completion of this joint review. The following ecological studies for clothianidin are still outstanding and need to be submitted.

OPPTS 850.1735: Whole Sediment Acute Toxicity Invertebrates, Freshwater. This is a 28 day test that measures survival, growth and emergence of *Chironomus riparius* that have been exposed to pesticide spiked sediment. EFED is requesting this acute sediment toxicity test because clothianidin is toxic to aquatic invertebrates, persistent in the environment, and binds to sediment over time.

OPPTS 850.1740: Whole Sediment Acute Toxicity Invertebrates, Estuarine and Marine - Testing with estuarine/marine invertebrates using the TGAI is required for clothianidin because clothianidin is toxic to aquatic invertebrates, persistent in the environment, binds to sediment over time. and the end-use product is expected to reach the marine/estuarine environment

because of it use in coastal counties.

Field Test for Pollinators (141-5): The possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues that result from seed treatment (corn and canola) has prompted EFED to require field testing (141-5) that can evaluate the possible chronic exposure to honey bee larvae and queen. In order to fully evaluate the possibility of this toxic effect, a complete worker bee life cycle study (about 63 days) must be conducted, as well as an evaluation of exposure and effects to the queen.

Seed Leaching Study: EFED believes that a seed leaching study would greatly increase certainty regarding a more realistic estimate of the amount of available clothianidin residues on the seed surface. This in turn would allow a refinement of exposure estimates and environmental concentration values (EECs).

Uncertainties

The uncertainties associated with clothianidin exposure in the environment are mainly focused in these areas; 1) accumulation of clothianidin in soils after repeated uses and the potential for transport/migration to surface water bodies and potential risk to sensitive aquatic invertebrates (e.g., sediment-dwelling benthic organisms); 2) repeated or continuous exposure of small mammals and birds to the pesticide presenting a potential reproduction and developmental risk; 3) the possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues to blooming, pollen-shedding or nectar-producing parts of plants that result from clothianidin's uses; and 4) repeated or continuous exposure to soil invertebrates and small mammals to clothianidin accumulated in soils after repeated uses.

For terrestrial screening risk assessments, a generic bird or mammal is assumed to occupy either the treated field or adjacent areas receiving pesticide at a rate commensurate with the treatment rate on the field. The actual habitat requirements of any particular terrestrial species are not considered, and it is assumed that species exclusively and permanently occupy the treated area being modeled. This assumption leads to a maximum level of exposure in the risk assessment. In the absence of specific data, EFED assumes the most conservative scenario. Screening-level risk assessments for spray applications of pesticides usually consider dietary exposure alone.

EFED Label Recommendations

Label Recommendations

Manufacturing Use Product

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

End Use Products

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Apply this product only as specified on the label.

This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

This compound is toxic to birds and mammals. Treated clothianidin seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect clothianidin seeds spilled during loading.

For products applied as a foliar spray, EFED recommends the following labeling statement: "This product is toxic to bees exposed to treatment and for more than 5 days following treatment. Do not apply this product to blooming, pollen-shedding or nectar-producing parts of plants if bees may forage on the plants during this time period, unless the application is made in response to a public health emergency declared by appropriate state or federal authorities."

Label statements for spray drift management:

Do not allow this product to drift onto neighboring crops or non crop areas or use in a manner or at a time other than in accordance with label directions because animal, plant or crop injury, illegal residues or other undesirable results may occur.

AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions. Where states have more stringent regulations, they should be observed.

Data Requirement Tables

	Table of Env	ironmental Fate 1	Data Requirements	
			Study	
Guide- line #	Data Requirement	MRID #	Classification	Is more data needed?
161-1	Hydrolysis	45422317	Core	no
161-2	Photodegradation in	45422318	Core	no
	Water	45422319	Supplemental	
		45422320	Core	
		45422321	Supplemental	
		45422322	Core	· · · ·
161-3	Photodegradation on Soil	45422323	Core	no
161-4	Photodegradation in Air		Waived	no
162-1	Aerobic Soil Metabolism	45422325	Core	no
		45422326	Core	
		45422327	Supplemental	
		45422328	Supplemental	
			/	
162-2	Anaerobic Soil Metabolism	N/A	N/A	no
162-3	Anaerobic Aquatic Metabolism	45422330	Core	no
162-4	Aerobic Aquatic	45422324	Supplemental	
102-4	Metabolism	45422324	Supplemental	yes
	Metabolishi	43422329	Supprementar	
163-1	Leaching-	45422311	Core	no
105 1	Adsorption/Desorption	45422312	Ancillary	no
		45422312	Supplemental	
		45422314	Supplemental	
		45422315	Supplemental	
		45422316	Supplemental	
163-2	Laboratory Volatility	N/A	N/A	Waived
163-3	Field Volatility	N/A	N/A	Waived

.

Guide- line #	Data Requirement	MRID #	Study Classification	Is more data needed?
164-1	Terrestrial Field	45490703	Core	no
	Dissipation	45490704	Core	
		45490705	Core	
		45422331	Supplemental	
		45422332	Core	
		45422333	Core	
		45422334	Core	
		45422335	Core	
		45422336	Core	
		45422508	Supplemental	
		45422604	Ancillary	
		45422612	Ancillary	· · · · · · · · · · · · · · · · · · ·
164-2	Aquatic Field Dissipation	N/A	N/A	Reserved
165-4	Accumulation in Fish	N/A	N/A	Waived
165-5	Accumulation- aquatic non-target	N/A	N/A	Reserved
166-1	Ground Water- small prospective	N/A	N/A	Yes
201-1	Droplet Size Spectrum	45490701	Supplemental (upgradable)	Reserved
202-1	Drift Field Evaluation	N/A		Reserved

	Table of Ec	ological Toxicity Da	ta Requirements	
Guideline #	Data Requirement	MRID #	Classification	Is more data needed?
71-1	Avian acute oral LD ₅₀			
	(mallard duck)	45422417	Core	No
	(japanese quail)	45422418	Supplemental	
5 4 0 ¹				
71-2	Avian subacute dietary LC_{50}	45422419	Core	No
	(bobwhite quai)l		1	110
	(mallard duck)	45422420	Core	
71-4	Avian reproduction	15100101		
	(bobwhite quail)	45422421	Core	No
	(mallard duck)	45422422	Supplemental	1.0
72-1	Freshwater fish acute LC ₅₀₀			
	(rainbow trout)	1		
	TGAI	45422406	Supplemental	
	DEG	45422408	Supplemental	
	DEG	45422409	Supplemental	No
	DEG	45422410	Supplemental	
			**	
	(bluegill sunfish)	45422407	Core	
	TGAI			
	Production in the second second			
72-2	Freshwater invertebrate acute EC_{50}			
•	(daphnia)	45 400000	0	
	TGAI	45422338	Core	·
	DEG	45422401	Core	
	DEG	45422340	Core	No
	DEG	45422339	Supplemental	
	(chironomid)			· ·
	TGAI	45422414	Supplemental	
OPPTS	Acute Freshwater Invertebrate Sediment ·			
850.1735	Toxicity			
	TGAI	not applicable	not applicable	Yes
72-3a	Estuarine/marine fish acute LC50	45422411	Supplemental	No
	(sheepshead minnow)	10122111	Sapponionui	
72-3b	Estuaring/moring invoitabate south EC	•		
12-30	Estuarine/marine invertebrate acute EC ₅₀ (eastern oyster)			
	(castell bystel)	45422404	Core	
	(mysid)	70722704	COL	No
	(myshd)	45422403	Core	
72-4a	Freshwater fish early life stage			
-	(fathead minnow)	45422413	Supplemental	No
			- FF	
72-4b	Freshwater invertebrate life cycle			
	(daphnia)	45422412	Supplemental	No
	•			
72-4d	Estuarine/marine life cycle			
12-40		45422405	Com	No
· · ·	(mysid)	43422403	Core	No
OPPTS	Acute Freshwater Invertebrate Sediment			
850.1740	Toxicity			
	TGAI	not applicable	not applicable	Yes
		Lot applicable	not upprouble	103
72-7	Aquatic Field Study		NA	No

	Table of B	cological Toxicity I	Data Requirements	
Guideline #	Data Requirement	MRID #	Classification	Is more data needed?
81-1	Acute mammalian oral LD ₅₀ (rat) (mouse)	45422621 45422622	Core	No
83-1	Mammalian Chronic (rat) (rat) (rabbit)	45422714-16 45422825 -26 45422712-13	Core Core Core	No
122-1(a)	Seedling Emergence - Tier I	45422501	Core	No
122-1(b)	Vegetative Vigor - Tier I	45422502	Core	No
122-2	Aquatic plant algae TGAI DEG DEG DEG	45422504 45422505 45422506 45422507	Core Core Core Core	Yes ¹
123-2	Aquatic plant acute EC_{50}	45422503	Core	No
141-1	Acute honey bee contact LD ₅₀	45422426	Core	No
Non₁guideline	Acute honey bee oral LD ₅₀ TGAI DEG DEG DEG DEG DEG	45422426 45422427 45422428 45422429 45422429	Supplemental Supplemental Supplemental Supplemental Supplemental	No
141-2	Honey Bee Residue on Foliage	45490702	Supplemental	Yes
141-5	Honey Bee Field Testing for Pollinators	45422431 45422432 45422433 45422435 45422435 45422436 45422437 45422440	Supplemental Supplemental Supplemental Supplemental Supplemental Supplemental Supplemental	Yes
OPPTS 850.6200	Earthworm Subchronic TGÁI DEG DEG	45422511 45422512 45422513	Core Core Core	No
Non-guideline	Earthworm Chronic	45422525 45422526	Supplemental Supplemental	No

1 EFED needs 3 more Tier I or Tier II Core clothianidin studies for the nonvascular surrogate species, marine diatom (Skeletonema costatum), blue-green algae (Anabaena flos-aquae), and a freshwater diatom.

Environmental Fate and Ecological Risk Assessment for the Registration of CLOTHIANIDIN for Use as a Spray on Potatoes and Grapes and also as a Seed Treatment for Sorghum and Cotton

Prepared by: N.E. Federoff, Wildlife Biologist/Team Leader M. Barrett, Senior Scientist/Water Modeler

Reviewed and Approved by: Mah T. Shamim, Chief Environmental Risk Branch V United States Environmental Protection Agency Office of Pesticide Programs Environmental Fate and Effects Division Environmental Risk Branch V Ariel Rios Building 1200 Pennsylvania Ave., NW Mail Code 7507C Washington, DC 20460

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I. Executive Summary

The registrant, Arvesta Corporation, is submitting clothianidin to be used on potatoes and grapes and also as a seed treatment on sorghum and cotton. This risk assessment primarily focuses on risk to honey bees from application of clothianidin. It also identifies any possible risk to small birds and mammals which may be exposed to residual clothianidin from spray and seed application methods. No risk was found for birds, mammals or aquatic species from either spray or seed treatment applications. The endangered species acute LOC for 15g mammals and freshwater invertebrates were exceeded. However, analysis of raw data from the mammalian and aquatic acute toxicity studies for clothianidin estimated a slope of 7.61 and 4.24 for mammals and freshwater invertebrates, respectively. Based on these slopes, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 7.21 x 10^{13} for small mammals and 1 in 5.76 x 10^7 for freshwater invertebrates.

Clothianidin's major risk concern is to nontarget insects (that is, honey bees). EFED expects adverse effects to bees if clothianidin is allowed to be sprayed on blooming, pollen-shedding, or nectar producing parts of plants. Clothianidin is a neonicotinoid insecticide that is both persistent and systemic. Acute toxicity studies to honey bees show that clothianidin is highly toxic on both contact and oral basis (contact $LD_{50} = 0.044 \ \mu g/bee$; oral $LD_{50} = 0.0037 \ \mu g/bee$). A registrant submitted residue foliage study (guideline 141-2) showed that clothianidin residues on foliage can be expected to remain toxic to bees for 5 days at an application rate of 0.07 lb ai/A from foliar sprays. Spray application rates proposed for the new uses to potatoes and grapes are 0.2 lb ai/A. Bees are attracted to blooming, pollen-shedding, and nectar producing parts of plants. Pesticides with residue toxicity greater than 12 hours will kill bees in substantial numbers if these pesticides are applied to the plant parts that attract bees. Because of this, EFED is recommending bee precautionary labeling prohibiting such clothianidin applications.

EFED's May 2003 environmental risk assessment for seed treatment showed that use of clothianidin to rape (canola) results in detectable levels (ranging from 1.0 to 8.6 ppb) of clothianidin in the nectar sampled from honeybees' stomach, nectar from rape flowers, pollen from forage bees, pollen from bee hives, and nectar from bee hives. Detectable levels were found in the commodities sampled more than 60 days after the clothianidin treated seeds were planted. Although EFED was not able to make an adverse effect determination to honey bees, there was uncertainity about the sublethal or chronic risk to bees. At the time it was not clear what the effect of exposure on the forage force would be. Exposed foragers could become disoriented and fail to return to the colony.¹ However, this scenario is an uncertainty. The likelyhood of clothianidin residues being carried back to the hives resulting in accumulation of the pesticide thus adversely effecting the colonies health is also an uncertainty. As a result, EFED recommended a honey bee field study to answer these questions.

¹ Other neonicotinoid compounds like imidacloprid (e.g., sunflower seed treatment) have resulted in incidents to honey bees. The National Union of French Beekeepers had concerns regarding imidacolprid (GAUCHO) seed treatment to sunflowers after beekeepers noted that honey bees were showing modifications of behavior that were reflected in foraging and orientation that eventually resulted in a drastic change in hive conditions and bee survival. Further research by the Le Centre Technique Interprofessional des Oleagineux (CETIOM) confirmed imidacolprid toxic residue levels in the sunflower nectar. This action has prompted France to ban the use of imidacloprid for sunflower seed treatment.

US EPA ARCHIVE DOCUMENT

EFED still has other uncertainties associated with seed treatment uses of clothianidin. These uncertainties are compounded with the new proposed uses of clothianidin. The earlier bee field studies for clothianidin demonstrated that clothianidin could be translocated to nectar and pollen in rape seed treatment use. EFED believes the proposed bee precautionary labeling would prevent clothianidin's direct foliar application to nectar or pollen producing parts of plants. However, EFED is uncertain about what would happen when foliar spray or granular applications of clothianidin are made prior to bloom. How likley could systemic clothianidin be translocated to the nectar or pollen producing parts of plants when applied as spray, as a granular or as a seed treatment? From the seed treatment field study results, it seems likely such a translocation would occur. If this were to occur, how much clothianidin can be expected in the nectar and pollen and would these amounts adversely affect bees? Because of this risk uncertainty EFED is requesting another field study for clothianidin's new proposed uses.

Based on the proposed application rates, acute risk to avian and mammalian species is unlikely. Endangered 15g mammals (RQ = 0.12) may be at risk from ingestion of clothianidin treated food items. However, analysis of raw data from mammalian terrestrial acute toxicity studies for clothianidin provided an estimate of slope (7.61) for females only (LD50 = 389M/465F mg/kg). Based on this slope, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 7.21 x 10¹³ for small mammals.

EFED identified residues on grasses and foliage (in nectar and pollen), residues in fruit, and depositions in soil as the most likely sources resulting in clothianidin exposure to nontarget terrestrial organisms. The terrestrial effects database for these species is incomplete and thus recommendations are made for additional studies or assessments to fill data gaps needed for a suitable screening level risk assessment. As part of the Tier 1 terrestrial plants and animals following the proposed turfgrass application rates provided by the registrant. For terrestrial birds and mammals, estimates of initial levels of clothianidin residues on various food items, which may be contacted or consumed by wildlife, were determined using the Fletcher nomogram followed by a first order decline model. Avian acute and chronic RQs were below LOCs (0.5 to 0.1 and 1, respectively). Mammalian chronic RQs do not exceed LOCs (highest RQ = 0.64 for clothianidin's use on turf).

The risk concerns for non-endangered aquatic species were evaluated in a Tier II assessment using the PRZM/EXAMS model to predict surface water clothianidin concentrations. EFED identified spray drift and runoff to adjacent bodies of water as the most likely sources resulting in clothianidin exposure to nontarget aquatic organisms. The freshwater fish LC₅₀s (ranging from >105 to > 117 ppm) showed clothianidin and it's degradates (TMG, MNG, and TZNG) were, practically nontoxic to freshwater fish. Since there were no mortalities or effects at these imprecise LC₅₀ levels, which exceed predicted clothianidin EECs, EFED does not expect an acute risk to freshwater fish. Chronic exposure from the proposed clothianidin usage patterns should not pose direct risk to freshwater fish either. The chronic NOAEC for freshwater fish is 9.7 ppm. Predicted exposure levels are below levels triggering a chronic risk to freshwater fish. EFED's risk assessment suggests that toxic risk to estuarine/marine fish appears low, although there were no toxicity data to assess chronic risk. Clothianidin does not appear to present risk to terrestrial plants (there were no significant effects in the studies submitted). In addition, it does not appear to present risk to aquatic vascular or nonvascular plants.

For acute endangered aquatic species, levels of concern for freshwater invertebrates (RQs ranged from 0.067 to 0.086) were exceeded, should exposure actually occur. A probit slope response relationship was evaluated to calculate the chance of an individual event corresponding to the listed species acute LOCs. Analysis of raw data from the aquatic acute toxicity studies for clothianidin estimate a slope of 4.24 (95% C.I. 0.276 and 8.22) for freshwater invertebrates. However, based on this slope, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 5.76 x 10^7 for freshwater invertebrates.

The RQ for 15g mammals slighty exceeded (RQ = 0.12) the endangered species LOC (0.1), thus risk is possible should exposure actually occur. Analysis of raw data from mammalian acute toxicity studies for clothianidin provided an estimate of slope (7.61). However, based on this slope, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 7.21 x 10^{13} for small mammals.

There is uncertainty surrounding clothianidin's possible role as an endocrine disruptor as noted from mammalian developmental and reproductive effects. Data suggests that clothianidin could be a candidate for additional screening and/or testing to better characterize effects related to endocrine disruption. Effects in avian species included significant decreases in eggshell thickness. Effects in mammalian reproduction studies included decreased body weight gains and delayed sexual maturation (males only), decreased absolute thymus weight in F1 pups (both sexes), increased stillbirths (F1 and F2 litters), decreased sperm mobility and increased number of sperm with detached heads (F1 and F2 litters).

The available environmental fate data for clothianidin indicates that the chemical is highly persistent, mobile and systemic. It is stable to hydrolysis at all pHs at environmental temperatures, has the potential to leach to groundwater, be transported via runoff to surface water bodies, and could accumulate in soils from year to year with repeated uses. The major route of dissipation for clothianidin would appear to be photolysis if exposure to sunlight occurs (e.g. the measured aqueous photolysis half-life was <1 day and aerobic half-lives were 148 to 1155 days). Major degradates include TMG, MNG, and TZNG.

The uncertainties associated with clothianidin exposure in the environment are mainly focused in these areas; 1) accumulation of clothianidin in soils after repeated uses and the potential for transport/migration to surface water bodies and potential risk to sensitive aquatic invertebrates (e.g., sediment-dwelling benthic organisms); 2) repeated or continuous exposure of small mammals and birds to the pesticide presenting a potential reproduction and developmental risk; 3) the possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues to blooming, pollen-shedding or nectar-producing parts of plants that result from clothianidin's uses; and 4) repeated or continuous exposure to soil invertebrates and small mammals to clothianidin accumulated in soils after repeated uses.

Proposed risk refinement measures include source control measures such as reduction in the

application rate, reduction in the number of applications (especially in the presence of pollinators or nesting birds), and increasing the interval between applications may be implemented for clothianidin as possible risk reduction measures. Sediment toxicity testing of sensitive species (i.e. burrowing mayflies, 28-day chironomid study) would provide data to address the uncertainty of possible risk to invertebrates because clothianidin persists in the environment representing a continual source as an environmental sink. Aquatic field studies (simulated or actual) could be performed to determine system-wide effects to the assemblages of organisms in aquatic communities. In order to fully evaluate the possibility of chronic exposure to honey bees with subsequent impacts to pollination, a complete worker bee life cycle continues to be required as well as an evaluation of exposure and effects to the queen. Additional modeling should be done to simulate the potential affects of repeated uses in order to determine if reproduction and development are affected in birds, mammals, and soil invertebrates.

II. Physical/Chemical Properties Characterization

A summary of selected physical and chemical parameters for clothianidin is presented in Table II.a.

Table II.a. Some Phy	vsical-Chemical and Other Properties of Clothianidin
CAS Name	[C(E)]-N-[(2-chloro-5-thiazolyl)methyl]-N'-methyl-N''- nitroguanidine
IUPAC Name	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2- nitroguanidine
CAS No	210880-92-5 (previously 205510-53-8)
Empirical Formula	$C_6H_8ClN_5O_2S$
Molecular Weight	249.7
Common Name	Clothianidin
Pesticide Type	Insecticide
Chemical Family	Neonicotinoid
Color/Form	Clear and colorless/solid, powder
Odor	odorless
Melting Point	176.8°C
Flash Point	N/A
Relative Density	1.61 g/ml (at 20°C), 1.59 g/cm ³
Water Solubility	0.327g/L (at 20°C)

Table II.a. Some Ph	ysical-Chemical and Other Properties of Clothianidin
Solubility in other solvents	heptane <0.00104 g/L (at 25°C) xylene 0.0128 dichloromethane 1.32 methanol 6.26 octanol 0.938 acetone 15.2 ethyl acetate 2.03
Vapor Pressure	3.8 x10 ⁻¹¹ Pa (at 20°C)
Henry's Law Constant	2.9 x 10 ⁻¹¹ Pa x m3/mol
K _{ow}	1.12 (at pH 7)

Pesticide Type, Class, Mode of Action

Although nicotine has been used as a pesticide for over 200 years, it degraded too rapidly in the environment and lacked the selectivity to be very useful in large scale agricultural situations. However, in order to address this problem, the neonicotinoids (chloronicotinyl insecticides) were developed as a substitute of nicotine, targeting the same receptor site (AChR) and activating post-synaptic acetylcholine receptors but not inhibiting AChE. Clothianidin, like other neonicotinoids, is an agonist of acetylcholine, the neurotransmitter that stimulates the nAChR. In insects, neonicotinoids cause symptoms similar to that of nicotine. The symptoms appear rapidly as increased restlessness followed by violent convulsions and death. The advantage of clothianidin and other neonicotinoids over nicotine is that they are less likely to break down in the environment.

III. Use Characterization

Currently Approved Crops

The following crops appear in the currently approved labels of clothianidin:

Table III.a. Currently App	roved Crops for Cloth	ianidin	
Crop	Application Rate	Maximum Rate lbs ai/A	Number of applications
Corn	5.64 fl.oz/80,000 seeds	0.1	1
Canola	3.84 - 15.36 fl.oz/100 lbs seed	0.05	1

Application Rates

Table III.b. is a summary of the rates from the various product labels for all proposed applications.

 Table III.b. Use of Clothianidin on potatoes and grapes and as a seed treatment for sorghum and cotton.

Сгор	Product	Appl. Rate (lb ai/A)	Max # Appl	Max Yr. Rate (lbs ai/A)	Min. Interval (days)	Application Methods
Potato	Belay™ 16 WSG	0.2	N/A	0.2	N/A	Ground spray (in-furrow or side-dress)
Grape	Belay [™] 16 WSG	0.2	N/A	0.2	N/A	Ground spray (including drip irrigation/ chemigation)
Potato	Clutch [™] 50 WDG	0.0667	3	0.2	14	Foliar spray
Grape	Belay [™] 16 WSG; Clutch [™] 50 WDG	0.1	2	0.2	7 .	Foliar spray. Proposed Clutch label appears to only allow 2 app. @ 0.64 Ib.
Sorghum	Poncho [™] 600	0.02	N/A	0.02	N/A	Seed treatment
Cotton	AE 1283742 imidacloprid/ clothianidin mix	0.02	N/A	0.02	N/A	Seed treatment

IV. Problem Formulation

The planning stage for an ecological risk assessment entails initial discussions between risk assessor and risk manager in order to define time lines, management goals, and the problem formulation. The management goals for the registration of the new uses of clothianidin is the protection of terrestrial and aquatic environments from unreasonable adverse effects (death or injury).

Problem formulation is the critical first step in establishing the direction and scope of an ecological risk assessment. Part A of the Guidelines for Ecological Risk assessment states that "in problem formulation, the purpose for the assessment is articulated, the problem defined, and a plan for analyzing and characterizing risk is determined." The analysis plan and rationale for developing a risk assessment for clothianidin is an iterative procedure for determining if the proposed new uses of this compound could result in residue exposure that has the potential for unreasonable adverse effects (risk) to nontarget organisms, as well as endangered/threatened organisms. The portion of the problem formulation which is an explicit statement of the characteristic of the environment to be protected is encompassed in a delineation of endpoints. These endpoints can include a particular species, a functional group of species, a community, or

an ecosystem.

Relative to the proposed use of clothianidin, EFED initially had concerns for risk to aquatic organisms due to high persistence and potential mobility of clothianidin to surface waters. In the case of this assessment, EFED relied on the clothianidin hazard assessment which considers standard single chemical toxicity testing (acute and chronic endpoints) submitted by the registrant and reviewed by the Agency. EFED used this information for selection of the most sensitive species tested in order to generate RQ values. Effects data are included under the section "Characterization of Ecological Effects," and represent registrant submitted data. The effects database is mostly complete for freshwater and estuarine/marine aquatic organisms and thus is suitable for a screening level risk assessment. The major endpoints related to aquatic environments at issue are:

(a). Direct effects to aquatic invertebrates in the water column via acute toxicity.

(b). Direct effects to benthic aquatic organisms dwelling in the sediment and/or pore water via acute and/or chronic toxicity.

(c). Indirect effects to benthic community assemblages (i.e. reductions in diversity and abundance) dwelling in the sediment and/or pore-water.

(d). Indirect effects to aquatic ecosystems from benthic community disturbances.

In addition to the concern for aquatic ecosystems, EFED is also concerned with potential impacts to terrestrial species and functional groups, including pollinators; nectar and fruit eating birds, mammals, and insects; and soil-inhabiting invertebrates and mammals (i.e. earthworms, burrowing mammals). Available effects data are included under the section "Characterization of Ecological Effects," and represent registrant submitted data. Although EFED does not conduct RQ based risk assessments on beneficial insects, there is potential for direct toxic effects to honey bees as suggested by the toxicity data. The terrestrial effects database for these species and functional groups is incomplete and thus recommendations are made for additional studies or assessments to fill data gaps needed for a suitable screening level risk assessment. The major endpoints related to terrestrial environments at issue are:

(a). Direct effects to mammals, insects, and soil invertebrates via acute toxicity.

(b). Direct effects on reproduction to birds (eggshell thinning), mammals (endocrine disruption), and insects via chronic toxicity.

(c). Direct effects to insects via toxicity of residues on foliage.

(d). Direct effects to foraging activity of pollinators

(e). Indirect effects from soil ecosystem alterations

(f). Indirect effects from reduced crop yield from impact to pollinators.

Problem formulation focused mainly on laboratory and field studies which indicate that clothianidin is persistent and mobile, stable to hydrolysis, has the potential to leach to groundwater, be transported via runoff to surface water bodies, and could accumulate in soils with repeated uses. Thus, the initial emphasis of the screening risk assessment was primarily about possible risk to freshwater and estuarine/marine fish and invertebrates as well as to terrestrial birds, mammals, and invertebrates which may be exposed to residual clothianidin after

spray and seed treatment applications.

Tier I Aquatic Assessment

Since clothianidin is not applied directly to water, EFED identified spray drift and runoff to adjacent bodies of water as the most likely sources resulting in clothianidin exposure to nontarget aquatic organisms. Relative to these uses, EFED examined the physical/chemical properties of clothianidin, its fate and disposition in the environment, and mode of application (e.g., seed treatment and foliar spray application) in order to develop a conceptual model (Figure 1.0). This scenario depicts seed treatment application to cotton and sorghum or spray application to grape and potato, which may cause spray drift and runoff subsequent to a rainfall event resulting in potential contamination of adjacent bodies of water. These events involve exposure of the stressor (clothianidin) to aquatic organisms (receptor). The direct predicted effects include acute morbidity, effects on growth, development, and reproduction. Indirect effects may include alterations in the diversity and abundance of benthic organisms, which in turn could affect fish populations resulting in possible adverse effects to fish population diversity, recreational fisheries and commercial aquaculture, should exposure occur. These indirect effects could result in ecosystem instability of water bodies receiving the spray drift and surface runoff.

The Tier II assessment using the PRZM/EXAMS model to predict surface water clothianidin concentrations was sufficient for aquatic assessment. The environmental fate database is complete for the parent compound clothianidin and suitable for risk assessment. No transformation products were considered in the aquatic ecological assessment as the degradates database was incomplete with regard to environmental fate data. Degradates, such as MNG, TZMU, TZNG, TMG and NTG might potentially contaminate drinking water; however, because of the very long persistence of parent clothianidin (and relatively high soil mobility and low adsorption to soil and sediment) including the degradates in exposure modeling would not likely significantly increase the total exposure level estimates. Available toxicity data for the degradates indicates that with the exception of TZNG, the other degradation products (MNG, TMG, TZMU, and MU) either exhibited the same toxic responses as clothiniadin or were less toxic to aquatic organisms. Daphnia magna were more sensitive to TZNG than clothianidin with an acute 48-hr EC₅₀ of 64 mg/L (NOEC of 11.2 mg/L) [MRID 45422401]. All of the degradates were less toxic than clothianidin to Chironomus riparius (48-hr EC₅₀'s ranging from >83.6 - >102 ppm). TZNG was also less toxic than clothianidin but more toxic than the other degradates with an EC_{50} of 0.386 ppm) [MRID 45422414]. Aquatic fate studies indicated that TMG was the primary degradate to accumulate significantly in the aerobic aquatic studies (which were not strictly aerobic in the sediment where the TMG was found) and that no degradate was found to accumulate significantly in the anaerobic aquatic studies.

The Tier II level surface water assessment for clothianidin took into consideration registered and proposed label use patterns, application rates and methods of application. This information was used in combination with both registrant-submitted data (e.g., environmental fate and effects) and information gleaned from peer reviewed open literature, in order to characterize possible risk.

In order to emphasize the relationships between the stressor (clothianidin) and the assessment endpoints, and to evaluate the potential risk to aquatic organisms from the use of clothianidin, risk quotients (RQs) were calculated. Risk quotients are calculated from the ratio of estimated environmental concentrations (EECs) to eco-toxicity values. EECs are developed using several models which are based on the maximum application rate of clothianidin for the proposed uses and the physical and chemical characteristics of clothianidin. These RQs were then compared to the LOC's used by EFED for determining potential risk to non-target organisms and the subsequent need for possible regulatory action.

Tier I Terrestrial Assessment

Through this evaluation, EFED identified residues on grasses and foliage (in nectar and pollen), residues in fruit, and depositions in soil as the most likely sources resulting in clothianidin exposure to nontarget terrestrial organisms. Relative to these uses, EFED examined the physical/chemical properties of clothianidin, its fate and disposition in the environment, and mode of application in order to develop a conceptual model (Figure 1.0). This scenario depicts ground application to grapes and potatoes in addition to seed treatment of sorghum and cotton. Laboratory and field studies indicate that clothianidin is highly persistent (aerobic soil metabolism and terrestrial field dissipation half-lives ranging from half a year to several years) and could accumulate in soils with repeated uses. Studies also indicate that residues of clothianidin are present in nectar and pollen of summer rape plants 60 days after application (MRID 45422431, 45422432, 45422433, 45422435, 45422436, 45422437]. These events involve exposure of the stressor (clothianidin) to terrestrial birds, mammals, and invertebrates (receptors). The direct predicted effects include acute morbidity, effects on growth, development, and reproduction, and effects on behavior (foraging activity of pollinators). Indirect effects may include toxic effects to soil communities due to the persistence/accumulation of clothianidin in soils from repeated uses and the potential for reduced crop yield from the impact to pollinators.

As part of the Tier I terrestrial assessment, EFED modeled exposure concentrations of clothianidin to nontarget terrestrial plants and animals following the proposed application rates provided by the registrant. For terrestrial birds and mammals, estimates of initial levels of clothianidin residues on various food items, which may be contacted or consumed by wildlife, were determined using the Fletcher nomogram followed by a first order decline model. LD50 sq/ft estimates of risk were calculated for the seed treatment applications.

In order to emphasize the relationships between the stressor (clothianidin) and the assessment endpoints, and to evaluate the potential risk to terrestrial organisms from the use of clothianidin, risk quotients (RQs) were calculated. Risk quotients are calculated from the ratio of estimated environmental concentrations (EECs) to eco-toxicity values. EECs are developed using several models which are based on the maximum application rate of clothianidin for the proposed uses and the physical and chemical characteristics of clothianidin. These RQs were then compared to the LOC's used by EFED for determining potential risk to non-target organisms and the subsequent need for possible regulatory action.

V. Analysis

Analysis is a process that examines the two primary components of risk, exposure and effects, and their relationships between each other and site characteristics. The objective is to provide the

ingredients necessary for determining or predicting ecological responses to pesticide uses under exposure conditions of interest. The products of analysis provide the basis for estimating and describing risks in risk characterization.

Environmental Fate Characterization

Summary

Clothianidin appears to be a persistent compound under most field conditions. Based on analysis of the laboratory studies alone, the major route of dissipation for clothianidin would appear to be photolysis if exposure to sunlight occurs (e.g., the measured aqueous photolysis half-life was <1 day and aerobic half-lives were 148 to 1155 days). Although photolysis appears to be much more rapid than other avenues of degradation/dissipation of clothianidin in the laboratory studies, the very slow rate of dissipation that was observed in field studies suggests that photolysis probably is not significant under most actual-use conditions. Photolysis may be quite important in surface waters if residues have reached clear bodies of water and are in solution rather than bound to sediment. Clothianidin is stable to hydrolysis at environmental pHs and temperatures. Degradation is also relatively rapid under anaerobic aquatic conditions (overall half-life of 27 days); however, metabolic degradation occurs very slowly in aerobic soil. Clothianidin is mobile to highly mobile in the laboratory [soil organic carbon partition coefficients (Koc) values were 84 to 129 for all test soils except for a sandy loam soil which had a Koc value of 345], although only a modest amount of leaching was observed in the submitted field studies. Previous studies have confirmed that compounds with a similar combination of mobility and persistence characteristics have a potential to leach to ground water at some use sites. Volatilization is not expected to be a significant dissipation process.

Degradation and Metabolism

Metabolism in aerobic soil occurred very slowly. At 20°C, clothianidin degraded in two soils with a first-order half-life of 148 and 239 days (Hofchen and Laacher soil series), in seven soils ranging in texture from sand to silt loam with half-lives of 495 to 1,155 days (BBA 2.2, Quincy, Sparta, Crosby, Susan, Elder, and Howe soil series), and in a tenth soil with a half-life that was nominally calculated to be 6,931 days (Fugay soil series). Degradation was too little in the Fugay soil study to accurately calculate the degradation rate over the 1-year study period (r2 = 0.05).

Under anaerobic aquatic conditions, metabolic degradation occurred relatively quickly (half-life of 14 days in water; 37 days in sediment; 27 days overall). Clothianidin was <1% of the applied in the water at and after 120 days and was <2.0% in the silt loam sediment at and after 183 days. No major degradates were isolated; clothianidin was converted primarily to soil-bound residues.

Clothianidin photodegraded with half-lives of <1 day in sterile buffer solution in the laboratory and in natural water outdoors, and approximately 34 days in soil in the laboratory. The range of values (1 to 34 days) given for surface water-source drinking water represents uncertainty with regard to the importance of photodegradation in the long-term fate of clothianidin in natural waters. In the laboratory, clothianidin photodegraded in sterile aqueous pH 7 buffer solutions with a half-life of 6.2-6.8 hours, based on a 12-hour light/12-hour dark cycle. Major degradates were N-(2-clorothiazol-5-ylmethyl)-N'-methylurea (TMZU), methylurea (MU), methylguanidine (MG), 4-hydroxy-2-methylamino-2-imidazolin-5-one (HMIO), 7-methylamino-4H-imidazo[5,1b][1,2,5]thiadiazin-4-one (MIT), formamide (FA), and CO₂. Outdoors, clothianidin degraded in nonsterile river water with a half-life of 25.1 to 27.7 hours under a cycle of approximately 9 hours sunlight/15 hours darkness. Major transformation products were MG, HMIO, MU, Urea, TMG, 3-methylamino-1*H*-imidazo [1,5-*c*]imidazole (MAI), 2-chlorothiazol-5-ylmethanol (CTCA), and CO₂. There was no degradation in the control samples held in the dark, which is consistent with clothianidin's observed stability to hydrolysis.

On moist soil, clothianidin photodegraded with a half-life of 8.2 days based on continuous irradiation (estimated to be equivalent to 34.2 solar summer days in Phoenix, AZ); degradation was not significant in the dark. At study termination (equivalent to 71 days solar summer days in Phoenix, AZ), 22.3% of the clothianidin remained undegraded. No degradates accumulated to significant levels during the study.

Soil sorption and mobility

In laboratory batch equilibrium studies, clothianidin had medium mobility in a US sandy loam soil and high mobility in US loamy sand and clay loam and German sand and sandy loam soils. In batch equilibrium studies using the same soils and similar conditions, MNG was very highly mobile, TZMU was highly to very highly mobile, TZNG was moderately mobile, and TMG was immobile or had low mobility. The mobility of clothianidin appeared to decrease as the length of time clothianidin was in contact with the soil increased; the longer clothianidin was aged in treated soil, the less likely it was to desorb from that soil.

Field dissipation

Clothianidin is expected to dissipate very slowly under terrestrial field conditions, based on the results of five bare ground field experiments conducted in the US and Canada. Half-lives of clothianidin, based on residues in the 0-15 cm soil depth, were 277 days (Wisconsin sand soil, incorporated), 315 days (Ohio silt loam soil, not incorporated), 365 days (Ontario silt loam soil, incorporated), and 1,386 days (North Dakota clay loam soil, not incorporated), and could not be determined at a fifth site due to limited dissipation during the 25-month study (Saskatchewan silty clay loam soil, incorporated). Incorporation did not appear to be a significant factor in determining the rate of dissipation. Clothianidin was generally not detected below the 45 cm soil depth except at one site, where it moved into the 45-60 cm depth. No degradates were detected at >10% of the applied, and degradates were generally only detected in the 0-15 cm soil layer. However, in many cases most of the parent remained untransformed at the close of the study; further accumulation of degradates could have occurred. Degradates that were increasing in concentration or at least continuing to persist towards the close of one or more field dissipation studies were: MNG (MRID 45422336) TZNG (MRID 45422335, 45422333), and TZMU (MRID 45422335).

Two studies were conducted to investigate leaching of clothianidin under field conditions (MRIDS 45422331 and 45422508). These studies were conducted in the Federal Republic of Germany and were apparently designed to fulfill certain European regulatory requirements. In these monolith lysimeter studies, 42 to 59% of the applied remained in the soil approximately 3 to 4 years following the first of two applications, and residues were primarily undegraded

clothianidin. The loss of radioactivity was attributed by the authors to mineralization of clothianidin, since $\leq 1\%$ of the total residues were detected in the leachate. Clothianidin was not detected in the leachate. There was also a significant amount of TZNG and/ or MNG that remained in monolith lysimeters at the close of multi-year studies. In one study (MRID 45422331), analysis of the soil in the lysimeter three years after the original application of clothianidin revealed TZNG was present as about 5% of the applied clothianidin. When the soil was analyzed more than 4 years after application in another lysimeter study (MRID 45422508) about 3% of the applied was present as MNG and 2% was present as TZNG. The substantial amount of clothianidin parent remaining in the soil profile at the close of these studies indicates that further leaching of clothianidin may occur in following years if sufficient precipitation occurs.

Aquatic Exposure Characterization

Based on laboratory and field studies, the available data on clothianidin show that the compound is persistent and mobile, stable to hydrolysis and has potential to leach to groundwater as well as to runoff to surface waters. Assessments in this analysis have been based on the contamination potential of the parent compound clothianidin, which appears to be the most significant contaminant of surface and ground waters. However, we note that limited environmental fate data for the degradates indicate that some of these compounds may be mobile and persistent.

Tier II EECs for clothianidin were calculated using PRZM/EXAMS. PRZM/EXAMS is a screening model designed to estimate the pesticide concentration found in water for use in ecological assessments.

While no groundwater monitoring studies have been conducted, the registrant did submit monolith lysimeter study results. In these studies, (MRIDS 45422508 and 45422331) there was no parent clothianidin detected in the leachate. The degradates were detected in small quantities in the leachate. In one study, MNG and NTG were detected in leachate samples; in the other study none of the degradates in the leachate were identified. Clothianidin was extremely persistent and still potentially available for leaching at the close of the lysimeter studies (3 or 4 years after initial application), in both studies 42 to 59% of the applied radioactivity remained in the soil approximately 3 to 4 years following the first two applications and residues were primarily undegraded clothianidin. These results highlight the potential for very high persistence of clothianidin and some degradates and the possibility of leaching to groundwater occurring even in soils of fairly low permeability several years after application of clothianidin.

The current exposure assessment is based solely upon the parent compound. Our understanding of the potential exposure to degradates of clothianidin is constrained by the high persistence of clothianidin parent and the concomitant lack of significant accumulation of any specific product in most laboratory and field studies. Major degradates detected in one or more of the aqueous photolysis studies which might or might not be important under some actual use conditions are TZMU, TMG, MU and MG (however, these studies were of very short duration and these degradates did not accumulate in the longer 17-day soil photolysis studies). TZMU was shown to be an important hydrolysis product in pH 9 solution at elevated temperature (no significant hydrolysis was observed at any pH at 25° C). Little degradation of parent occurred in each of the

10 soils used for aerobic metabolism investigation (54 to 95% of the parent compound remaining in the soil at the close of these studies) but there was still some evidence of accumulation of TZNG, MNG and NTG in some of the test soils. TMG accumulated significantly in the aerobic aquatic studies (which were not strictly aerobic in the sediment where the TMG was found). In the anaerobic aquatic study, no degradate was found to accumulate significantly. In soil adsorption - desorption studies, MNG and TZMU were shown to be extremely mobile in soil and could, if they form and persist in the soil, be significant ground water contaminants. All four of the degradates for which soil sorption was investigated (MNG, TZMU, TZNG and TMG) could occur in runoff water if they form in significant amounts. No soil sorption studies were conducted for NTG. We conclude that degradates such as MNG, TZMU, TZNG, TMG and NTG might potentially contaminate water; however, because of the very long persistence of parent clothianidin (and relatively high soil mobility and low adsorption to soil and sediment) including the degradates in exposure modeling would not likely significantly increase the total exposure level estimates.

Estimated Environmental Concentrations (EECs) for Aquatic Ecological Effects Table Va summarizes the input values used in the PRZM/EXAMS model. Fate parameters were obtained from studies submitted by the registrant and modified, if necessary, according to the *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides, Version II* (February 28, 2002). The modeling results associated with the maximum allowable rate per year for representative crops are presented in Table Vb.

calculati	ng surface wate	r eecs.	
Parameter	Value	Source	Comments
Molecular weight (gMole ⁻¹)	249.7	MRID 45422317	
Vapor Pressure (Torr)	4.27x10 ⁻¹⁰	MRID 45422317	
Solubility (mg/L)	300	MRID 45422317	
Hydrolysis (days)	Stable	MRID 45422317	
Aquatic photolysis half-life (days)	1.1 to 34	MRID 45422323 (soil); 45422318, 45422322, 45422319, 45422321 (water)	Longest half-life of 34 days used instead of aqueo photolysis hald-life because of demonstrated persistence in water and on soil surface exposed t sunlight. Lower value of 1.1 days from natural wa photolysis study was not used in the modeling fo this assessment.
Organic carbon partition coefficient (KOC)	188	MRID 45422311	Mean Value
Soil aerobic metabolic half- life (days)	744*	MRIDs 45422325; 45422326	90% upper confidence bound on 9 values.
Aquatic metabolic half-life (days)	1,488	MRID 45422324	2X aerobic soil half-life used since there was no acceptable aerobic aquatic study

Parameter	Value	Source	Comments
Anaerobic Aquatic metabolic half-life (days)	27x3	MRID 45422320	Selected input parameters were multiplied by 3 according to Guidance for selecting input parameter in modeling for environmental fate and transport of pesticides. Version II. February, 2002.
Crop name	grapes, potato sorghum & cotton	Proposed label	
Maximum application rate (lb/acre)	seed=0.02 spray=0.2	Proposed label	
Number of applications	sced treatment=1 spray=variable	Proposed label	
Method of application	seed treatment or spray	Proposed label	
Incorporation depth (inches)	seed=0.75** spray=0	EFED	According to Guidance for selecting input parameter in modeling for environmental fate and transport of pesticides. Version II. February, 2002.
http://www.gaseed.com/PRODU Plant sorghum seed just beneath In heavy soils, plant at 3/4 - 1	the surface level. The 3/4 inch depth. plant u	soil is warmer there and the se	ed can germinate and emerge faster.
Planting just below the surface I http://www.uaex.edu/Other_Are The ultimate goal is to plant the the spring when soils are cool ar season as soils warm the plantin recommended.	as/publications/PDF/M grain sorghum seed as ad wet and rainfall is lil g depth may be increas	o attain moisture. ease and herbicide injury, whi P297/2_cultural_practices.pdf shallow as possible and still of kely to occur soon after plantin ed to a maximum depth of 1.5	y conditions. ch could result in suspended plant growth. btain good soil to seed contact. When planting early in g, a planting depth of 0.75 to 1 inch is best. Later in th inches. Planting deeper than 1.5 inches is not
Planting just below the surface I nttp://www.uaex.edu/Other_Are The ultimate goal is to plant the the spring when soils are cool ar season as soils warm the plantin recommended. Cotton seed treatment was also depth). References: nttp://www.ext.vt.edu/pubs/cott Planting depth depends on the y seedbed. http://www.oznet.ksu.edu/librar	helps prevent insect, dis as/publications/PDF/M grain sorghum seed as ad wet and rainfall is lil g depth may be increas assumed to be a uniforr on/424-300/planting.pd ear and sometimes the y/crps12/mf1088.pdf	o attain moisture. tease and herbicide injury, whi P297/2_cultural_practices pdf shallow as possible and still of tely to occur soon after plantin ed to a maximum depth of 1.5 nly incorporated application to ff day. Seed placement to a depth	y conditions. ch could result in suspended plant growth. btain good soil to seed contact. When planting early in g, a planting depth of 0.75 to 1 inch is best. Later in th inches. Planting deeper than 1.5 inches is not o a 0.75 inch (1.91 cm) depth (shallowest recommended of 3/4 inch in the soil is optimum in a good, moist
Planting just below the surface I http://www.uaex.edu/Other_Are The ultimate goal is to plant the the spring when soils are cool ar season as soils warm the plantin recommended. Cotton seed treatment was also depth). References: http://www.ext.vt.edu/pubs/cott	helps prevent insect, dis as/publications/PDF/M grain sorghum seed as ad wet and rainfall is lil g depth may be increas assumed to be a uniforr on/424-300/planting.pd ear and sometimes the y/crps12/mf1088.pdf	o attain moisture. tease and herbicide injury, whi P297/2_cultural_practices pdf shallow as possible and still of tely to occur soon after plantin ed to a maximum depth of 1.5 nly incorporated application to ff day. Seed placement to a depth	y conditions. ch could result in suspended plant growth. btain good soil to seed contact. When planting early in g, a planting depth of 0.75 to 1 inch is best. Later in th inches. Planting deeper than 1.5 inches is not o a 0.75 inch (1.91 cm) depth (shallowest recommende n of 3/4 inch in the soil is optimum in a good, moist

Table V.b.	below summarize	es results from	PRZM/EXAM	S.
	•		· · · · · ·	

Стор	Application rate (lbs ai/A)	Number of applications	Peak (ppb)	21 day (ppb)	60 day (ppb)
Sorghum (seed)	0.02	1	0.044	0.043	0.041
Cotton (seed)	0.02	1	0.153	0.149	0.143
Grape	0.2	1	0.600	0.577	0.546
Grape	0.1	2	1.070	0.916	0.849
Potato	0.2	. 1	1.408	0.548	0.232
Potato	0.0667	3	1.897	1.045	0.870

Terrestrial Effects Characterization

Avian and Mammalian Species

An extensive assessment of the potential exposure and risk to avian guideline species exposed to clothianidin by oral intubation or in the diet concluded that clothianidin was moderately toxic to bobwhite quail on an acute basis (LD_{50} > 200 mg/kg) and non-toxic to the mallard duck and bobwhite quail on a sub-acute basis (5 day LC_{50} >5040 ppm and 5230 ppm), respectively. A Tier I screening assessment based on the exposure of bobwhite quail to residual clothianidin after application (0.2 lb ai/A maximum application rate) was performed using the FATE model. Based on the proposed uses and application rates of clothianidin in this assessment, it is assumed acute exposure to avian species as the result of residual product on grass, fruits and berries as the result of field application would not present a risk to avian species.

The submitted chronic toxicity data show that exposure of 525 ppm of clothianidin in the diet adversely affected eggshell thickness (MRID #45422421). Because birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season, additional modeling should be done to determine if birds are at risk from repeated uses of clothianidin.

Likewise, an assessment of potential exposure and risk to small mammals exposed to clothianidin by the oral route suggests that clothianidin is moderately toxic to small mammals on

an acute oral basis (mouse $LD_{50} = 389$ to 465 mg/kg/day). A Tier I screening assessment based on the exposure of a mouse to residual clothianidin after application (0.2 lb ai/A maximum application rate) was performed using a FATE based model. Based on the proposed uses and application rates of clothianidin in this assessment it is assumed acute exposure to mammalian species as the result of residual product on grass, fruits and berries as the result of field application should not present risk. The RQ (0.12) for endangered 15g mammals exceeded the LOC. However, analysis of raw data from mammalian terrestrial acute toxicity studies for clothianidin provided an estimate of slope (7.61). Based on this slope, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 7.21 x 10¹³ for small mammals.

Reproduction studies in rats indicate that concentrations of 500 ppm clothianidin resulted in increased stillbirths and delayed sexual maturation in males. Developmental studies in rabbits indicate that concentrations of 75 mg/kg/day resulted in premature deliveries, decreased gravid uterine weights, and increased litter incidence of missing lung lobes/fetus. Because small mammals may feed on fruit or burrow in the soils and thus, be subject to repeated or continuous exposure to the pesticide, additional modeling should be done to determine if mammals are at risk from repeated uses of clothianidin.

Nontarget Insects and Terrestrial Invertebrates

Currently, EFED does not assess risk to nontarget insects or terrestrial invertebrates using the risk quotient method. However, it appears that clothianidin exposure to honeybees has the potential for high toxicity on both an acute contact and oral basis. Acute toxicity studies to honey bees show that clothianidin has the potential to be highly toxic on both a contact and an oral basis (contact $LD_{50} = 0.044 \ \mu g/bee$; oral $LD_{50} = 0.0037 \ \mu g/bee$), while its degradates (e.g.,, TMG, MNG, TZMU, and TZNG) are moderately to practically non-toxic on an oral basis ($LD_{50} = 3.9 - >153 \ \mu g/bee$). One honey bee field study (MRID # 45422435) showed that mortality, pollen foraging activity, and honey yield were negatively affected by residues of clothianidin; however, residues were not quantified in this study. Another honey bee field study (MRID 45422440) showed that pollen treated with clothianidin at a measured concentration level up to 19.7 μg a.i./kg produced no significant adverse effects to mortality, foraging activity (including pollen and honey collection), comb production, honey storage behavior, population growth (including egg, larvae, pupae, and adult growth stages), and behavioral anomalies. However, only one replicate hive per treatment level was tested, therefore, statistical analysis of the data could not be performed.

Pesticides toxic to honey bees require bee precautionary labeling on all end-use formulations and registrants are required to submit data in accordance with Guideline 141-2 - Honey Bee Toxicity of Residues on Foliage. A scientifically sound study was performed. Alfalfa foliage was sprayed with Clothianidin, as V-10066, at application rates of 30, 60, and 90 g a.i./acre. Honey bees, three replicates/rates, were exposed in the lab to the weathered foliage at varying times until the mortality of bees exposed to residues was lower than 25%. Sublethal observations were also

made. The RT_{25}^2 for clothianidin (V-10066) at 30 (0.07 lb ai/A), 60 (0.13 lb ai/A), and 90 (0.21 lb ai/A) g a.i./acre were 111.68 (4.7days), 179.51 (7.5days), and 512.39 (21.3days) hours, respectively. The rates of application were determined to be highly hazardous to honey bees. Results indicate that clothianidin, as V-10066, should not be applied to blooming, pollinating, or nectar producing parts of plants.

Subchronic invertebrate toxicity studies showed that clothianidin adversely affected earthworm mortality and body weight ($LC_{50} = 15.5$ ppm) and its degradates reduced body weight ($LC_{50} = 982.6$ ppm). There were no apparent effects of clothianidin on earthworm reproduction or population dynamics.

VI. Risk Characterization

Risk Estimation

2

A means of integrating the results of exposure and ecotoxicity data is called the deterministic method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on non-target organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals) (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). An example of a toxicity test effect level derived from the results of long-term laboratory studies that assess chronic effects is: (1) NOAEC (birds,

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 RT_{25} is the residual time required to reduce the activity of the test material and bring bee mortality down to 25% in cage test exposures to field-weathered spray deposits (Mayer and Johansen, 1990). The time period determined by this toxicity value is considered to be time that the test material is expected to remain toxic to bees in the field from the residual exposure of the test material on vegetation at an expressed rate of application (lb ai/A).

fish and aquatic invertebrates).

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below:

Risk Presumption	RQ	LOC
Birds:		
Acute High Risk	EEC1/LC50 or LD50/sqft ² or LD50/day ³	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1
Wild Mammals:		
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1

EEC=abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items <u>mg/ft²</u> LD50 * wt. of bird mg of toxicant consumed/day LD50 * wt. of bird

Risk Presumption	RQ	LOC
Acute High Risk	EEC ¹ /LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOAEC	· 1

EEC = (ppm or ppb) in water

Table VI.c. Risk Presumptions for	or Plants	
Risk Presumption	RQ.L.	LOC
Terrestrial and Semi-Aquatic Plants:		
Acute High Risk	EEC ¹ /EC25	1
Acute Endangered Species	EEC/EC05 or NOAEC	. 1
Aquatic Plants:		
Acute High Risk	EEC ² /EC50	1
Acute Endangered Species	EEC/EC05 or NOAEC	1

 1 EEC = 1bs ai/A

² EEC = (ppb/ppm) in water

Exposure and Risk to Nontarget Freshwater Aquatic Animals

Non-target aquatic organisms (freshwater and estuarine/marine fishes and invertebrates) can be exposed to clothianidin by spray drift and runoff into surface water.

Freshwater Fish

Acute and chronic risk quotients are tabulated in Table VI.d. An analysis of the acute test results show there were no mortalities or effects at the indefinite $LC_{50}s$ shown and, though indecisive, these acute toxicity values are well above predicted EECs. Because of this, EFED did not calculate acute RQ values for the proposed uses. EFED does not expect risk to freshwater fish. Chronic exposure from the proposed clothianidin usage patterns should not pose direct risk to freshwater fish either. The chronic NOAEC for freshwater fish is 9.7 ppm. These predicted exposure levels are below levels triggering a chronic risk to freshwater fish.

Table VI.d.	() () C	Risk Quotients for Freshwater Fish Based On Acute Exposure (LC50 >105 ppm) to Rainbow Trout (Oncorhynchus mykiss) and Chronic Exposure (NOAEC = 9.7 ppm) to Fathead Minnow (Pimephales promelas)					
Crop/application	Organism	LC50 (ppm)	NOAEC (ppm)	EEC Acute (ppb)	EEC Chronic (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAE)
Potato (0.2 x 1)	Rainbow trout	>105	N/A	1.408	N/A	0.00	N/A
	Fathead Minnow	N/A	9.7	N/A	0.232	N/A	0.00
Potato (0.0667 x3)	Rainbow trout	>105	N/A	1.897	N/A	0.00	N/A
	Fathead Minnow	N/A	9.7	N/A	0.870	N/A	0.00
Grape (0.2 x 1)	Rainbow trout	>105	N/A	0.600	N/A	0.00	N/A
	Fathead Minnow	N/A	9.7	N/A	0.546	N/A	0.00
Grape (0.01 x 2)	Rainbow trout	>105	N/A	1.070	N/A	0.00	N/A
· · · · · · · · · · · · · · · · · · ·	Fathead Minnow	N/A	9.7	N/A	0.849	N/A	0.00
Sorghum seed (0.02 x 1)	Rainbow trout	>105	N/A	0.044	N/A	0.00	N/A
	Fathead Minnow	N/A	9.7	N/A	0.041	N/A	0.00
Cotton seed (0.02 x 1)	Rainbow trout	>105	N/A	0.153	N/A	0.00	N/A
	Fathead Minnow	N/A	9.7	N/A	0.143	N/A	0.00

Freshwater Invertebrates

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The acute and chronic risk quotients are tabulated in Table VI.e. EFED's evaluation of the calculated RQ values show that the proposed use of clothianidin on potatoes may result in acute risk to endangered aquatic freshwater invertebrates (RQs ranged from 0.00 to 0.086). Chronic RQ values (RQs ranged from 0.00 to 0.14) for freshwater invertebrates appear to be below EFED's LOC, suggesting low chronic risk.

Table VI.e.	Exj	Risk Quotients for Freshwater Invertebrates Based On Acute Exposure (EC50 = 0.022 ppm) to <i>Chironomus riparius</i> and Chronic Exposure (NOAEC = 0.042 ppm) to <i>Daphnia magna</i>						
Crop/application	Organism	LC50 (ppm)	NOAEC (ppm)	EEC Acute (ppb)	EEC Chronic (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)	
Potato (0.2 x 1)	Chironomus riparius	0.022	N/A	1.408	N/A	0.067	N/A	
	Daphnia magna	N/A	0.042	N/A	0.548	N/A	0.013	
Potato (0.0667 x 3)	Chironomus riparius	0.022	N/Å	1.897	N/A	0.086	N/A	
	Daphnia magna	N/A	0.042	N/A	1.045	N/A	0.024	
Grape (0.2 x 1)	Chironomus riparius	0.022	N/A	0.600	N/A	0.027	N/A	
	Daphnia magna	N/A	0.042	N/A	0.577	N/A	0.14	
Grape (0.1 x 2)	Chironomus riparius	0.022	N/A	1.070	N/A	0.048	N/A	
· · · · · · · · · · · · · · · · · · ·	Daphnia magna	N/A	0.042	N/A	0.916	N/A	0.021	
Sorghum seed (0.02 x 1)	Chironomus riparius	0.022	N/A	0.044	N/A	0.00	N/A	
	Daphnia magna	N/A	0.042	N/A	0.043	N/A	0.00	
Cotton seed (0.02 x 1)	Chironomus riparius	0.022	N/A	0.153	N/A	0.00	N/A	
Chironomus riparius 48hr EC	Daphnia magna	N/A	0.042	N/A	0.149	N/A	0.00	

⁷Chironomus riparius 48hr EC50 = 0.022 ppm ² Daphnia magnia NOAEC/LOAEC = 0.042/0.12 ppm reproductive effects

Estuarine and Marine Fish

The acute risk quotients are tabulated in Table VI.f. An analysis of the acute test results show that since there were no mortality or effects (limited studies) RQ values would not be calculated for the proposed usage and that acute risk to estuarine/marine fish is not expected.

Table VI.f. Risk Quotients for Estuarine/Marine Fish Based on Acute Exposure (LC50 >93.6 ppm) to Sheepshead Minnow (Cyprinodon variegatus)								
Сгор	Organism	LC50 (ppm)	NOAEC (ppm)	EEC Acute (ppb)	Acute RQ (EEC/LC50) (EEC/NOAEC)	Chronic RQ		
Potato (0.2 x 1)	Sheepshead	>93.6	N/A	1.408	0.00	N/A		
Potato (0.0667 x3)	Sheepshead	>93.6	N/A	1.897	0.00	N/A		
Grape (0.2 x 1)	Sheepshead	>93.6	N/A	0.600	0.00	N/A		
Grape (0.1 x 2)	Sheepshead	>93.6	N/A	1.070	0.00	N/A		
Sorghum seed (0.02 x 1)	Sheepshead	>93.6	N/A	0.044	0.00	N/A		
Cotton seed (0.02 x 1)	Sheepshead	>93.6	N/A	0.153	0.00	<u>N/A</u>		

Estuarine and Marine Invertebrates

The acute and chronic risk quotients are tabulated in Table VI.g. EFED's evaluation of the calculated RQ values show that the proposed use of clothianidin should not result in acute risk to aquatic estuarine/marine invertebrates (RQs ranged from 0.00 to 0.04). Chronic RQ values (RQs ranged from 0.0 to 0.20) also do not exceed the LOC and suggest low chronic risk to estuarine/marine invertebrates.

Table VLg Risk Quotients for Estuarine/Marine Invertebrates Based on Acute (LC50 = 0.051 ppm) and Chronic Toxicity Values (NOAEC = 0.0051 ppm) for Mysid Shrimp (Mysidopsis bahia)								
Сгор	Organism	LC50 (ppm)	NOAEC (ppm)	EEC Acute (ppb)	EEC Chronic (ppb)	Acute RQ (EEC/LC50)	Chronic RQ (EEC/NOAEC)	
Potato (0.2 x 1)	Mysid	0.051	0.0051	1.408	0.548	0.03	0.10	
Potato (0.0667 x 3)	Mysid	0.051	0.0051	1.897	1.045	0.04	0.20	
Grape (0.2 x 1)	Mysid	0.051	0.0051	0.600	0.577	0.01	0.11	
Grape (0.1 x 2)	Mysid	0.051	0.0051	1.070	0.916	0.02	0.18	
Sorghum seed (0.02 x 1)	Mysid	0.051	0.0051	0.044	0.043	0.00	0.00	
Cotton seed (0.02 x 1)	Mysid	0.051	0.0051	0.153	0.149	0.00	0.00	

Terrestrial Risk Quotients and Comparison to LOCs

Avian and Terrestrial Mammals

Predicted residual concentrations (EECs) of clothianidin were compared to toxicity values for northern bobwhite quail and mouse to estimate acute and chronic risk quotients (Table VI h). The quail and mouse were chosen as representative terrestrial bird and mammal, respectively. Avian acute and chronic RQs were less than the LOCs (0.5 to 0.1 and 1, respectively). However, the mammalian acute RQ (RQ = 0.12) for 15g mammals slightly exceeded the endangered species LOC of 0.1. Mammalian chronic RQs did not exceed chronic LOCs for both endangered and non-endangered species. Neither endangered and non-endangered birds or mammal species are at risk from ingestion of clothianidin treated seed (Table VI i). It would seem unlikely birds or mammals would or could ingest the amount of seed needed to reach an LD50 dose.

Table VI.h			10 ppm; NOAEC = 205 to Clothianidin Residu		manan (1050 = 389
Crop	Organism	Short Grass	Broadleaf Grass/ Small Insects	Large Insects	Seeds and Fruit
Grapes and	Avian EEC	48	22	27	3
potatoes	Acute	0.00	0.00	0.00	0.00
0.2 x 1 app	Chronic	0.2	0.1	0.1	0.07
Grapes and	Mammal EEC	48	22	27	3
potatoes	Acute (15g)	0.12	0.05	0.06	0.00
0.2 x 1 app	Acute (35g)	0.08	0.04	0.04	0.00
	Acute (1000g)	0.019	0.00	0.01	0.00
	Chronic	0.3	0.1	0.2	0.02

¹ RQs determined by a FATE based model. Avian RQs based on bobwhite quail acute and chronic toxicity values. Mammalian RQs based on acute mouse toxicity values.

Table VI.i

Avian Acute Risk Quotients for Single Applications of Clothianidin Treated Seed Based on a Japanese Quail (*Coturnix coturnix japonica*) LD50 of 423 mg ai/kg.

Site/Application Method Pounds Planted Seed per Acre ³ Seed Treatment (lb ai/100 lb seed) Row width (feet)	Application Rate (lb ai/A)	Bird Body Weight (grams)	% (decimal) of Pesticide Left on the Surface ⁶	Exposed ¹ (mg ai/sq. ft)	Acute RQ ² (LD50/sq. ft)	Seeds per pound ³	Mg ai per seed ⁴	Number of Seeds Consumed to Reach LD50 ⁵
Cotton [®] /In-furrow- Incorporated 10 0.22 0.1	0.022	20 180 1000	0.01	0.07	0.0081 0.0009 0.0002	3,636	0.27	31 278 1,544
Sorghum ^b /In-furrow- Incorporated 9 0.25 0.1	0.022	20 180 1000	0.01	0.03	0.0035 0.0004 0.0001	25,000	0.045	187 1,679 9,326

1 Exposed = App. Rate (lbs ai/A)* 453,590 mg/lbs * % (decimal) on surface/[linear ft of row/A (ft/A)* row width(ft)]

2 RQ = Exposed (mg ai/sq ft)/[LD50 (mg ai/kg) * Weight of the Animal (g)/1000 (g/kg)]

RQ greater or equal to 0.5 exceeds acute high, acute restricted use and acute endangered species LOCs.

RQ greater or equal to 0.2 exceeds acute restricted use and acute endangered species LOCs.

RQ greater or equal to 0.1 exceeds acute endangered species LOCs.

3 Sources: Cotton: (EPA file source); Code of Federal Regulations, Section 7, Part 201, Federal Seed Act Regulations (2003) & AE 1283742 label

Sorghum: (EPA file source); Code of Federal Regulations, Section 7, Part 201, Federal Seed Act Regulations (2003); & Clothianidin 600 FS label

4 Mg ai per seed = seed treatment rate (lb ai/100lb seed)/100 lb seed/seeds per lb * 453, 590 mg/lb

5 Number of Seeds Consumed to Reach LD50 = [LD50(mg ai/kg) * Weight of the Animal (g)/1000 (g/kg)]/mg ai per seed

6 Incorporation efficiency: Banded (covered with specified amount of soil), in-furrow, drill or shanked-in = 99% Side-dress, banded or broadcst (all mixed or lightly incorporated with soil) = 85%

Side-dress, banded, broadcast, aerial broadcast (all unincorporated) = 0%

a Assumes 36 inch row spacing or 14,520 linear ft of row per acre

b Assumes 15 inch row spacing or 34,848 linear ft of row per acre

Mammalian Acute Risk Quotients based on LD50 sq ft for Single Applications	of Clothianidin Treated Seed
Based on a Mouse (Mus musculus) LD50 of 389 mg ai/kg.	
Jubeu en u meube (mus museumus) 1250 et 665 mg unge	

Site/Applicat ion Method Pounds Planted Seed per Acre ³ Seed Treatment (lb ai/100 lb seed) Row width (feet)	Application Rate (lb ai/A)	Mammal Body Weight (grams)	% (decimal) of Pesticide Left on the Surface ⁶	Exposed ¹ (mg ai/sq. ft)	Acute RQ ² (LD50/sq. ft)	Seeds per pound ³	Mg ai per seed ⁴	Number of Seeds Consumed to Reach LD50 ⁵
Cotton ^a /In- furrow- Incorporated 10 0.22 0.1	0.022	15 35 1000	0.01	0.07	0.012 0.005 0.0002	3,636	0.27	21 50 1,420
Sorghum ^b /In- furrow- Incorporated 9 0.25 0.1	0.022	15 35 1000	0.01	0.03	0.0050 0.0022 0.0001	25,000	0.045	129 300 8,576

1 Exposed = App. Rate (lbs ai/A)* 453,590 mg/lbs * % (decimal) on surface/[linear ft of row/A (ft/A)* row width (ft)]

2 RQ = Exposed (mg ai/sq ft)/[LD50 (mg ai/kg) * Weight of the Animal (g)/1000 (g/kg)]

RQ greater or equal to 0.5 exceeds acute high, acute restricted use and acute endangered species LOCs.

RQ greater or equal to 0.2 exceeds acute restricted use and acute endangered species LOCs.

RQ greater or equal to 0.1 exceeds acute endangered species LOCs.

3 Sources: Cotton (EPA file source); Code of Federal Regulations, Section 7, Part 201, Federal Seed Act Regulations (2003) & AE 1283742 label

Sorghum: (EPA file source); Code of Federal Regulations, Section 7, Part 201, Federal Seed Act Regulations (2003); & Clothianidin 600 FS label

4 Mg ai per seed = seed treatment rate (lb ai/100lb seed)/100 lb seed/seeds per lb * 453, 590 mg/lb

5 Number of Seeds Consumed to Reach LD50 = [LD50(mg ai/kg) * Weight of the Animal (g)/1000 (g/kg)]/mg ai per seed

6 Incorporation efficiency:Banded (covered with specified amount of soil), in-furrow, drill or shanked-in = 99%Side-dress, banded or broadcst (all mixed or lightly incorporated with soil) = 85%Side-dress, banded, broadcast, aerial broadcast (all unincorporated) = 0%

a Assumes 36 inch row spacing or 14,520 linear ft of row per acre b Assumes 15 inch row spacing or 34,848 linear ft of row per acre

Nontarget Insects and Plants

Insects

Currently, EFED does not assess risk to non-target insects using an RQ method. Results of acceptable studies are used for recommending appropriate label precautions. Direct contact and dietary exposure studies of honeybees indicate that clothianidin is highly toxic to honeybees (acute contact $LD_{50} = 0.0439 \ \mu g$ /bee and acute oral $LD_{50} = 0.0037 \ \mu g$ /bee). There is the potential for toxic exposure to honeybees, as well as other nontarget pollinators, through the translocation of clothianidin residues in nectar and pollen. In addition, studies indicate that clothianidin residues may affect foraging behavior. Data from studies determining the toxicity of residues on foliage indicate that clothianidin will remain toxic to bees for days after a spray application. In honey bees, the effects of this toxic exposure may include lethal and/or sublethal effects in the larvae and reproductive effects to the queen. The field study EFED is requesting should resolve uncertainties dealing with clothianidin's affects on bees.

Plants

Clothianidin does not appear to present risk to terrestrial plants (seedling emergence $EC_{25} > 0.2$ lbs ai/A; vegetative vigor EC25 > 0.2 lbs ai/A). In addition, it does not appear to present risk to aquatic vascular plants (*Lemna gibba* $EC_{50} > 121$ ppm) or aquatic nonvascular plants (*Selenastrum capricornutum* EC_{50} averages 70 ppm) although EFED is still requesting aquatic nonvascular plant testing on four more surrogate species. The maximum peak, 21-day, and 60-day of modeled EECs were 1.897 to 0.870 ppb for 3 application on potato fields. This predicted exposure level is below levels triggering an acute risk to aquatic plants.

Risk Description Characterization

Clothianidin's major risk concern is to nontarget insects (that is, honey bees). EFED expects adverse effects to bees if clothianidin is allowed to be sprayed on blooming, pollen-shedding, or nectar producing parts of plants. Avian acute and chronic RQs were less than the LOCs (0.5 to 0.1 and 1, respectively). However, the mammalian acute RQ (RQ = 0.12) for 15g mammals

slightly exceeded the endangered species LOC of 0.1. Mammalian chronic RQs did not exceed LOCs for either endangered and non-endangered species. Neither endangered and non-endangered birds or mammal species are at risk from ingestion of clothianidin treated seed. It would seem unlikely birds or mammals would or could ingest the amount of seed needed to reach an LD50 dose. Clothianidin does not appear to present risk to terrestrial (there were no significant effects in the studies submitted), aquatic vascular or nonvascular plants. Lastly, acute endangered species LOCs for 15 g mammals and freshwater invertebrates were exceeded thus risk is possible should exposure actually occur. However, the estimated chance of individual mortality following clothianidin exposure is 1 in 7.21 x 10^{13} for small mammals and 1 in 5.76 x 10^7 for freshwater invertebrates.

The available data on clothianidin shows that the compound is relatively persistent to very persistent under most circumstances. Clothianidin is stable to hydrolysis at all pH's at environmental temperatures, moderately to highly stable under aerobic soil metabolism conditions (half-lives range from 148 to 6,900 days), and shows moderate stability under anaerobic aquatic metabolism (half-life of 27 days for the overall system). Laboratory data suggests that photolysis appears to play a role in the dissipation of the chemical (half-life of 14.4 hours in sterile water, 25.4 hours in natural water, and 34 days on soil). Clothianidin has medium to very high mobility in soils. The fact that the K_{0C} 's of four of the five soils were of similar order of magnitude (range 84 to 129) indicates that there may be a correlation of the mobility with the organic carbon content of the soil. Certain degradates appeared to accumulate in some soils under some conditions [e.g., TZNG MNG, NTG, (aerobic) and TMG (anaerobic)]; over the very long term significant contamination of soil and water with these products might occur. The terrestrial field dissipation studies confirm the findings in the laboratory studies. Clothianidin was found to be persistent in the field (half-lives of 277 days, 1,400 days, and too high to calculate). Based on the overall picture that the laboratory and field studies provided, EFED concluded that there is a very high likelihood that clothianidin would persist and accumulate from year to year after repeated uses.

The potential impact to water quality from the use of clothianidin appears to be most likely due to the parent compound. The laboratory studies indicate that clothianidin is initially labile and then relatively persistent under most environmental conditions. This makes the chemical available for lengthy periods of time for runoff and exposure to aquatic environments. The impact of clothianidin to aquatic environments will also be affected by its mobility. The available studies indicated that clothianidin is persistent and mobile, stable to hydrolysis and has potential to leach to ground water and be transported via runoff to surface water, and will accumulate and persist in soils.

Non-target aquatic organisms (freshwater and estuarine/marine fish and invertebrates) can be exposed to clothianidin by runoff or spray drift into surface water. However, EFED's risk assessment suggests that toxic risk to freshwater and estuarine/marine fish and invertebrates appears low. Acute, restricted use, and endangered species levels of concern for fish and invertebrates were not exceeded for application rates and uses evaluated. However, there is the

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possibility of acute toxic risk (RQ = 0.086) to freshwater benthic invertebrates, via runoff especially if repeated uses occur. Because the clothianidin toxicity threshold is low for freshwater benthic invertebrates on an acute basis, their vulnerability represents acute potential risk from accumulations of clothiandin in sediments. As a dynamic trophic level, invertebrates add to the diversity of an aquatic system. Since clothianidin is persistent in the sediment, sediment toxicity testing will be needed to address the uncertainty of possible risk to the assemblages of benthic communities in order to determine potential impacts to aquatic systems.

EFED's risk characterization of terrestrial animals was focused on the potential for acute and chronic toxic risk from exposure to residual clothianidin after application. Based on proposed application rates and uses, acute risks to terrestrial birds and mammals is unlikely. Mammalian chronic RQs also did not exceed LOCs for both endangered and non-endangered species. No species were at risk from ingestion of clothianidin treated seed. It would seem unlikely small birds or mammals would or could ingest the amount of granules needed to reach an LD50 dose.

There is uncertainty surrounding clothianidin's possible role as an endocrine disruptor as noted from mammalian developmental and reproductive effects. This issue is compounded by the fact that clothianidin is an analog of nicotine and that studies in the published literature suggest that nicotine, when administered, causes developmental toxicity, including functional deficits, in animals and/or humans that are exposed in utero. Mammalian data shows that exposure to clothianidin can result in developmental effects (rabbit) that include premature deliveries, decreased gravid uterine weights, and increase incidence of missing lung lobe in fetus. The mammalian data also suggests that chronic toxicity in mammals can be manifested as systemic effects that can include decreased body weight gains and delayed sexual maturation (males only); decreased absolute thymus weight in F1 pups (both sexes), and increased stillbirths (F1 and F2 litters). Reproductive effects were also noted for adult rats that included decreased sperm motility and increased number of sperm with detached heads. Although these effects did not reduce rat fecundity, they do raise an uncertainty as to possible reproductive effects to other species that may have a more limited (less frequent) reproductive capability. Because small mammals may feed on fruit and thus, be subject to repeated or continuous exposure to the pesticide, additional modeling should be done to determine if mammals are at risk from repeated uses of clothianidin.

Accumulation of clothianidin in soils as the result of multiple applications and repeated or continuous exposure may adversely affect soil invertebrates. Subchronic invertebrate toxicity studies showed that clothianidin adversely affected earthworm mortality and body weight ($LC_{50} = 15.5$ ppm) and its degradates reduced body weight ($LC_{50} = 982.6$ ppm). Additional testing (chronic study) or modeling is needed to determine if soil invertebrates are at risk from repeated uses of clothianidin. Because small mammals may burrow in the soils, additional modeling should be done to determine if mammals are at risk from repeated uses of clothianidin.

Although EFED does not conduct a risk quotient based risk assessment on non target insects, information from standard tests and field studies, as well as incident reports involving other neonicotinoids insecticides (e.g., imidacloprid) also suggest the potential for long term toxic risk

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to honey bees and other beneficial insects. Other neonicotinoid compounds like imidacloprid (e.g., sunflower seed treatment) have resulted in incidents to honey bees. The National Union of French Beekeepers had concerns regarding imidacolprid (GAUCHO) seed treatment to sunflowers after beekeepers noted that honey bees were showing modifications of behavior that were reflected in foraging and orientation that eventually resulted in a drastic change in hive conditions and bee survival. Further research by the Le Centre Technique Interprofessional des Oleagineux (CETIOM) confirmed imidacloprid toxic residue levels in the sunflower nectar. This action has prompted France to ban the use of imidacloprid for sunflower seed treatment. Since clothianidin has a similar toxicity profile as imidacloprid and is a member of the same family of compounds, there is uncertainty regarding the toxic risk to honey bee development and foraging behavior, as well as the welfare of the queen from long term exposure to clothianidin residues that can be stored in the hive in honey and/or pollen. Further studies may be needed to determine toxicity to honeybees from granular, seed treatment or foliar spray applications.

The uncertainties associated with clothianidin exposure in the environment are mainly focused in four areas; 1) accumulation of clothianidin in soils after repeated uses and the potential for transport/migration to surface water bodies and potential risk to sensitive aquatic invertebrates (e.g., sediment-dwelling benthic organisms), 2) repeated or continuous exposure of small mammals and birds to the pesticide presenting a potential reproduction and developmental risk, 3) potential toxic risk to pollinators (e.g. honeybees) as the result of accumulation of foliar spray on plants/blooms from repeated uses in orchards, and 4) repeated or continuous exposure to soil invertebrates and small mammals to clothianidin accumulated in soils after repeated uses.

Incident Characterization

The EPA/OPP 6(a)(2) incident reporting data base currently does not contain incident reports for clothianidin. However, other neonicotinoid compounds like imidacloprid have resulted in incidents to honey bees. The National Union of French Beekeepers had concerns regarding imidacloprid (GAUCHO) seed treatment to sunflowers. Beekeepers noted that bees were showing modifications of behavior that was reflected in foraging and orientation that eventually resulted in a drastic change in hive conditions and bee survival. Further research by the CETIOM confirmed imidacloprid toxic residue levels in the sunflower nectar. France has banned the use of imidacloprid for sunflower seed treatment. This may be a concern since AE 1283742 seed treatment contains not only clothianidin, but also imidacloprid

Endocrine Disruption

Data suggests that clothianidin could be a candidate for additional screening and/or testing to better characterize effects related to endocrine disruption. Effects in avian species included significant decreases in eggshell thickness. Effects in mammalian reproduction studies included decreased body weight gains and delayed sexual maturation (males only), decreased absolute thymus weight in F1 pups (both sexes), increased stillbirths (F1 and F2 litters), decreased sperm mobility and increased number of sperm with detatched heads (F1 and F2 litters).

EPA is required under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by

FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and or testing protocols being considered under the Agency's Endocrine Disruptor Screening and or testing to better characterize effects related to endocrine disruption.

Threatened and Endangered Species Concerns

The following section discusses the screening level assessment for Federally listed threatened and endangered species (listed species).

Applications

For scenarios used to evaluate risk to aquatic organisms, the LOC (0.05) for acute effects to listed species of freshwater invertebrates (RQs ranged from 0.067 to 0.086) were exceeded for the potato use for both single and multiple applications.

For listed species of small mammals, clothianidin may pose slight acute (RQ = 0.12) risk of adverse effects, should exposure actually occur. Endangered small (15g) mammal species may be at risk from ingestion of clothianidin treated food items. No species were found to be at risk from ingesting treated seed. It would seem unlikely that small birds or mammals would or could ingest the amount of granules needed to reach an LD50 dose.

Endangered insects may also be at risk due to the toxicity profile for honeybees (clothianidin is toxic to honeybees thus risk is assumed) should exposure actually occur.

Listed Species

The following table lists the number of listed species within taxonomic groups for which RQs exceed the listed species LOCs. Some of these listed species may not be at risk through exposure to clothianidin based on size, food items and habitat. The entire list of listed endangered/threatened species is given in Appendix VI.

Crop	STATE	Mammal	Crustacean	Arachnids_	Insects	Snails	Clams
Grape							
	AL	4	1			10	29

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	AZ	. 8				1	
· · ·	AR	3	1		1	1	6
* •	CA	22	8		22	1	
. ·	СО	2			1		
-	СТ	1			1		1
	DE	1			•	· · ·	
•	FL	. 8	1				7
,	GA	4					16
	HI	2	1	1	1	1	•
	ID	4	-			- 6	
	IL .	2	1		2	1	6
- · ·	IN	2			2		9
· · · ·	IA	1				1	2
	KS	2			2		
•	KY	3	1				21
	LA	2	. · · ·				2
	ME	1					
	MD	2			2		1
	MA	1.		÷	3		
	MI	2			3		. 2
	MN	1	,				2
	MS	1					3
	МО	2	2	• .	1	1	5
	MT	3					
	NE	1	-				
	NV				· - 1		
	NH	1	•		1		• 1
	NJ	1					
	NM	. 5	1			2	
	NY	1			1	1	1
	NC	5		1 .	1	1	5

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	·	<u>`</u>				5
ND						
ОН	1			1		6
OK	3			1		2
OR	· 1	1		2		
PA	2					2
RI	1			1		
SC	2					1
SD	1			1		
TN	4	1	1		2	27
TX	5	1	10	8		
UT	2					
VT	. 1					1
VA	5	2		1	1	18
WA	4			1 .		
WV	4				1	. 3
WI	1			2		2
WY.	1					
	60	19	12	42	29	69
					;	
AL	4				9	27
AK						
AZ	7				1	•
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		8	, .	20	1	
co	2			2		
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IL.	2	1		2		4
IN	2			2		8
IA	1				1	2
KS	2			1		
KY	3	1				19
LA	1					1
ME	2	<u> </u>				
MD	3			2		1
MA	2			,3		
MI	2	·		3		2
MN	1	· · · ·				2
MS	1					
MO	2			1	1	. 2
MT	3					
NE	1					
NV	· ·	·		2		
NH	1			1		1
NJ .	2					
NM	2	· · <u>1</u>			2	
NY	. 2			1	1	1
NC	6		1	· · ·	1	5
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OH	1			1		5
ок	3			1		5
OR	1			2		-
PA	2					2
RI	· · 1.	· · ·		1		
SC	3					1
SD	1			1		
TN	4	1	1		1	28
TX	4_	·	8	5		

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	UT	2					
	VT	1	i.				1
	VA	6	2		1	1	18
	WA	4					
	WV	5				1	5
	ŴI	1			2		2
	WY	4					
TOTALS		59	16	10	- 39	29	62

Taxonomic Groups Potentially at Risk

For the mammalian and aquatic invertebrate species evaluated in this risk assessment, RQs exceeded the LOCs for endangered species for the exposure scenarios considered other than seed treatment. The registrant must provide information on the proximity of Federally listed endangered species to the use sites. This requirement may be satisfied in one of three ways: 1) having membership in the FIFRA Endangered Species Task Force (Pesticide Registration Notice 2000-2); 2) citing FIFRA Endangered Species Task Force data; or 3) independently producing these data, provided the information is of sufficient quality to meet FIFRA requirements. The information will be used by the OPP Endangered Species Protection Program to develop recommendations to avoid adverse effects to listed species.

Action Area

The Endangered Species Act defines the action area for a Federal action as being the footprint of possible effects stemming from the action, not necessarily limited to where the immediate action occurs. For screening-level purposes, the risk assessment conservatively assumes that listed species are co-located with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be located on or adjacent to the treated field and aquatic organisms are assumed to be located in a surface water body adjacent to the treated field. This assumption places the listed species within an assumed area of high potential exposure to the pesticide. If these assumptions result in RQs that are below the listed species LOCs, a no effect conclusion is made. However, in situations where the screening assumptions lead to RQs in excess of the listed species LOCs there a potential for may affect conclusion exists. In such cases, additional information on the biology of listed species, the locations of these species, and the locations of use sites would be considered to determine the extent to which screening assumptions apply to a particular listed organism. These subsequent refinement steps would consider how this information would impact the action area for a particular listed organism and may include exposures that are downwind and downstream of the pesticide use site.

Indirect Effects Analysis

The Agency acknowledges that pesticides have the potential to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering the extent of

nesting habitat, and creating gaps in the food chain. In conducting a screen for indirect effects, direct effect LOCs for each taxonomic group are used to make inferences concerning the potential for indirect effects upon listed species that rely upon non-endangered organisms in these taxonomic groups as resources critical to their life cycle.

Because screening-level acute RQs exceed the endangered species acute LOCs, the Agency uses the dose response relationship from the toxicity study used for calculating the RQ to estimate the probability of acute effects associated with an exposure equivalent to the EEC (see Probit Analysis below). This information serves as a guide to establish the need for and extent of additional analysis that may be performed using Services-provided "species profiles" as well as evaluations of the geographical and temporal nature of the exposure to ascertain if a "not likely to adversely affect" determination can be made. The degree to which additional analyses are performed is commensurate with the predicted probability of adverse effects from the comparison of the dose response information with the EECs. The greater the probability that exposures will produce effects on a taxa, the greater the concern for potential indirect effects for listed species dependent upon that taxa, and therefore, the more intensive the analysis on the potential listed species of concern, their locations relative to the use site, and information regarding the use scenario (e.g., timing, frequency, and geographical extent of pesticide application).

Birds and Mammals

Screening-level chronic RQs for birds and mammals that feed on short grass, tall grass, broadleaf plants and small insects, and fruits, pods, and large insects (multiple applications only for fruit foliar type) that exceed the LOC may indicate a potential concern for indirect effects. The Agency considers this to be indicative of a potential for adverse effects to those listed species that rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependent) for some important aspect of their life cycle. The Agency may determine if listed organisms for which plants are a critical component of their resource needs are within the pesticide use area. This is accomplished through a comparison of Service-provided "species obligates or plant dependent reside within the pesticide use area, a no effect determination on listed species is made. If plant species obligate or dependent organism may reside within the pesticide use area, the Agency may consider temporal and geographical nature of exposure, and the scope of the effects data, to determine if any potential effects can be determined to not likely adversely affect a plant species obligate or dependent listed organism.

Indirect effects to terrestrial animals may result from reduced food items to animals, behavior modifications from reduced or a modified habitat, and from alterations of habitats. Alterations of habitats can affect the reproductive capacity of some terrestrial animals.

Probit Slope Analysis

The probit slope response relationship is evaluated to calculate the chance of an individual event corresponding to the listed species acute LOCs. If information is unavailable to estimate a slope

for a particular study, a default slope assumption of 4.5 is used as per original Agency assumptions of typical slope cited in Urban and Cook (1986).

a. Terrestrial Species

Analysis of raw data from mammalian terrestrial acute toxicity studies for clothianidin provided an estimate of slope (7.61) for females only (LD50 = 389M/465F mg/kg). Based on this slope, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 7.21 x 10¹³ for small mammals.

b. Aquatic Species

Analysis of raw data from the aquatic acute toxicity studies for clothianidin estimate slopes of 4.24 (95% C.I. 0.276 and 8.22) for freshwater invertebrates and 4.70 (95% C.I. 2.70 and 6.70) for estuarine/marine invertebrates. Based on these slopes, the corresponding estimate chance of individual mortality following clothianidin exposure is only 1 in 5.76 x 10^7 for freshwater invertebrates and 1 in 2.1 x 10^9 for estuarine/marine invertebrates.

Critical Habitat

In the evaluation of pesticide effects on designated critical habitat, consideration is given to the physical and biological features (constituent elements) of a critical habitat identified by the U.S Fish and Wildlife and National Marine Fisheries Services as essential to the conservation of a listed species and which may require special management considerations or protection. The evaluation of impacts for a screening level pesticide risk assessment focuses on the biological features that are constituent elements and is accomplished using the screening-level taxonomic analysis (risk quotients, RQs) and listed species levels of concern (LOCs) that are used to evaluate direct and indirect effects to listed organisms.

The screening-level risk assessment has identified potential concerns for indirect effects on listed species. In light of the potential for indirect effects, the next step for EPA and the Service(s) is to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether the pesticide's potential impacts on non-endangered species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources, or have constituent elements that fall into, the taxa that may be directly or indirectly impacted by the pesticide. Then EPA would determine whether use of the pesticide overlaps the critical habitat or the occupied range of those listed species. At present, the information reviewed by EPA does not permit use of either analytical approach to make a definitive identification of species that are potentially impacted indirectly or critical habitats that is potentially impacted directly by the use of the pesticide. EPA and the Service(s) are working together to conduct the necessary analysis.

This screening-level risk assessment for critical habitat provides a listing of potential biological

features that, if they are constituent elements of one or more critical habitats, would be of potential concern. These correspond to the taxa identified above as being of potential concern for indirect effects and include small and medium sized mammals. This list should serve as an initial step in problem formulation for further assessment of critical habitat impacts outlined above, should additional work be necessary.

Possible Risk Refinement Measures

Source control measures such as reduction in the application rate, reduction in the number of applications (especially in the presence of pollinators or nesting birds), and increasing the interval between applications may be implemented for clothianidin as possible risk reduction measures.

In order to fully evaluate the possibility of chronic exposure to honey bees with subsequent impacts to pollination, a complete worker bee life cycle study has been required as well as an evaluation of exposure and effects to the queen.

Additional modeling should be done to simulate the potential affects of repeated uses in order to determine if reproduction and development are affected in birds and mammals by chronic exposure.

Additional modeling or toxicity testing should be done to determine if repeated uses may present a risk to soil invertebrates and burrowing mammals.

Sediment toxicity testing of sensitive species (i.e. burrowing mayflies) would provide data to address the uncertainty of possible risk to invertebrates that inhabit or come into contact with sediment receiving surface water runoff or drift from treated fields. An OPPTS 850.1735 (Whole Sediment Acute Toxicity Invertebrates, Freshwater) toxicity test would also provide data concerning the potential chronic effects to benthic organisms because clothianidin persists in the environment representing a continual source as an environ/mental sink. This is a 28 day test that measures survival, growth and emergence of Chironomus riparius that have been exposed to pesticide spiked sediment.

Since clothianidin may serve as an environmental sink in aquatic sediments, additional information is needed to address potential effects of repeated uses. Aquatic field studies should be performed to determine system-wide effects to the assemblages of organisms in aquatic communities.

Appendix I. Summary of Individual Environmental Fate Studies

161-1 Hydrolysis (MRID 45422317)

[Thiazolyl-¹⁴C]clothianidin did not significantly hydrolyze in sterile pH 5, 7 and 9 buffer solutions at 25°C; \geq 94% of the applied was undegraded at 33 days (study termination; MRID 45422317). Clothianidin did degrade quickly in pH 9 buffer solutions at 62°C and 74°C, with half-lives of 3.7 and 0.7 days, respectively. At pH 9 and the elevated temperatures, two significant degradates were formed. At 62°C, 2-chlorothiazol-5-ylmethylamine (ACT) and N-(2chlorothiazol-5-ylmethyl)-N'-methylurea (TZMU) reached a maximum concentration of 53.6% and 14.7% of applied, respectively, at 7 days posttreatment. At 74°C, ACT and TZMU reached maximum concentrations of 59.2% and 22.6% of applied, respectively, at 1.9 days posttreatment.

161-2 Photolysis in Water (MRIDs: 45422318, 45422319, 45422320, 45422321, 45422322) Nitroimino- and thiazolyl- [¹⁴C]clothianidin photodegraded rapidly in sterile pH 7 buffer solution at 25°C under continuous irradiation; half-lives were 3.4 and 3.1 hours, respectively (MRIDs 454223-18, 20, 22). Less than 1% of the clothianidin remained undegraded after 24 hours of irradiation. No significant degradation occurred in the dark controls. The predicted environmental half-life was 14.4 hours (extrapolating from the actual study conditions assuming mid-summer sunny conditions in Phoenix, Arizona; based on continuous irradiation; 5.76 hours of irradiation were equivalent to 1 day of clear midday midsummer sunlight).

[Nitroimino-¹⁴C]clothianidin degraded mainly to methylguanidine (MG), TZMU, 4-hydroxy-2methylamino-2-imidazolin-5-one (HMIO) and methylurea (MU), with maximum concentrations of 34.7% (432 hours), 29.3% (24 hours), 26.6% (24 hours), and 11.0% (432 hours) of the applied, respectively. [Thiazolyl-¹⁴C]clothianidin degraded mainly to TZMU, formamide (FA), 7-methylamino-4H-imidazol[5,1-b][1,2,5]thiadiazin-4-one (MIT), and CO₂, with maximum concentrations of 39.7% (24 hours), 16.1% (120 hours), 11.8% (24 hours), and 34.1% (432 hours) of the applied, respectively. In nonsterile river water (pH 7.0-9.6) under sunlight, nitroimino- and thiazolyl-[¹⁴C]clothianidin degraded with half-lives of 25.1 and 27.7 hours, respectively (MRIDs 454223-19, -21). Temperatures averaged approximately 25°C (range 21.5 to 31.3°C) and average daylight was 8.7 hours (range 0.7 to 14.4 hours). Clothianidin was <5% of the applied at and after 4 days posttreatment. No significant degradation occurred in the dark controls. This study suggests a longer transformation period than the sterile buffer study; however, variable conditions (temperature, pH, sunlight) make precise comparisons difficult.

In the river water, [nitroimino-¹⁴C]clothianidin degraded mainly to MG, HMIO, and MU with maximum concentrations of 46.5% (696 hours), 28.0% (120 hours), and 12.0% (432 hours) of the applied, respectively. [Thiazolyl-¹⁴C]clothianidin degraded mainly to CO_2 , with a maximum concentrations of 28.5% (696 hours) of the applied; other major degradates were Urea, N-(2-clorothiazol-5-ylmethyl)-N'-methyguanidine (TMG), 3-methylamino-1H-imidazo [1,5-c]imidazole (MAI), and 2-chlorothiazol-5-lymethanol (CTCA) with maximum concentrations of 18.1% (264 hours), 17.2% (120 hours), 13.6% (120 hours), and 13.3% (432 hours) of the

applied, respectively.

161-3 Photodegradation on Soil (MRID: 45422323)

Clothianidin degraded with a half-life of 8.2 days in a sandy loam soil at 20°C, based on continuous irradiation; 5.76 hours of irradiation were equivalent to 1 day of clear midday midsummer sunlight at 40°N latitude (MRID 45422323). The equivalent environmental half-life calculated assuming 5.76 hours under study conditions equals one day under natural summer sunlight is 34 days. At study termination (17 days), 22.3% of the clothianidin remained undegraded. No significant degradation occurred in the dark controls. No degradates accumulated to significant levels during the study.

161-4 Photodegradation in Air (Waived)

162-1 Aerobic Soil Metabolism (MRIDs 45422325, 45422326)

Clothianidin degraded in two soils with a half-life of 148 and 239 days, in seven soils ranging in texture from sand to silt loam with half-lives of 495 to 1,155 days, and in a tenth soil (loamy sand, 0.35% OC) with a half-life of 6,932 days (MRIDs 45422325 and 45422326). In all cases, the data were extrapolated beyond the duration of the study and assumed that decay would continue at a first order rate.

All of the soils were studied at 20°C with a moisture content of 75% of 1/3 bar except for the Laacher Hof silt loam and Hofchen silt soils from Germany, which were studied at a moisture content of 40% of maximum water holding capacity. Since all studies were conducted at 20°C, clothianidin might have been less persistent than if the studies had been conducted at 25°C, the temperature of most laboratory soil metabolism studies. The Hofchen, Laacher Hof, and BBA 2.2 soils were treated with [nitroimido-¹⁴C]clothianidin. The remaining soils were treated with [thiazolyl-¹⁴C]clothianidin.

Summary	of aerobic	soil metabolism	study for	r clothianidin,	presented in	order of ascending half-
lives.						·

Soil	% OC	pH in water /0.01 <u>M C</u> aCl2	% Remaining at end of study	Extrapolated half- life, days
Hofchen silt from Germany (MRID 45422325)	2.66	7.8/7.2	54.3% at 120 days	148
Laacher Hof (AII) silt loam from Germany (MRID 45422325)	0.86	8.1/7.3	68.6% at 120 days	239
Loamy sand (BBA 2.2) from Germany (MRID 45422325)	2.5	6.0/6.3	57.8% at 365 days	495
Quincy loamy sand (MRID 45422326)	0.4	6.8/	80.8% at 181 days	533

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Soil	% OC	pH in water /0.01 M CaCl2	% Remaining at end of study	Extrapolated half- life, days
Sparta sand (MRID 45422326)	0.73	6.22/5.31	79.5% at 181 days	533
Crosby silt loam (MRID 45422326)	1.37	6.74/6.01	60.3% at 379 days	578
Susan silt loam (MRID 45422326)	3.27	6.66/5.91	78.3% at 181 days	693
Howe sandy loam . (MRID 45422325)	1.12	6.7/6.7	75.8% at 365 days	990
Elder loam (MRID 45422326)	1.41	6.67/5.84	87.5% at 181 days	1155
Fuguay loamy sand (MRID 45422326)	0.35	6.67/5.84	95.3% at 181 days	6932

<u>Residue analysis</u>. Residues were analyzed using thin-layer chromatography (TLC) in multiple solvent systems and radiographic imaging. In MRID 45422325, clothianidin and four nonvolatile degradates [<u>N</u>-methyl-<u>N</u>'-nitroguanidine (MNG); nitroguanidine (NTG); <u>N</u>-(2-chlorothiazol-5-ylmethyl)-<u>N</u>'-nitroguanidine (TZNG); and <u>N</u>-(2-chlorothiazol-5-ylmethyl)-<u>N</u>'-methylurea (TZMU)] were identified by comparison to reference standards. In MRID 45422326, clothianidin, TZNG, and TZMU were identified by comparison to reference standards and LC/MS. There were no unidentified extractable degradation products.

MNG, a degradate originating from the nitroimino moiety, was a maximum 0.7 and 9.5% of the applied in the Laacher Hof and Hofchen soils and 5.9% in the BBA 2.2 soils (MRID 45422325). The maximum concentrations were measured either at the final sampling interval or, if measured prior to the final interval, showed no pattern of decline through study termination. In sandy loam and silt loam Laacher Hof soils and the Hofchen silt soil at 20°C and 50% of maximum water holding capacity, MNG degraded with half-lives of 65-116 days (MRID 45422327).

NTG, a degradate originating from the nitroimino moiety, was a maximum 3.7-6.7% of the applied; in all three soils the maximum was measured at the final sampling interval (MRID 45422325).

TZNG was a maximum 5.1-9.1% of the applied in the Laacher Hof, Hofchen, and BBA 2.2 soils and 2.5% in the Howe sandy loam soil at the final sampling interval (MRID 45422325). In all other soils, the maximum was $\leq 0.5\%$ of the applied (MRID 45422326). In sandy loam and silt loam Laacher Hof soils and the Hofchen silt soil at 20°C and 50% of maximum water holding capacity, TZNG degraded with half-lives of 53-122 days (MRID 45422328).

TZMU was $\leq 2.4\%$ of the applied in all soils (MRIDs 45422325 and 45422326).

The maximum concentrations of MNG and TZNG in the soils are probably limited by the relatively

rapid rate of degradation of these compounds compared to the slower rate of degradation of clothianidin. No additional information was submitted on the rate of degradation of NTG, so it is not certain if significant additional accumulation would occur. TZMU is most likely a minor degradate under all conditions.

 CO_2 was a major transformation product in soils in several soils in which significant degradation occurred prior to study termination (MRIDs 45422325 and 45422326).

162-2 Anaerobic Soil Metabolism

No anaerobic soil metabolism study has been conducted; however, an anaerobic aquatic soil metabolism study was conducted in lieu of this study.

162-3 Anaerobic Aquatic Metabolism (MRID: 45422330)

Clothianidin degraded in with half-lives of 14 days in the water phase, 37 days in the sediment phase, and 27 days overall in an anaerobic water:silt loam sediment (3:1, v:w) system at 20°C (MRID 45422330). Clothianidin was <1% of the applied in the water phase at and after 120 days and was <2.0% in the sediment at and after 183 days. No major degradates were isolated and no minor degradates were identified, in large part because the majority of the residues were not extracted from the sediment at later sampling intervals despite the use of more harsh extraction procedures.

162-4 Aerobic Aquatic Metabolism (MRIDs: 45422324 and 45422329)

No acceptable aerobic aquatic metabolism studies have been conducted. Although two studies were submitted by the registrant under this guideline, the experimental designs of both were inadequate to define the pattern of decline of clothianidin under aerobic aquatic conditions (MRIDs 45422324 and 45422329). The experimental design was not in compliance with guidelines (soil and water were pre-incubated before applying the test substance) and aerobic conditions were not fully maintained during the course of the study as indicated by the low redox potential that developed in the sediment

163-1 Mobility, Adsorption/Desorption Batch Equilibrium (MRIDs: 45422311 and 45422312) Clothianidin has medium to very high mobility in soils ranging from sand to clay loam, with Freundlich adsorption coefficients ranging between 0.52 and 4.14 (MRID 45422311). Soil organic carbon partition coefficients (K_{oc}) values were 84 to 129 for all test soils except the US sandy loam soil, which had a K_{oc} value of 345. For all five test soils, Freundlich desorption coefficients and soil desorption carbon coefficients were slightly higher than those obtained for adsorption.

Soil		Adsorption			Desorption			
	K _d	1/n	r ²	K _{oc}	K _d	1/n	r ²	K _{oc}
Quincy loamy sand	0.52	0.8351	0.9952	129	0.62	0.8068	0.9982	154
BBA 2.1 sand	0.59	0.8648	0.9974	119	0.85	0.8843	0.9966	170

Freundlich adsorption and desorption constants of clothianidin in the soils.

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Soil		Adsorption			Desorption			
•	K _d	1/n	r ²	K _{oc}	K _d	1/n	r ²	K _{oc}
Crosby clay loam	1.48	0.8216	0.9992	123	1.67	0.8240	0.9987	139
Laacher Hof sandy loam	1.77	0.8146	0.9998	84	1.99	0.8136	0.9981	95
Elder sandy loam	4.14	0.8088	0.9997	345	4.58	0.8115	0.9987	382

In addition, the desorption of aged clothianidin was studied using Laacher Hof AXXa sandy loam and Laacher Hof AIII silt loam soils from Germany, adjusted to 40% of the maximum water holding capacity, dosed at 0.13 or 1.35 mg a.i./kg, and incubated at $20 \pm 1^{\circ}$ C for up to 99 days (MRID 45422312). After aging, the soils were equilibrated for 24 hours. Clothianidin comprised approximately 57% of the applied in the soil at 99 days. Clothianidin has low to moderate mobility in the soils after aging. Freundlich desorption coefficients and soil organic carbon partition coefficients (Koc) increased over time in the low-dose soils.

~ ~	Days of Aging Prior to Desorption								
Soil	0	2	7	14	27	55	99		
Sandy loam				•					
K _d	2.09	2.51	3.99	3.26	3.65	4.86	5.94		
K _{oc}	205	246	391	319	357	477	582		
Silt loam									
K _d	1.17	1.40	2.37	2.01	2.23	3.34	4.05		
K _{oc}	120	143	242	205	228	341	413		

Freundlich desorption constants of clothianidin in the low-dose soils.

Similar results were observed in the high-dose soils aged for 99 days. Freundlich adsorption coefficients increased from 1.56 to 3.30 for the sandy loam soil and from 0.96 to 3.05 for the silt loam soil after 99 days; corresponding increases in soil organic partition coefficients were 153 to 323 and 98 to 311. The study author attributed the increasing Koc values to changes in the sorption process, leading to stronger adsorption to soil and diffusion processes into less accessible sorption sites.

163-1 Mobility of the transformation products of clothianidin (MRIDs: 45422313, 45422314, 45422315, 45422316)

The mobility of four clothianidin degradates (MNG, TZMU, TZNG, and TMG) was also studied in three US and two German soils using batch equilibrium experiments. The mobilities of the degradates varied from very highly mobile to immobile. MNG had very high mobility in the five test soils, with Freundlich adsorption coefficients between 0.0199 and 0.3736, and soil organic

carbon partition coefficients ranging from 5.2 to 34.3 (MRID 45422313). TZMU had high to very high mobility, with Freundlich adsorption coefficients ranging between 0.1764 and 1.0445, and corresponding soil organic carbon partition coefficients between 46.4 and 95.8 (MRID 45422315). TZNG was moderately mobile in the test soils, with Freundlich adsorption coefficients ranging between 0.6274 and 4.7137 and corresponding soil organic carbon partition coefficients between 204.5 to 432.5 (MRID 45422314). TMG was immobile or had low mobility in the test soils; Freundlich adsorption coefficients were between 2.4381 and 39.4584 and corresponding soil organic carbon partition coefficients were 525.0 to 6159.4 (MRID 45422316). Freundlich desorption coefficients and soil organic carbon partition coefficients (when calculated) for the four degradates were higher than those obtained for adsorption, except were lower for MNG in the US silt loam soil.

Freundlich adsorption and desorption constants of clothianidin	degradates MN	NG, TZMU,	TZNG,
and TMG in three US and two German soils.	*		1

		Adso	rption	2	Desorption			
Soil	K _d	1/n	r ²	K _{oc}	K _d	1/n	r ²	K _{oc}
			M	ING				
Quincy sand	0.0514	1.1012	0.9726	21.4		Not ca	lculated	
BBA 2.1 sand	0.0199	0.7017	0.8920	5.2	Not ca	lculated due	e to low ads	orption
Crosby silt loam	0.1928	0.9249	0.9983	16.5	0.1520	0.8764	0.9812	13.0
Laacher Hof Alla sandy loam	0.2584	0.9005	0.9999	25.3	0.3561	0.8907	0.9998	34.9
Elder sandy loam	0.3736	0.9083	0.9988	34.3	0.4795	0.9697	0.9993	44.0
			TZ	MU				
Quincy sand	0.1280	0.9276	0.9999	53.3	0.1511	0.8463	0.9995	63.0
BBA 2.1 sand	0.1764	0.8695	0.9999	46.4	0.2604	0.8659	0.9999	68.5
Crosby silt loam	0.6547	0.8645	0.9999	56.0	0.8329	0.8716	1.0000	71.2
Laacher Hof Alla sandy loam	0.5867	0.8804	0.9996	57.5	0.7832	0.8781	0.9996	76.8
Elder sandy loam	1.0445	0.8430	0.9996	95.8	1.3390	0.8554	0.9998	122.8
			TZ	ZNG				
Quincy sand	0.6274	0.9010	0.9963	261.4	0.8309	0.8975	0.9958	346.2
BBA 2.1 sand	0.7772	0.8059	0.9994	204.5	1.0290	0.7923	0.9988	270.8
Crosby silt loam	2.8387	0.8070	0.9999	242.6	3.2321	0.8059	0.9999	276.2
Laacher Hof AXXa sandy loam	2.4072	0.8003	0.9999	236.0	2.8622	0.7924	0:9999	280.6

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	Adsorption				Desorption			
Soil	K _d	1/n	r ²	K _{oc}	K _d	. 1/n	r ²	K _{oc}
Elder sandy loam	4.7137	0.7832	0.9997	432.5	5.7460	0.7924	0.9997	527.2
TMG								
Quincy sand	14.7825	0.7798	0.9984	6159.4	21.6317	0.7858	0.9982	9013.2
BBA 2.1 sand	2.4381	0.8256	1.0000	641.6	2.9727	0.8214	1.0000	782.3
Crosby silt loam	15.7889	0.7803	0.9997	1349.5	18.5460	0.7859	0.9994	1585.1
Laacher Hof Alla sandy loam	5.3550	0.8493	0.9990	525.0	6.1451	0.8094	0.9998	602.5
Elder sandy loam	39.45.84	0.7297	0.9977	3620.0	54.4096	0.7348	0.9976	4991.7

163-2 Laboratory Volatility

Data waived due to low vapor pressure.

163-3 Field Volatility

Data waived due to low vapor pressure.

164-1 Terrestrial Field Dissipation (MRIDs: 45422332, 45422333, 45422334, 45422335, 45422336, 45490703, 45490704, 45490705)

TI-435 FS 600 Terrestrial field dissipation. Terrestrial field dissipation studies of clothianidin applied to bare soil have been submitted from Wisconsin (MRID 45422332), Ohio (MRID 45422333), North Dakota (MRID 45422334), Ontario (MRID 45422335) and Saskatchewan (MRID 45422336). Clothianidin was applied as a broadcast spray using the test formulation (a seed treatment for corn and canola seeds) in all five studies. The application rate in the field studies was 243 or 660 g a.i/ha, approximately two and six times the maximum proposed label rate (corn; 1.5 mg/seed, equivalent to 122 g a.i./ha).

Half-lives of clothianidin, based on residues in the 0-15 cm soil depth, ranged from 277 days (Wisconsin test site, sand soil) to 1,386 days (North Dakota test site, clay loam soil); a half-life could not be determined for the Saskatchewan (clay loam soil) test site due to limited dissipation during the study. DT90 values ranged from 980 days to 2,780 days and could not be determined for the Saskatchewan test site. No degradates were detected at >10% of the applied, with the exception of a single detection of TZMU at 10.1% of the applied the Ohio test site. Clothianidin was generally not detected below the 45 cm soil depth, except in the Wisconsin sand soil at a maximum depth of 45-60 cm. Degradates were generally only detected in the 0-15 cm soil layer.

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Geographic location	Soil texture (0-15 cm)	Application rate (target)	Incorporated	Time to maximum conc. ¹	Conc. at study termination ¹	Half-life ²	DT90 ³
Wisconsin, USA	Sand	660 g a.i./ha	Yes, depth not reported	0.319 mg/kg (7 days)	0.030 mg/kg (823 days)	277 days $(r^2 = 0.80)$	1,330 days
Ohio, USA	Silt loam	660 g a.i./ha	No	0.235 mg/kg (7 days)	0.0305 mg/kg (735 days)	315 days $(r^2 = 0.85)$	980 days
North Dakota, USA	Clay loam	243 g a.i./ha	No	0.124 mg/kg (15 days) ⁴	0.0353 mg/kg (864 days)	1,386 ($r^2 = 0.10$)	2,780 days
Ontario, Canada	Silt loam	660 g a.i./ha	Yes, 5 cm	0.278 mg/kg (7 days)	0.0576 mg/kg (798 days)	365 days $(r^2 = 0.51)$	1,160 days
Saskatchewan, Canada ⁵	Silty clay loam	243 g a.i./ha	Yes, 5 cm	0.0811-0.0985 mg/kg (day 0) ⁶	0.0638-0.0796 mg/kg (775 days)	Could not be determined ⁷	Could not be determined ⁷

Dissipation of clothianidin in five field studies following a single application of TI-435 FS 600 to bare soil.

¹ Concentration in the 0-15 cm soil layer.

² Reviewer-calculated, based on residues in the 0-15 cm soil layer.

³ Registrant-calculated, based on residues in all soil layers.

⁴ Excludes outlier at 842 days posttreatment (TI-435 detected at 0.146 mg/kg, mean of three replicates).

⁵ Two trials were conducted at the Saskatchewan test site.

⁶ Day 0 (post-incorporated values). The maximum concentration of TI-435 observed in trials 1 and 2 occurred at 61 days (0.122 mg/kg) and 678 days (0.0916 mg/kg), respectively.

⁷ A half-life could not be determined at the Saskatchewan test site due to limited dissipation during the study.

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TI-435 50WDG Terrestrial field dissipation. Terrestrial field dissipation studies of clothianidin (TI-435 50WDG) applied to bare soil have been submitted from California (MRID 45490703), Washington (MRID 45490704) and Georgia (MRID 45490705). Clothianidin was applied as a broadcast spray using the test formulation TI-435 50WDG in all three studies. The application rate in the field studies was 229 g a.i/ha. The label application rate was not provided.

Cothianidon concentrations in the California study varied widely with no pattern of decline; sequently, it was not possible to calculate half-lives or DT90. In the other studies half-lives of clothianidin, based on residues in the 0-15 cm soil depth, ranged from 257 days for the Washington study to 990 days for the Georgia test site. However, due to the extreme variability of the data for the Georgia study the calculated half-life is deemed to have limited value by the reviewer. DT90 values ranged from 686 days (Washington) to 3070 days (Georgia). No degradates were detected at >10% of the applied.

US EPA ARCHIVE DOCUMENT

Geographic location	Soil texture (0-15 cm)	Application rate (target)	Incorporated	Time to maximum conc. ¹	Conc. at study termination ¹	Half-life ²	DT90 ³
California, USA	Loam/sandy loam	225 g a.i./ha	No	96.8 µg/kg (day 0)	78.1 μg/kg (982 days)	Not calculable	Not calculable
Washington, USA	Loam/sandy loam	225 g a.i./ha	No	129 µg/kg (day 0)	12.6 μg/kg (623 days)	257 days $(r^2 = 0.43)$	686 days
Georgia, USA	Sandy loam/sandy clay loam	225 g a.i./ha	No	82.6 µg/kg (365 days)	23.9 μg/kg (739 days)	990^4 days (r ² = 0.15)	3070 ⁴ days

Dissipation of clothianidin in three field studies following a single application of TI-435 50 WDG to bare soil.

¹ Concentration in the 0-15 cm soil layer.

² Reviewer-calculated, based on residues in the 0-15 cm soil layer.

³ Registrant-calculated, based on residues in all soil layers.

⁴ Excludes outlier at 365 days posttreatment, reviewer considers half-life calculation of limited value due to variability of data.

In lysimeter studies conducted in the Federal Republic of Germany (FRG), clothianidin was applied to the same sandy loam soil (0-10 cm depth: 70.8% sand, 20.7% silt, 8.6% clay, pH 7.2, 1.8% organic carbon; Appendix 5, p. 45) in Monheim, FRG. In the first study, [nitroimino- 14 C]clothianidin, formulated as TI-435 200 SC, was applied twice (10 months apart) at approximately 160 g a.i./ha/application to an enclosed plot (1 m² x 1.3 m depth) of sandy loam soil planted with turf (MRID 45422508). In the second study, [Thiazolyl-¹⁴C]clothianidin, formulated as TI-435 70 WS, was applied twice (400 days apart) as a seed treatment at approximately 100 g a.i./ha and 138 g a.i./ha, respectively, to an enclosed plot (1 m² x 1.3 m depth) of sandy loam soil (MRID 45422331).

In the MRID 45422508 study, approximately three years following the first application, 42-45% of the applied was detected in the soil and approximately 1% was detected in the leachate; the loss of radioactivity, approximately 54-56%, was attributed to mineralization of clothianidin. Grass clippings were not analyzed separately. Approximately 39.5-40.4% of the applied was detected within the top 0-30 cm of soil, with clothianidin accounting for the majority of the extracted radioactivity (maximum of 18.02 μ g/kg soil in the 0-10 cm soil layer). The degradates MNG, TZNG and NTG were detected at maximum concentrations of 1.57 μ g/kg soil, 3.05 μ g/kg soil and 0.77 μ g/kg soil, respectively, in the 10 cm soil layer. MNG and NTG were also detected in the leachate samples; clothianidin was not detected in any leachate samples.

In the MRID 45422331 study, winter barley seeds were treated and sown for the first application and winter wheat seeds were treated and sown for the second application; the lysimeter was cropped with untreated winter wheat during the third year of the study. Approximately three years following the first application, 59% of the applied was detected in the soil, 3% was detected in the harvested crops and 0.3% was detected in the leachate; the loss of radioactivity, approximately 37%, was attributed to mineralization of clothianidin. Approximately 57% of the applied was detected within the top 0-30 cm of soil, with clothianidin accounting for the majority of the extracted radioactivity (maximum of 25.4 μ g/kg soil in the 0-10 cm soil layer). The only degradate detected was TZNG, at a maximum concentration of 5.21 μ g/kg soil in the 10 cm soil layer. Clothianidin and TZNG were detected in the harvested crops, with the majority of the radioactivity being detected in the hulls/straw and chaff. Four unknown degradates were detected in the leachate samples; clothianidin was not detected in any leachate samples.

Ancillary studies - The extraction efficiency of two analytical methods to determine clothianidin and its degradates TZNG, MNG, TZMU and TNG was compared in two aged German soils (MRID 45422604). Radiolabeled test substances were applied to the two soils (a sandy loam and a silt loam) at a concentration equivalent to 300 g a.i./ha and maintained in the dark at 20 ± 1 °C and at 75% of 1/3 bar moisture under static aerobic conditions for 92 days. For the "lab method", 100 g soil samples were extracted four times with acetonitrile and once with water by shaking; following centrifugation, extracts were filtered and analyzed by TLC. For the "field method", 20 g soil samples were mixed with 4 g hydromatrix and extracted using an Accelerated Solvent Extractor with acetonitrile:water:acetic acid:guanidine hydrochloride (200:800:0.8:8, v:v:v:w) at a temperature of 140°C and a pressure of 140 bar; extracts were analyzed by TLC. Both total radioactive residues extracted and extraction efficiencies for each individual test substance were generally greater with the field method as compared to the lab method. The study author speculated that the lower recoveries for the lab method may have been a result of the higher metabolism/mineralization capacity of the 100 g soil samples used in the lab method as compared to the 20 g soil samples used in the field method; however, neither bound residues nor CO_2 were measured.

$\lambda = 10^{-10}$	Lab m	ethod	Field r	nethod
Soil	Total extracted ¹⁴ C	Total identified ¹⁴ C	Total extracted ¹⁴ C	Total identified ¹⁴ C
Sandy loam			· · · ·	
TI-435 TZNG MNG TZMU TMG	105.3 89.3 89.4 35.8 73.3	76.5 52.4 56.0 20.2 62.1	102.9 90.1 90.4 61.0 83.5	82.2 69.9 66.8 41.6 78.9
Silt loam		•		
TI-435 TZNG MNG TZMU TMG	100.2 85.1 86.6 20.9 64.3	70.3 50.1 44.4 13.4 58.2	109.4 89.5 79.5 34.6 84.6	81.9 61.4 49.0 20.8 80.7

In a storage stability study, no significant degradation of clothianidin and the degradates TZNG, TZMU, TMG, and MNG was observed in frozen samples of Howe soil fortified with parent and degradates at approximately 50 μ g/kg and stored frozen for 12 months at temperatures between -18 and -25°C (MRID 45422612). Following storage, clothianidin and the degradates were extracted from soil with acetonitrile:water:acetic acid:guanidine hydrochloride (200:800:0.8:8, v:v:v:w) using an Accelerated Solvent Extractor (ASE). After extraction, an internal standard solution was added and the volume adjusted with acetonitrile:water (1:4, v:v). Extracts were analyzed by LC-MS/MS. Isotopically labeled internal standards (d₃-TI-435; ¹³C, ¹⁵N-TZNG; d₃-TZMU; d₃-MNG and d₃-TMG) were used to compensate for possible matrix effects in the MS/MS detector. Mean recoveries of TI-435 were 106% at day 0, 98.4% at 118 days, 96.1% at 180 days, and 91.2% following 356 days of storage. Mean recoveries of TZNG were 94.6% at day 0, 101% at 118 days, 98.6% at 180 days, and 92.4% following 356 days of storage. Mean recoveries of TZMU were 104% at day 0 and 118 days, 95.6% at 180 days, and 93.7% following 356 days of storage. Mean recoveries of TMG were 95.6% at day 0, 82.3% at 118 days, 94.4% at 180 days, and 83.4% following 356 days of storage. Mean recoveries of MNG were 95.7% at day 0, 96.1% at 118 days, 110% at 180 days, and 101% following 356 days of storage. The study "is still running for at least one more year."

164-2 Aquatic Field Dissipation Reserved.

165-4 Bioaccumulation in Fish (waived)

This data requirement has been waived. Octanol/water partitioning (Kow) data provided in an aerobic aquatic metabolism study indicates a low potential for clothianidin to accumulate (Kow for clothianidin = 1.12 at pH 7; MRID 45422329).

165-5 Accumulation – Aquatic Non-target Organisms Reserved.

166-1 Groundwater – Small Prospective The study was requested and is required.

201-1 Droplet Size Spectrum (MRIDs: 45490701)

A single droplet size spectrum study has been complete which has been classified as supplemental (upgradedable). It was considered to be scientifically valid, but cannot be used to fulfill the requirement for an atomization droplet size spectra because the test substance/solution was not adequately characterized. The atomization droplet size spectra of (E)-N-[(2-Chloro-5-thiazolyl)methyl]-N'-methyl-N"-nitroguanidine (clothianidin; TI-435 50 WDG) was studied by spraying the test substance mixed with water and oil (0.25% v:v) under controlled conditions at a rate of 90 g a.i./acre in spray mixture volumes of 150 and 300 gallons/acre. Spray conditions were simulated through four disk-core nozzle types, D14-25, D10-25, D6-25 and D3-46 (0° nozzle orientation, straight back from the wind tunnel airstream), in combination with wind tunnel airstream velocities of 74 and 136 mph. Liquid pressure at the nozzle tips was either 150 psi (treatments 1-16) or 100 psi (treatments 17-24).

For application methods at a liquid pressure of 150 psi (airstream velocities of 74 and 136 mph, rate 150 and 300 gallons/acre), the mean $D_{v0.5}$ ranged from 161-274 μ m. At a liquid pressure of 100 psi, $D_{v0.5}$ ranged from 185-343 μ m.

Although no statistical analysis was reported, there was good agreement in atomization data between replicates of each treatment. The sprays became finer in the following nozzle order: D3-46 (coarsest)> D14-25> D10-25> D6-25 (finest). Sprays were also slightly coarser at the greater dilution rate (300 gallons/acre). The study author proposed that likely resulted from the higher dynamic surface tension expected with the more dilute tank mix.

Sprays were much finer with at the higher airstream velocity due to greater air shear, with the exception of the D3-46 nozzle, which was only slightly finer at the higher velocity. Higher pressure (150 psi) at the nozzle tips also produced a finer spray. The effect of the application volume rate dilution on atomization was much lower than effects of nozzle size, airstream velocity and spray pressure.

The sprays were classified as fine to medium (V < 141μ m) according to the British Crop Protection Council (BCPC) and American Society of Agricultural Engineers (ASAE) spray quality classification scheme for droplet size categories.

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Reserved.

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Appendix II. Ecological Toxicity Data Summaries

Toxicity to Terrestrial Animals

Birds, Acute and Subacute

An oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the acute toxicity of clothianidin to birds. The preferred guideline test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). The data that were submitted show that the 14-day oral LD_{50} is >2,000 mg/kg for bobwhite quail. The NOAEL is 500 mg/kg with observed effects including reduced mean body weights, mortality and clinical effects (subdued birds) in the 1,000 and 2,000 mg/kg test groups. A study conducted on a non-guideline species, Japanese quail, showed that the 14-day oral LD_{50} is 423 mg/kg. The NOAEL is 12.5 mg/kg bw based on clinical signs of toxicity (lethargy and ruffled appearanced) at the 25 mg/kg treatment level. Based on these results, clothianidin is categorized as ranging from practically non-toxic to moderately toxic to avian species on an acute oral basis; the guideline (71-1) is fulfilled (MRID #45422417).

Species, and the second	% ai	LD50 (mg/kg)	Toxicity Category	MRID No. Author, Year	Study Classification
Northern bobwhite quail (Colinus virginianus)	96.0	>2,000	Practically non- toxic	45422417 Johnson, 1998	Core
Japanese Quail (Coturnix coturnix japonica)	97.6	423	Moderately toxic	45422418 Gallagher et al., 2000	Supplemental

Avian Acute Oral Toxicity

Two dietary studies using the TGAI are required to establish the subacute toxicity of clothianidin to birds. The preferred test species are mallard duck and bobwhite quail. The data that were submitted show that the 8-day acute dietary LC_{50} is >5,000 ppm; therefore, clothianidin is categorized as practically non-toxic to avian species on a subacute dietary basis. The 8-day NOAEC's for each species based on sublethal effects (reduced body weight gain) were 309 ppm for the quail and 646 ppm for the mallard. The guideline (71-2) is fulfilled (MRID #45422419; MRID #45422420).

Avian Subacute Dietary Studies

Species	% ai	5-Day LC50 (ppm) ¹	Toxicity Category	MRID No. Author, Year	Study Classification
Northern bobwhite quail (Colinus virginianus)	96	>5,230	Practically non- toxic	45422419 Johnson, 1998	Core
Mallard duck (Anas platyrhynchos)	96	10000 >5,040 10000 >5,040 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000 10000	Practically non- toxic	45422420 Johnson, 1998	

Birds, Chronic

Avian reproduction studies using the TGAI are required for clothianidin because birds may be subject to repeated or continuous exposure to the pesticide, especially preceding or during the breeding season. The preferred test species are mallard duck and bobwhite quail. The submitted data show that clothianidin exposure of 525 ppm adversely affected eggshell thickness for bobwhite quail, but did not result in chronic effects during reproduction for mallard duck; the guideline (71-4) is fulfilled (MRID #45422421; MRID #45422422).

Species	% ai	NOAEC/LOAEC (ppm)	LOAEC Endpoints	MRID. No. Author, Year	Study Classification
Northern bobwhite quail (Colinus virginianus)	97.6	205/525 ^{1,11,11,11,11,11,11,11,11,11,11,11,11,1}	Eggshell thickness	45422421 Gallagher et al., 2000	
Mallard duck (Anas platyrhynchos)	97.6	525/>525	No effect on reproduction	45422422 Gallagher et al, 2000	Supplemental

Avian Reproduction

Mammals, Acute and Chronic

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported below.

Mammalian Acute and Chronic Toxicity

Species	% a.i.	Test Type	Toxicity	Affected Endpoints	MRID No. Author, Year
Rat (Rattus norvegicus)	96	Acute	LD ₅₀ =5,000 mg/kg/day	Mortality	45422621 Gardner, 1997
Mouse (Mus musculus)	96	Acute states to the second states of the second sta	$LD_{50} = 389-465 \text{ mg/kg/day}$	Mortality	45422622 Gardner, 1997
Rat (Rattus norvegicus)	96 · · · · · · · · · · · · · · · · · · ·	2-Generation Reproduction	NOAEL (M/F) = 9.8/11.5 mg/kg/day (150/500 ppm) ⁵ LOAEL (M/F) = 31.2/36.8 mg/kg/day (500/500 ppm) ⁵	Offspring	4522714-16 and 45422825-26, 2000 and 2001
			NOAEL (M) = 31.2 mg/kg/day (500 ppm0) ⁵ LOAEL (M)= 163.4 mg/kg/day (2500 ppm) ⁵	Reproduction ²	
Rabbit (Sylvilagus sp.)	96	Developmental	NOAEL/LOAEL = $25/75$ mg/kg/day ($825/2,475$ ppm) ⁴	Development ³	45422712 and -13, 1998

¹ Decreased body weight gains and delayed sexual maturation (males only); decreased absolute thymus weight in F1 pups (both sexes), and increased stillbirths (F1 and F2 litters).

² Decreased sperm mobility and increased number of sperm with detatched heads (F1 and F2 litters).

³ Premature deliveries, decreased gravid uterine weights, and increased litter incidence of missing lobe of the lung per fetus.

ppm conversion based on:

1 mg/kg/day = 20 ppm in adult rats, 10 ppm in younger rats, 7 ppm in mice and 33 ppm in rabbits. (Nelson, 1975)

⁵ ppm value determined from study.

The results indicate that clothianidin is categorized as practically non-toxic to small mammals on an acute oral basis ($LD_{50} = 389$ ->5,000 mg/kg/day).

In the 2-generation rat reproduction study, offspring systemic toxicity was detected for males and females at 500 ppm and reproductive toxicity was detected in males at 2500 ppm. The NOAEL for offspring systemic toxicity was 150 and 500 ppm for males and females, respectively, and the NOAEL for reproduction was 500 ppm. In the rabbit developmental study, toxicity was observed at 75 mg/kg/day; the NOAEL was 25 mg/kg/day.

Insects, Acute Contact and Oral

A honey bee acute contact study using the TGAI is required for clothianidin because its foliar application treatment use will result in honey bee exposure. The acute contact LD_{50} , using the honey bee, Apis mellifera, is an acute contact, single-dose laboratory study designed to estimate the quantity of toxicant required to cause 50% mortality in a test population of bees. The acute contact LD_{50} for clothianidin is 0.0439 μ g a.i./bee and it is, therefore, classified as highly toxic to bees on a contact exposure basis [$LD_{50} < 2 \mu$ g a.i./bee, based on toxicity categories in Atkins (1981)]. The guideline (141-1) is fulfilled (MRID No. 45422426).

Five acute oral toxicity studies are available for clothianidin and its metabolites; however, they are categorized as supplemental because the submission of honey bee acute oral toxicity studies is not a guideline requirement. The Office of Pesticide Programs (OPP) does not have a categorization scheme for acute oral toxicity to honey bees. However, based on the ICBB (1985) acute oral toxicity categorization scheme, clothianidin would be considered highly toxic to the honey bee by the oral route. With the exception of TZNG, the clothianidin metabolites TMG, MNG, and TZMU would be virtually non-toxic to honey bees. TZNG would be moderately toxic.

Species/Study Duration	% ai	LD50 (µg ai/bee)	Toxicity Category	MRID No. Author, Year	Study Classification
Honey bee Acute	Contact Toxicity - C	lothianidin			
Honey bee (Apis mellifera) 48 hour	96	0.0439	highly toxic	45422426 Weyman, 1998	Core
Honey bee Acute (Oral Toxicity - Cloth	anidin			
Honey bee (Apis mellifera) 48 hour	96	0.0037	not applicable	45422426 Weyman, 1998	Supplemental

Nontarget Insect Acute Contact and Oral Toxicity

Species/Study Duration	% ai	LD50 (µg ai/bee)	Toxicity Category	MRID No. Author, Year	Study Classification			
Honey bee (Apis mellifera) 48 hour	96	≥152	not applicable	45422427 Wilkins, 2000	Supplemental			
Honey bee Acute Oral Toxicity - Clothianidin Metabolite - MNG								
Honey bee (Apis mellifera) 48 hour	99.2	>153	not applicable	45422428 Wilkins, 2000	Supplemental			
Honey bee Acute O	ral Toxicity - Clothiar	nidin Metabolite - TZI	MU					
Honey bee (Apis mellifera) 48 hour	98.8	>113	not applicable	45422429 Wilkins, 2000	Supplemental			
Honey bee Acute Oral Toxicity - Clothianidin Metabolite - TZNG								
Honey bee (Apis mellifera) 48 hour	98.6	3.95	not applicable	45422430 Wilkins, 2000	Supplemental			

Insects, Mortality, Reproduction, and Feeding Capacity

Two studies were submitted to show acute effects of corn (MRID 45422520) and summer rape (MRID 45422521) seeds treated with TI 435 FS600 (formulated product) on carabid beetles (Poecilus cupreus) under extended laboratory test conditions. The goal of these studies was to evaluate whether or not exposing carabid beetles to clothianidin treated corn or rape seeds increased mortality or decreased feeding rate compared to the controls. About one third of the adult carabid beetles exposed to the treated corn seeds at a seed treatment rate of 0.45 lb ai/A showed abnormalities (undescribed signs of intoxication). Rape seed treated with clothianidin at an application rate of 0.095 lb ai/A caused behavioral impacts (intoxication) to 63 % of adult carabid beetles in the treatment group. The feeding rate of beetles in the treatment group was significantly reduced. There was also a significant difference in mortality (13.3 %) of the treatment group compared to the control. These studies were scientifically sound and classified as Supplemental.

Three studies (MRID Nos. 45422524, 45422522, & 45422523) were submitted to show effects of clothianidin on the life cycle of rove beetles (Aleochara bilineata) under extended laboratory conditions. The first study (MRID No. 45422524) was designed to evaluate the effects clothianidin would have on the beneficial ground beetles exposed to the pesticide in treated soil. Study endpoints were adult mortality and reproduction (total number of progeny produced). In this study, there were no significant differences observed between the control and clothianidin treatment groups for adult mortality. Reproductive performance (as indicated by decreased number of progeny) was affected in the two highest clothianidin treatment groups (200 and 250 μ g a.i./kg soil). The goal of final two (2) rove beetle studies was to evaluate whether or not exposure of rove beetles to corn seeds (MRID No. 45422522) treated at a rate of 0.55 lb ai/A and to rape seeds (MRID No. 45422523) treated at a rate of 0.095 lb ai/A (10 g a.i./kg TI 435 FS 600) would result in significantly increased mortality of parent beetles and whether or not the offspring production rate would be adversely affected. The beetles exposed to the treated corn seed experienced a significant increase in mortality (55%) but no significant reproductive difference

when compared to the controls. The reproductive performance of the rove beetles was determined by counting the number of rove beetles which emerged from the host pupae between days 39 and 77 after treatment. Rove beetles exposed to the treated rape seed experienced an increase in mortality and a reduced parasitization capacity. The number of offspring that emerged (reproductive performance) in the rape seed treated test groups was not significantly lower than the control group. These studies were scientifically sound and classified as Supplemental.

Insects, Residual Contact

A honey bee toxicity of residues on foliage study is required on an end-use product for any pesticide intended for outdoor application when the proposed use pattern indicates that honey bees may be exposed to the pesticide and when the formulation contains one or more active ingredients having an acute contact honey bee LD_{50} which falls in the moderately toxic or highly toxic range. The purpose of this guideline study is to develop data on the residual toxicity to honey bees. Bee mortality determinations are made from bees exposed to treated foliage harvested at various time periods after treatment. Clothianidin, as indicated in the acute toxicity test (MRID 45422426), is highly toxic to honey bees on a contact basis. Pesticides toxic to honey bees require bee precautionary labeling on all end-use formulations and registrants are required to submit data in accordance with Guideline 141-2 - Honey Bee Toxicity of Residues on Foliage. A scientifically-sound study was performed.

Alfalfa foliage was sprayed with Clothianidin, as V-10066, at application rates of 30, 60, and 90 g a.i./acre. Honey bees, three replicates/rate, were exposed in the lab to the weathered foliage at varying times until the mortality of bees exposed to residues was lower than 25%. Sublethal observations were also made. The RT_{25} for V-10066 at 30, 60, and 90 g a.i./acre were 111.68, 179.51, and 512.39 hours, respectively. EFED expects clothianidin's residue on treated foliage to remain toxic to bees for days after clothianidin is applied. Results indicate that clothianidin, as V-10066, should not be applied to blooming pollen-shedding or nectar-producing parts of plants.

Species	g all/acre	RT ₂₅ (hours) ¹	MRID No. Author/Year	Study Classification
Honey Bee	30	111.68	45490702	Supplemental
(Apis mellifera)	(0.07 lb ai/A)	(4.7 days)	Mayer, 2000	
Honey Bee	60	179.51	45490702	Supplemental
(Apis mellifera)	(0.13 lb ai/A)	(7.5 days)	Mayer, 2000	
Honey Bee	90	512.39	45490702	Supplemental
(Apis mellifera)	0.21 (lb ai/A)	(21.3 days)	Mayer, 2000	

Non-target Insects - Toxicity of Residues on Foliage

1 RT_{25} is the residual time required to reduce the activity of the test material and bring bee mortality down to 25% in cage test exposures to field-weathered spray deposits (Mayer and Johansen, 1990). The time period determined by this toxicity value is considered to be time that the test material is expected to remain toxic to bees in the field from the residual exposure of the test material on vegetation at an expressed rate of application (lb ai/A).

Insects, Field Testing for Pollinators

Six honey bee field studies were undertaken in various locations (Sweden, United Kingdom, France, Canada, United States, and Germany) to determine the residue levels of clothianidin in various parts of summer rape plants grown from seeds treated at various application rates (8.62 lb ai/1000 lb seed or 0.038 lb ai/acre; 10.4 lb ai/1000 lb seed or 0.046 lb ai/acre; 6 lb ai/1000 lb seed

or 0.04 lb ai/acre; and 1 lb ai/100 lb seed or 0.025 lb ai/acre). Residue levels in the honey bees that foraged on the plants grown from the treated seeds were also determined. These studies were considered scientifically sound; however, they do not fulfill the requirements for a pollinator field test (OPPs Guideline 141-5) because the protocol was not approved by EPA. They are classified as Supplemental. An approved protocol would have required that the studies be conducted in the United States, longer duration of honey bee activity observations, and the use of replications in the treatments and controls for statistical analyses. Field exposure to the test substance and the bee observation period were too brief (< 30 days) to fully evaluate the impact the exposure levels of clothianidin would have had on the bee colonies tested. The complete life cycle for an individual worker bee during the time period tested would be approximately 63 days.

These field studies evaluated the effects to small honey bee colonies hived on clothianidin rape seed treated and untreated (control) plots. Colonies were placed on the treated and untreated plots during the rape bloom stage approximately two months after the rape crops were planted. Bees were monitored for short periods of time to determine if they were being adversely affected by the clothianidin exposure as a result of the systemic activity demonstrated by clothianidin. Residues of clothianidin in the nectar from rape flowers ranged from 1.0 to 7.2 μ g ai/kg. Nectar sampled from beehives ranged from 0.9 to $3.7\mu g$ ai/kg and nectar sampled from forage bees honey stomachs contained 8.6 μ g ai/kg clothianidin. Residues of clothianidin were also found in forage bees (1.4 μ g ai/kg), rape flowers (3.3 - 4.1 μ g ai/kg), pollen taken from foraging bees (1.7 - 2.5 μ g ai/kg), and pollen from beehives (1.6 - 3.0 μ g ai/kg). These residues were a result of the clothianidin seed treatments performed approximately 60 days prior to sampling the commodities. Two (2) studies (MRID 45422436 & 45422437) also tested for the clothianidin metabolites, TZMU and TZNG, but residues of these metabolites were not found in the nectar and pollen samples analyzed. With the exception of one study (MRID 45422435), none of the studies reported mortality or adverse effects to the foraging activity of the bees. However, the residue levels in the nectar taken from the bees, 8.6 μ g ai/kg, exceeds the honey bee acute oral LD₅₀ of 3.7μ g ai/kg (MRID 45422426). One honey bee field study (MRID # 45422435) showed that mortality, pollen foraging activity, and honey yield were negatively affected by residues of clothianidin; however, residues were not quantified in this study.

MRID #	Study Classification	Study Location & Plant Date of Treated Seed	Chemical Application Rate	Sample Date(s)	Commodity Sampled	Clothianidin Residues Found (µg ai/kg)
45422431	Supplemental	Borlunda- Skelinge,	<u>Clothianidin</u>	1 st week of July '98	forage bees	1.4
		Sweden 4/28/98	or	1 st week of July '98	nectar in bees	8.6
			seed or 0.038 lb ai/acre	7/3/98 and 7/2/98	nectar from rape flowers	1.2 and 7.2
			a = 1 + 1	1 st week of July '98	rape flowers	4.1

Non-target Insect Field Studies

MRID #	Study Classification	Study Location & Plant Date of Treated Seed	Chemical Application Rate	Sample Date(s)	Commodity Sampled	Clothianidin Residues Found (µg ai/kg)
45422432	Supplemental	Elm Farm., United Kingdom	<u>Clothianidin</u> 10.4 lb ai/1000 lb	6/22-6/24/98	rape flowers	3.3
· .		3/28/98	seed or 0.046 lb ai/acre	6/22-6/24/98	forage bees	none detected
45422433	Supplemental	Conches in Northern France	<u>Clothianidin</u> 10.4 lb ai/1000 lb	6/15-6/18/98	pollen taken from forage bees	1.7
		3/19/98	seed or 0.046 lb ai/acre		bees	
45422435	Supplemental	Ontario, Canada	<u>Clothianidin</u> 6 lb ai/1,000 lb	6/26-7/20/00	pollen from bee hives	3.0 (61 days after application)
		5/3/00	seed or 0.04 lb ai /A			1.6 (68 days after application)
•					nectar from bee hives	3.7 (61 days after application)
:			· ·			0.9 * (68 days after application)
		Minnesota, US 5/16/00		6/28-7/28/00	pollen from bee hives	2.3 (50 days after application)
				2		2.8 (57 days after application)
					nectar from bee hives	1.1 (50 days after application)
- - -		1. A		• •		1.0 (57 days after application

Non-target Insect Field Studies

MRID #	Study Classification	Study Location & Plant Date of Treated Seed	Chemical Application Rate	Sample Date(s)	Commodity Sampled	Clothianidin Residues Found (µg ai/kg)
45422436	Supplemental	Monheim, Germany 5/2/00	Clothianidin 1056 g a.i./100 kg seed or 1 lb ai/100 lb seed or 0.025 lb ai/A	7/6/00 and 7/7/00	nectar from rape flowers	2.8 and 3.0
45422437	Supplemental	Burscheid, Germany 4/28/00	Clothianidin 1056 g a.i./100 kg seed or 1 lb ai/100 lb seed or 0.025 lb ai/A	6/30/00 and 7/6/00 combs sampled 7/12/00; forage bees	nectar from rape flowers pollen from combs/forage bees	5.4 and 1.0 1.9 to 2.5
		· · · ·		sampled on 7/2 and 7/18/00		

Non-target Insect Field Studies

* <Level of Quantification (LOQ) =1.0 μ g/kg and Level of Detection (LOD) = 0.3 μ g/kg

A seventh honey bee field study (MRID No. 45422440), reviewed under guideline 141-5, evaluated the effects of clothianidin treated pollen on the development of small honey bee colonies and on the behavior and mortality of honey bees. Three treatment levels and two controls were tested. One small beehive (about 500 bees) per treatment and control was tented on oat plots in cages and fed treated maize pollen. Pollen treated with clothianidin at a measured concentration level up to 19.7 μ g ai/kg produced no significant adverse effects to the parameters measured in this study based upon the visual inspection of the data. The parameters measured included mortality, foraging activity (including honey and pollen collection), comb production, honey storage behavior, population growth (including egg, larvae, pupae, and adult growth stages) and behavioral anomalies. Since there was only one replicate hive per treatment level, a statistical analysis could not be made of the data provided. MRID No. 45422440 was determined to be scientifically sound and classified as Supplemental.

Spider, Mortality and Feeding Capacity

Two extended laboratory studies (MRID Nos. 45422518 & 45422519) evaluated the effects of clothianidin treated seed on the wolf spider, Pardosa spp. (Araneae, Lycosidae). The goal of these studies was to evaluate whether or not exposing wolf spiders to treated corn and rape seeds increased mortality or decreased feeding rate compared to the controls. The seed treatment rate for the corn seeds was 48.8 g a.i./Unit (1 Unit = 50,000 seed) with 2 corn seeds per 1170 cm² test box equivalent to 0.15 lb ai/A. The seed treatment rate for the rape seeds was 10 g a.i./kg TI 435 FS 600 with 4 rape seeds per 178 cm² test box equivalent to 0.06 lb ai/A. The studies' results

indicated that the wolf spider mortality and feeding capacity in the clothianidin treatments were not significantly different from the controls. These studies were scientifically sound and classified as Supplemental.

Earthworm, Acute and Chronic

Five acute/chronic earthworm studies were reviewed for clothianidin and its metabolite/transformation products. These studies were conducted in compliance with the Organization for Economic Cooperation and Development (OECD) guidelines for testing of chemicals and were reviewed, by EFED, under EPA Ecological Effects Test Guidelines (U.S. EPA Ecological Effects Test Guidelines, April, 1996). EFED does not have a toxicity categorization for earthworms. The clothianidin earthworm LC_{50} (conc. in soil) was determined to be 15.5 mg/kg (MRID No. 45422511) with the metabolite, MNG, and transformation product, TZNG, being less toxic to earthworms than the parent compound. EPA does not presently require reproductive or population toxicity testing with earthworms for pesticide registration; however, two studies indicate that clothianidin exhibits no apparent effect to earthworm reproduction at application rates equal to or greater than 0.054 lb ai/A (MRID 45422525) or population density/biomass at application rates equal to or greater than 0.08 lb ai/A (MRID 45422526).

Species/Study Duration	% ai	LC50/ EC50 (mg/kg in dry soil or lb ai/A)	NOAEC/ LOAEC (mg/kg in dry soil or lb ai/A)	Endpoints	MRID# Author/Year	Study Classification
Eisenia foetida 14 days	96	15.5 mg/kg (nominal)	< 10.0 mg/kg (nominal)	mortality	45422511 Weyman, 1998	Acceptable
Eisenia fetida 56 days	48	> 0.054 lb ai/A ¹ (nominal)	≥ 0.054 lb ai/A ¹ (nominal)	no significant treatment- related effects on mortality, body weight, or # offspring/ surviving adult	45422525 Meisner, 2000	Supplemental
Lumbricus terrestris, L.rubellus, L. castaneus, Apporrectodea caliginosa, A. terrestris longa Allolobophora chlorotica 1 year	47.8	> 0.08 lb ai/A ² (measured)	≥ 0.08 Ib ai/A ² (measured)	no significant treatment- related effect on number and biomass of earthworms	45422526 Heimbach, 2000	Supplemental

Earthworm Acute a	and Chro	onic Toxicity				
Species/Study Duration	% ai	LC50/ EC50 (mg/kg in dry soil or lb ai/A)	NOAEC/ LOAEC (mg/kg in dry soil or lb ai/A)	Endpoints	MRID# Author/Year	Study Classification
Eisenia fetida 14 days	99.2	> 1,000 mg/kg (nominal)	320 mg/kg (nominal)	reduction in body weights	45422512 Noack, 2000	Acceptable
Clothianidin Transfo	ormation	Product - TZNG		•		
Fisenia fetida	00	982 mg/kg	125 mg/kg	mortality	45422513	Acceptable

Eisenia fetida	99	982 mg/kg (nominal)	125 mg/kg (nominal)	mortality	45422513 Noack, 2000	Acceptable
14 days	•		63 mg/kg (nominal)	reduction in body weight		

1 Equivalent to >500,000 clothianidin dressed corn seeds/ha

MRID No. 45422525 - Earthworm (continued)

 $\frac{2.7 \text{ x } 10^{-6} \text{ lb ai}}{\text{corn seed}} * \frac{500,000 \text{ seed}}{\text{HA}} = \frac{1.33 \text{ lb ai}}{\text{HA}} = \frac{0.054 \text{ lb ai}}{\text{A cre}}$

<u>2 Equivalent to > 91.4 g a.i./ha</u>

MRID No. 45422526 - Earthworm

ha 2.47 Acre Acre

Toxicity to Aquatic Organisms

Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the acute toxicity of clothianidin to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). The acute studies that were submitted that tested the parent compound showed that clothianidin is practically non-toxic to freshwater fish ($LC_{50} > 105.8 - 117$ ppm). Studies on degradates (TMG, MNG, and TZNG) indicated a similar practically non-toxic profile ($LC_{50} > 105$ ppm). EFED will use the worst case value ($LC_{50} > 105.8$ ppm) for evaluating acute toxic exposure to freshwater fish. The guideline (72-1) is fulfilled (MRID #45422407; MRID# 45422406).

Freshwater Fish Acute Toxic	ity	The second s			
Species	% ai	96-hour LC50 (ppm) (nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Bluegill sunfish (Lepomis macrochirus)	97.6	>117	Practically non- toxic	45422407 Palmer et al., 2000	Core

reshwater Fish Acute Toxic	ity				
Species	% ai	96-hour LC50 (ppm) (nominal)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout (Oncorhynchus mykiss)	96	>105.8	Practically non- toxic	45422406 Wilhelmy et al., 1998	Supplementa
Rainbow trout (Oncorhynchus mykiss)	95.1 TMG	>110	Practically non- toxic	45422408 Dorgerloh, 2000	Supplementa
Rainbow trout (Oncorhynchus mykiss)	99.0 MNG	>105	Practically non- toxic	45422409 Dorgerloh, 2000	Supplementa
Rainbow trout (Oncorhynchus mykiss)	99.0 TZNG	>116	Practically non- toxic	45422410 Dorgerloh, 2000	Supplementa

Freshwater Fish, Chronic

A freshwater fish early life-stage test using the TGAI is required for clothianidin because the enduse product may be transported to water from the intended use site, and the following conditions are met: (1) clothianidin is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; (2) studies on aquatic invertebrates showed reproductive effects (daphnid 21-day LOAEC = 0.12 ppm) and (3) clothianidin is persistent in water (e.g., half-life of 744 days aerobic soil metabolism).

A chronic early life stage study conducted on the fathead minnow showed that exposure of 20 ppm has the potential to affect length and dry weight of freshwater fish. The NOAEC of 9.7 ppm will be used for risk assessment purposes. The guideline (72-4) is fulfilled (MRID #45422413).

Freshwater Fish Early Li	fe-Stage To:	xicity Under Flow-Thro	ugh Conditions		
Species	% ai	NOAEC/LOAEC	Endpoints Affected	MRID No. Author/Year	Study Classification
Fathead Minnow (Pimephales promelas)	97.6	9.7/20	Length and dry weight	45422413 Drottar et al., 2000	Supplemental

Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of clothianidin to aquatic invertebrates. The preferred test species is Daphnia magna. The data that was submitted that tested the parent compound showed that clothianidin is practically nontoxic to Daphnia magna with an acute 48-hour EC₅₀ value of >119 ppm, but that it is very highly toxic to Chironomus riparius with an acute 48-hour EC₅₀ value of 0.022 ppm. EFED will use the worst case value (EC₅₀= 0.022 ppm) for evaluating acute toxic exposure to freshwater invertebrates. Additional data (48-hour EC₅₀) on degradates (TZNG, MNG, and TMG) indicated a practically non-toxic to slightly toxic profile (EC₅₀ = 64.0 to >115.2 ppm). The guideline requirements (72-2) for acute invertebrate toxicity are fulfilled (MRID #45422338; MRID #45422414).

Freshwater Invertebrate Acute Toxicity for Clothianidin

Species	% ai	48-hour EC ₅₀ (ppm)	Toxicity category	MRID No. Author/Year	Study Classification
Waterflea (Daphnia magna)	99	>119	Practically non- toxic	45422338 Palmer, 2000	Core
Midge (Chironomus riparius)	97.6	0.022*	Very highly toxic	45422414 Mattock, 2001	Supplemental
Waterflea (Daphnia magna)	99.0 TZNG	64	Slightly toxic	45422401 Hendel, 2000	Core
Waterflea (Daphnia magna)	99.0 MNG	>100.8	Practically non- toxic	45422340 Hendel, 2000	Core
Waterflea (Daphnia magna)	95.1 TMG	>115.2	Practically non- toxic	45422339 Hendel, 2000	Supplemental

* The EC₅₀ value for exposure to Clothianidin TI-435 was the most sensitive; EC₅₀ values for TZMU, MU, and TZNG were >102 ppm, >83.6 ppm, and 0.386 ppm, respectively.

Freshwater Invertebrate, Chronic

A freshwater aquatic invertebrate life-cycle test using the TGAI is required for clothianidin because the end-use product may be transported to water from the intended use site, and the following conditions are met: (1) the presence of clothianidin in water is likely to be continuous or recurrent and (2) aquatic acute LC_{50} or EC_{50} values are less than 1 ppm (i.e., 0.022 ppm), and (3) physicochemical properties indicate that clothianidin is persistent in the aquatic environment (e.g., half-life of 744 days aerobic soil metabolism).

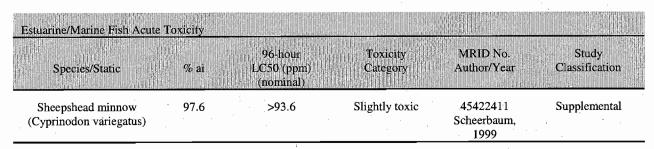
The preferred test is a 21-day life cycle on Daphnia magna. The data that were submitted show that clothianidin has the potential for chronic toxicity to daphnids and possibly other freshwater invertebrates. Exposure to 0.12 ppm can result in reproductive effects, including the reduced number of juveniles produced per adult. The NOAEC of 0.042 ppm will be used in assessing risk. The guideline (72-4) is fulfilled (MRID #45422412).

Freshwater Aquatic	: Invertebr	ate Chronic Toxicity				
Species/ Static Renewal	% ai	21-day NOAEC/LOAEC (ppm)	(ppm)	Affected	MRID No. Author/Year	Study Classification
Waterflea (Daphnia magna) Static Renewal	96	0.042/0.12	ND	Reproduction	45422412 Noack et al., 1998	Supplemental

Freshwater Field Studies No data submitted.

Estuarine and Marine Fish, Acute

The preferred test species is sheepshead minnow. The data submitted showed that the $LC_{50} = 93.6$ ppm; therefore, clothianidin is categorized as slightly toxic to estuarine/marine fish on an acute basis. The guideline (72-3) is fulfilled (MRID #45422411).



Estuarine and Marine Fish, Chronic No data submitted.

Estuarine and Marine Invertebrates, Acute

Acute toxicity testing with estuarine/marine invertebrates using the TGAI is required for clothianidin because the end-use product is expected to reach this environment due to its potential use on crops with significant acreage in coastal counties. The preferred test species are mysid shrimp and eastern oyster. The data showed that clothianidin significantly reduced survival of mysid shrimp at 0.051 ppm, categorizing the compound as very highly toxic. Clothianidin was categorized as practically non-toxic to Eastern oyster because adverse effects did not occur for this species up to concentrations of 129.1 ppm. EFED will use the worst case value, $LC_{50} = 0.051$ ppm, for evaluating acute toxic exposure to estuarine/marine invertebrates. The data requirements (72-3b) are fulfilled (MRID # 45422404; MRID #45422403).

Species/Static or Flow-through	% ai.	96-hour LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Eastern oyster Crassostrea virginica)	97.6	EC ₅₀ >129.1	Practically non- toxic	45422404 Scheerbaum, 1999	Core
Mysid Americamysis bahia)	97.6	LC ₅₀ =0.051	Very highly toxic	45422403 Drottar et al., 2000	Core

Estuarine and Marine Invertebrate, Chronic

An estuarine/marine invertebrate life-cycle toxicity test using the TGAI is required for clothianidin because the end-use product is expected to transport to an estuarine/marine environment from the intended use site, and the following conditions are met: (1) the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity, (2) an aquatic acute LC_{50} or EC_{50} is less than 1 ppm (e.g., mysid $LC_{50} = 0.051$ ppm), and (3) studies of other organisms indicate that the reproductive physiology of fish and/or invertebrates may be affected, physicochemical properties indicate cumulative effects, or the pesticide is persistent in water (e.g., half-life of 744 days aerobic soil metabolism).

The preferred test species is mysid shrimp. The data submitted indicate that clothianidin reduced the number of young per reproductive day at 9.7 ppb. The NOAEC of 5.1 ppb will be used in

Estuarine/Marine Inve	ertebrate Life-	Cycle Toxicity			
Species	% ai	39-day NOAEC/LOAEC (ppb)	Endpoints Affected	MRID No. Author/Year	Study Classification
Mysid (Mysidopis bahia)	97.6	5.1/9.7	Reproduction	45422405 Drottar et al., 2000	Core

assessing risk. The guidelines (72-4c) have been fulfilled (MRID #45422405).

Estuarine and Marine Field Studies No data submitted.

Aquatic Plants

Several aquatic plant toxicity studies using the TGAI are required to establish the toxicity of clothianidin to non-target aquatic plants. The recommendation is for testing on five species: freshwater green alga (Selenastrum capricornutum), duckweed (Lemna gibba), marine diatom (Skeletonema costatum), blue-green algae (Anabaena flos-aquae), and a freshwater diatom. Studies submitted for two of the five recommended species showed that exposure to clothianidin at levels greater than or equal to 3.5 ppm reduced biomass of aquatic non-vascular plants and increased the incidence of necrotic fronds in aquatic vascular plants. Studies on degradates (TMG, MNG and TZNG) showed reductions in green algal cell density when exposed to levels >1.46 ppm. The EC₅₀ of 64 ppm will be used for evaluating acute toxic exposure to non-target aquatic plants. The guideline requirements (122-2 and 123-2) are fulfilled (MRID #45422503; MRID #45422504) for two of the five required species. EFED needs 3 more Core clothianidin studies for the nonvascular surrogate species, marine diatom (*Skeletonema costatum*), blue-green algae (*Anabaena flosaquae*), and a freshwater diatom.

uble B 10. Non turget riquite i funt i okien					
Species [Study Type]	% a.i.	EC ₅₀ /NOAEC (ppm)	Endpoints Affected	MRID No. Author, Year	Study Classification
Duckweed (Lemna gibba) [Tier 2]	97.6	>121/59	Necrotic fronds	45422503 Palmer et al., 2000	Core
Green Algae (Selenastrum capricornutum) [Tier 2]	97.6	64/3.5	Biomass	45422504 Sutherland et al., 2000	Core
Green Algae (Selenastrum capricornutum) [Tier 2]	95.1 TMG	10/1.46	Cell density	45422505 Dorgerloh, 2000	Core
Green Algae (Selenastrum capricornutum) [Tier 1]	99.0 MNG	>100.6/100.6	None	45422506 Dorgerloh, 2000	Core

Table B-16: Non-target Aquatic Plant Toxicity

Green Algae (Selenastrum	99.0 TZNG	>103/<103	Cell density	45422507 Dorgerloh, 2000	Core
capricornutum) [Tier 1]					

Terrestrial Plants

Terrestrial Tier II studies are required for all low dose pesticides (those with the maximum use rate of 0.5 lbs a.i./A or less) and for any pesticide showing a negative response equal to or greater than 25% in Tier I studies. Two Tier I terrestrial plant toxicity studies were conducted to establish the toxicity of clothianidin to non-target terrestrial plants. The recommendations for seedling emergence and vegetative vigor studies are for testing of (1) six species of at least four dicotyledonous families, one species of which is soybean (Glycine max) and the second of which is a root crop, and (2) four species of at least two monocotyledonous families, one of which is corn (Zea mays). The studies that were submitted tested formulated products of clothianidin (49.3% TI-435 50% WDG). The results of these studies showed that exposure elicited no effect (that is, $\geq 25\%$) on non-target terrestrial plants, so Tier II tests were not necessary. The guidelines (122-1a and 122-1b) are fulfilled (MRID #45422501; MRID #45422502).

Non-target Terrestrial Plant Toxicity									
•	Species [Study Type]	% a.i.	Application Rate (lb ai/A)	Endpoints Affected	MRID No. Author, Year	Study Classification			
			- 						
	<u>Dicots</u> : Soybean (Glycine max), Pinto bean (Phaseolus vulgaris), Radish (Raphanus sativus), Cabbage (Brassica oleracea), Lettuce (Lactuca sativa), Tomato (Lycopersicon esculentum) <u>Monocots</u> : Corn (Zea mays), Wheat (Triticum aestivum), Ryegrass (Lolium perenne), Onion (Allium cepa)	49.3 TI-435 50% WDG	0.2	No significant effect on seedling emergence	45422501 Brignole et al., 2000	Core			
	[Tier I Seedling Emergence] <u>Dicots</u> : Soybean (Glycine max), Pinto bean (Phaseolus vulgaris), Radish (Raphanus sativus), Cabbage (Brassica oleracea), Lettuce (Lactuca sativa), Tomato (Lycopersicon esculentum) <u>Monocots</u> : Corn (Zea mays), Wheat (Triticum aestivum), Ryegrass (Lolium perenne), Onion (Allium cepa) [Tier 1 Vegetative Vigor]	49.3	0.2	No significant reduction in height or shoot weight	45422502 Brignole et al., 2000	Core			

Non-target Terrestrial Plant Toxicity

The following studies have been submitted to the Agency and provide either core or some supplemental information about clothianidin.

MRID 45490703 Cassidy, P.S. 2001. TI-435 - Terrestrial field dissipation study, California 1998. Unpublished study performed by Plant Sciences, Inc., Watsonville, CA and Ricerca, LLC, Concord, OH; sponsored and submitted by Tomen Agro, Inc., San Francisco, CA. Plant Sciences Project No. 98.322, Ricerca Project No. 7572-98-0092; Tomen Report No. TMN-0153 and Ricerca Report No.: 7572-98-0092-CR-001. Experiment initiation July 8, 1998 (p. 13) and completion March 16, 2001 (field phase; p. 32). Final report issued July 19, 2001.

MRID 45490704 Cassidy, P.S. 2001. TI-435 - Terrestrial field dissipation study, Washington 1998. Unpublished study performed by Qualls Agricultural Laboratory, Ephrata, WA and Ricerca, LLC, Concord, OH; sponsored and submitted by Tomen Agro, Inc., San Francisco, CA. Qualls Project No. 98-54, and Ricerca Project No. 7570-98-0093; Tomen Report No. TMN-0155, and Ricerca Report No.: 7570-98-0093-CR-001. Experiment initiation July 7, 1998 and completion March 7, 2001 (field phase; p. 30). Final report issued July 19, 2001.

MRID 45490705 Cassidy, P.S. 2001. TI-435 - Terrestrial field dissipation study, Georgia 1998. Unpublished study performed by Research Options, Inc., Montezuma, GA, Ricerca, LLC, Concord, OH, and A&L Great Lakes Laboratory, Inc., Fort Wayne, IN; sponsored and submitted by Tomen Agro, Inc., San Francisco, CA. Research Options Project No. 98-051, Ricerca Project No. 7574-98-0091-CR, A&L Great Lakes Laboratories, Inc. Project No.: F98845-001, Tomen Report No. TMN-0154 and Ricerca Report No. 7574-98-0091-CR-001. Experiment initiation July 22, 1998 and completion January 15, 2001 (field phase; p. 31). Final report issued July 19, 2001.

MRID 45490701 Hewitt, A.J. Orchard airblast atomization droplet size spectra for V-10066/TI-435 50 WDG. Unpublished study performed by Stewart Agricultural Research Services, Inc., Macon, MO; sponsored by Valent USA Corp., Walnut Creek CA (p. 26); and submitted by Tomen Agro, Inc., San Francisco, CA; Laboratory project no.: V00-22832. Final report issued August 29, 2001.

Mayer, D. and C. Johansen. Pollinator Protection: A Bee & Pesticide Handbook. Wicwas Press. Cheshire, CT (1990).

Nelson, A.N. 1975. Appraisal of the Safety of Chemicals: Approximate Relation of Parts Per Million in Diet to Mg/Kg/Day. Quarterly Report to the Editor on Topics of Current Interest. Association of Food and Drug Officials of the United States.

Appendix IV.

Clothianidin (TI 435)

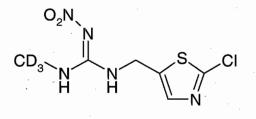
US EPA ARCHIVE DOCUMENT

IUPAC name:(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine.CAS name:[C(E)]-N-[(2-Chloro-5-thiazolyl)methyl]-N'-methyl-N''-nitroguanidine.CAS No:210880-92-5 (formerly 205510-53-8)SMILES string:CNC(=NN(=O)=O)NCc1cnc(s1)Cl

Unlabeled

O₂N CI H₂C NH Ń

clothianidin-d₃



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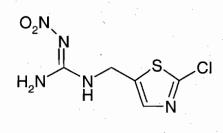
TZNG (thiazolyl-nitroguanidine)

EPA ARCHIVE DOCUMENT

U

IUPAC name: Not reported.CAS name:N-(2-Chlorothiazol-5-ylmethyl)-N'-nitroguanidine.CAS No:Not reported.





[¹³C,¹⁵N]TZNG

O₂N CI H₂N Ĥ Ν

* Position of the radiolabel.

TZMU (thiazolyl-methylurea)

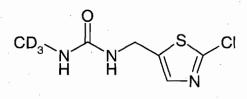
EPA ARCHIVE DOCUMENT

IUPAC name: Not reported.CAS name:N-(2-Chlorothiazol-5-ylmethyl)-N'-methylurea.CAS No:Not reported.

Unlabeled

H₃C C

TZMU-d₃



D = deuterium, ²H.

MNG (methyl-nitroguanidine)

IUPAC name: Not reported.

CAS name: CAS No:

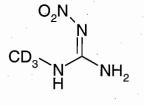
US EPA ARCHIVE DOCUMENT

N-Methyl-N'-nitroguanidine. Not reported.

Unlabeled

0₂N H₃C NH₂ H

MNG-d₃

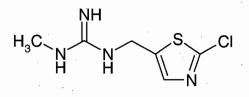


 $D = deuterium, {}^{2}H.$

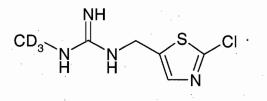
TMG (thiazolyl-methylguanidine)

IUPAC name: Not reported.CAS name:N-(2-Chlorothiazol-5-ylmethyl)-N'-methylguanidine.CAS No:Not reported.





 $TMG-d_3$



 $D = deuterium, {}^{2}H.$

Appendix V. Results of FATE Model

As part of the Tier I screening risk assessment, EPA uses models to estimate exposure of nontarget plants and animals to clothianidin. For terrestrial birds and mammals, estimates of initial levels of clothianidin residues on various food items consumed by wildlife using the Fletcher nomogram followed by a first order decline model such as FATE. The following table shows predicted residues immediately after a single turfgrass application (proposed label) on terrestrial food items following a single application of clothianidin calculated from Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994).

Table VIa. Estimated En	vironmental Concentrations on Av	vian and Mammalian Food Items (ppm) Following a Single
Application of Clothianid	<u>in at 0.2 lb ai/A.</u>		
Food It	ems	EEC (ppm)	
		Predicted Maximum Reside	ıe
Short Gross		40	

Tall Grass22Forage and small insects27Fruits, pods, seeds and large insects3	Short Grass		48	,	
	Tall Grass	· · · ·	22		
Fruits, pods, seeds and large insects 3	Forage and small insects		27		
	Fruits, pods, seeds and large insects		3	2 4	

EECs determined by FATE5 model

Predicted residual concentrations (EECs) of clothianidin were compared to toxicity values for northern bobwhite quail and mouse to estimate acute and chronic risk quotients. The quail and mouse were chosen as representative terrestrial bird and mammal.

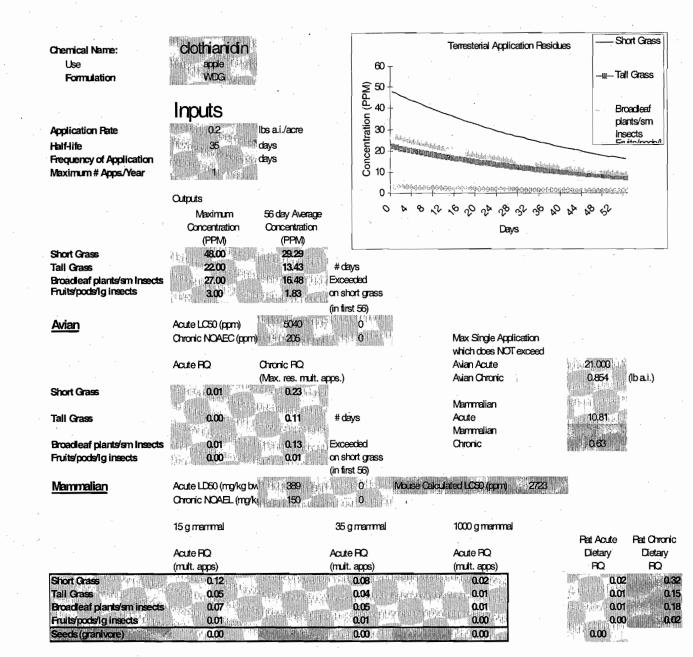


Figure Appendix V-2: Clothianidin's Use on Apples ELL-Fate Version 1.4

Appendix VI: List of Listed Endangered/Threatened Species

Species Detail by State for Preliminary Assessment

* Some species (gray wolf, etc...) were omitted from the listings because they are not likely to be exposed due to to size, habitat, eating habits or other mitigating factors.

SPIDER, MADLA'S CAVE Cicurina madla Arachnid SPIDER, KAUAI CAVE WOLF Adelocosa anops Arachnid SPIDER, ROBBER BARON CAVE Cicurina baronia Arachnid SPIDER, SPRUCE-FIR MOSS Microhexura montivaga Arachnid HARVESTMAN, ROBBER BARON CAVE Texella cokendolpheri Arachnid SPIDER, TOOTH CAVE Neoleptoneta myopica Arachnid CICURINA VENII (NCN) Cicurina venii Arachnid SPIDER, VESPER CAVE Cicurina vespera Arachnid PSEUDOSCORPION, TOOTH CAVE Tartarocreagris texana Arachnid SPIDER, GOVERNMENT CANYON CAVE Neoleptoneta microps Arachnid HARVESTMAN, BEE CREEK CAVE Texella reddelli Arachnid HARVESTMAN, BONE CAVE Texella reyesi Arachnid PEARLYMUSSEL, TURGID-BLOSSOM Epioblasma turgidula Clam PEARLYMUSSEL, PALE LILLIPUT Toxolasma cylindrellus Clam RIFFLESHELL, TAN Epioblasma florentina walkeri (=E. walkeri) Clam ROCK-POCKETBOOK, OUACHITA (=WHEELER'S Arkansia wheeleri Clam PM) PEARLYMUSSEL, PINK MUCKET Lampsilis abrupta Clam PEARLYMUSSEL, WHITE CAT'S PAW Epioblasma obliquata perobliqua Ciam PEARLYMUSSEL, TUBERCLED-BLOSSOM Epioblasma torulosa torulosa Clam PEARLYMUSSEL, WHITE WARTYBACK Plethobasus cicatricosus Clam PEARLYMUSSEL, YELLOW-BLOSSOM Epioblasma florentina florentina Clam PEARLYMUSSEL, PURPLE CAT'S PAW Epioblasma obliquata obliquata Clam PIGTOE, FINE-RAYED Fusconaia cuneolus Clam POCKETBOOK, FAT Potamilus capax Clam POCKETBOOK, SHINY-RAYED Lampsilis subangulata Clam PEARLYMUSSEL, DROMEDARY Dromus dromas Clam POCKETBOOK, SPECKLED Lampsilis streckeri Clam PEARLYMUSSEL, ORANGE-FOOTED Plethobasus cooperianus Clam PIGTOE, SOUTHERN Pleurobema georgianum Clam SLABSHELL, CHIPOLA Elliptio chipolaensis Clam RABBITSFOOT, ROUGH Quadrula cylindrica strigillata Clam PIGTOE, SHINY Fusconaia cor Clam

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		PIGTOE, ROUGH
		PIGTOE, OVAL
		CLUBSHELL, OVATE
		PIGTOE, FLAT (=MARSHALL'S MUSSEL)
		RIFFLESHELL, NORTHERN
		PIGTOE, DARK
		PIGTOE, CUMBERLAND (=CUMBERLAND PIGTOE MUSSEL
		CLUBSHELL
	• .	POCKETBOOK, FINE-LINED
		CLUBSHELL, BLACK (=CURTUS' MUSSEL)
		SPINYMUSSEL, JAMES RIVER
		SPINYMUSSEL, TAR RIVER
		CLUBSHELL, SOUTHERN
		COMBSHELL, CUMBERLAND
	· · ·	COMBSHELL, SOUTHERN (=PENITENT MUSSEL
		COMBSHELL, UPLAND
		PIGTOE, HEAVY (≈JUDGE TAIT'S MUSSEL)
		MUSSEL, DWARF WEDGE
		ACORNSHELL, SOUTHERN
		HEELSPLITTER, INFLATED
		HEELSPLITTER, CAROLINA
2		MOCCASINSHELL, COOSA
		THREERIDGE, FAT
		FANSHELL
\mathbf{O}		MUSSEL, WINGED MAPLELEAF
OCUMEN		MUSSEL, SCALESHELL BANKCLIMBER, PURPLE
		MUSSEL, OYSTER
		KIDNEYSHELL, TRIANGULAR
_		MUCKET, ORANGE-NACRE
		MOCCASINSHELL, OCHLOCKONEE
		MOCCASINSHELL, GULF
		PEARLYMUSSEL, LITTLE-WING
		PEARLYMUSSEL, HIGGINS' EYE
		MOCCASINSHELL, ALABAMA
_		ELKTOE, APPALACHIAN
\mathbf{O}		ELKTOE, CUMBERLAND
		FATMUCKET, ARKANSAS
ΩŽ.		MUSSEL, RING PINK (=GOLF STICK PEARLY)
		PEARLYMUSSEL, CUMBERLAND MONKEYFAC
		PEARLYMUSSEL, CRACKING
		PEARLYMUSSEL, BIRDWING
-		BEAN, PURPLE
S EPA ARC		PEARLYMUSSEL, CUMBERLAND BEAN
		STIRRUP SHELL
П		PEARLSHELL, LOUISIANA
		PEARLYMUSSEL, APPALACHIAN
		PEARLYMUSSEL, CURTIS'
2		PEARLYMUSSEL, GREEN-BLOSSOM
		PEARLYMUSSEL, ALABAMA LAMP
		AMPHIPOD, KAUAI CAVE
		SHRIMP, ALABAMA CAVE

	Pleurobema plenum	Clam
•	Pleurobema pyriforme	Clam
	Pleurobema perovatum	Clam
	Pleurobema marshalli	Clam
	Epioblasma torulosa rangiana	Clam
	Pleurobema furvum	Clam
	Pleurobema gibberum	Clam
	Pleurobema clava	Clam
	Lampsilis altilis	Clam
	Pleurobema curtum	Clam
	Pleurobema collina	Clam
	Elliptio steinstansana	Clam
	Pleurobema decisum	Clam
	Epioblasma brevidens	Clam
L)	Epioblasma penita	Clam
	Epioblasma metastriata	Clam
	Pleurobema taitianum	Clam
	Alasmidonta heterodon	Clam
	Epioblasma othcaloogensis	Clam
	Potamilus inflatus	Clam
	Lasmigona decorata	Clam
	Medionidus parvulus	Clam
	Amblema neislerii	Clam
		Clam
	Cyprogenia stegaria	Clam
	Quadrula fragosa	Clam .
	Leptodea leptodon Elliptoideus sloatianus	Clam . Clam
	Epioblasma capsacformis	Clam
	Ptychobranchus greeni	Clam
	Lampsilis perovalis	Clam
	Medionidus simpsonianus	Clam
	Medionidus penicillatus	Clam
	Pegias fabula	Clam
	Lampsilis higginsii	Clam
· •	Medionidus acutissimus	Clam
•	Alasmidonta raveneliana	Clam
	Alasmidonta atropurpurea	Clam
, í	Lampsilis powelli	Clam
	Obovaria retusa	Clam
CE	Quadrula intermedia	Clam
CL	Hemistena lata	Clam
	Conradilla caelata	Clam
	Villosa perpurpurea	Clam
	Villosa trabalis	Clam
	Quadrula stapes	Clam
	Margaritifera hembeli	Clam
	-	
	Quadrula sparsa Epichlasma florentina curtisii	Clam
	Epioblasma florentina curtisii	
	Epioblasma torulosa gubernaculum	Clam Clam
	Lampsilis virescens	
	Spelaeorchestia koloana Palaemonias alabamae	Crustacean Crustacean
	i alachionias alaoaniac	Crustacean

CRAYFISH, SHASTA SHRIMP, CALIFORNIA FRESHWATER SHRIMP, CONSERVANCY FAIRY SHRIMP, KENTUCKY CAVE CRAYFISH, NASHVILLE CRAYFISH, CAVE (CAMBARUS ACULABRUM) AMPHIPOD, ILLINOIS CAVE SHRIMP, SAN DIEGO FAIRY SHRIMP, SQUIRREL CHIMNEY CAVE ISOPOD, LEE COUNTY CAVE ISOPOD, MADISON CAVE ISOPOD, SOCORRO AMPHIPOD, PECK'S CAVE SHRIMP, RIVERSIDE FAIRY SHRIMP, VERNAL POOL FAIRY SHRIMP, VERNAL POOL TADPOLE SHRIMP, LONGHORN FAIRY SKIPPER, PAWNEE MONTANE GRASSHOPPER, ZAYANTE BAND-WINGED BEETLE, OHLONE TIGER MOTH, BLACKBURN'S SPHINX MOTH, KERN PRIMROSE SPHINX BEETLE, VALLEY ELDERBERRY LONGHORN SKIPPER, LAGUNA MOUNTAIN BEETLE, TOOTH CAVE GROUND BEETLE, PURITAN TIGER BEETLE, NORTHEASTERN BEACH TIGER BEETLE, KRETSCHMARR CAVE MOLD BEETLE, AMERICAN BURYING BEETLE, DELTA GREEN GROUND BEETLE, COMAL SPRINGS RIFFLE BEETLE, COMAL SPRINGS DRYOPID BEETLE, COFFIN CAVE MOLD BEETLE, MOUNT HERMON JUNE SKIPPER, CARSON WANDERING FLY, DELHI SANDS FLOWER-LOVING DRAGONFLY, HINES EMERALD NAUCORID, ASH MEADOWS BUTTERFLY, PALOS VERDES BLUE BEETLE, HELOTES MOLD RHADINE EXILIS (NCN) BUTTERFLY, FENDER'S BLUE BUTTERFLY, LANGE'S METALMARK. BUTTERFLY, KARNER BLUE BUTTERFLY, MITCHELL'S SATYR BUTTERFLY, MYRTLE'S SILVERSPOT BUTTERFLY, UNCOMPAHGRE FRITILLARY BUTTERFLY, SMITH'S BLUE BUTTERFLY, LOTIS BLUE BEETLE, HUNGERFORD'S CRAWLING WATER BUTTERFLY, MISSION BLUE RHADINE INFERNALIS (NCN) BUTTERFLY, BAY CHECKERSPOT BUTTERFLY, BEHREN'S SILVERSPOT

Pacifastacus fortis Syncaris pacifica Branchinecta conservatio Palaemonias ganteri Orconectes shoupi Cambarus aculabrum Gammarus acherondytes Branchinecta sandiegonensis Palaemonetes cummingi Lirceus usdagalun Antrolana lira Thermosphaeroma thermophilus Stygobromus (=Stygonectes) pecki Streptocephalus woottoni Branchinecta lynchi Lepidurus packardi Branchinecta longiantenna Hesperia leonardus montana Trimerotropis infantilis Cicindela ohlone Manduca blackburni Euproserpinus euterpe Desmocerus californicus dimorphus Pyrgus ruralis lagunae Rhadine persephone Cicindela puritana Cicindela dorsalis dorsalis Texamaurops reddelli Nicrophorus americanus Elaphrus viridis Heterelmis comalensis Stygoparnus comalensis Batrisodes texanus Polyphylla barbata Pseudocopaeodes eunus obscurus Rhaphiomidas terminatus abdominalis Somatochlora hineana Ambrysus amargosus Glaucopsyche lygdamus palosverdesensis Batrisodes venyivi Rhadine exilis Icaricia icarioides fenderi Apodemia mormo langei Lycaeides melissa samuelis Neonympha mitchellii mitchellii Speyeria zerene myrtleae Boloria acrocnema Euphilotes enoptes smithi Lycaeides argyrognomon lotis Brychius hungerfordi Icaricia icarioides missionensis Rhadine infernalis Euphydryas editha bayensis Speyeria zerene behrensii

Crustacean Insect Insect

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BUTTERFLY, CALLIPPE SILVERSPOT BUTTERFLY, EL SEGUNDO BLUE BUTTERFLY, SCHAUS SWALLOWTAIL BUTTERFLY, SAN BRUNO ELFIN BUTTERFLY, SAINT FRANCIS' SATYR BUTTERFLY, OREGON SILVERSPOT BUTTERFLY, OUINO CHECKERSPOT BAT. GRAY WOODRAT, RIPARIAN SOURREL, VIRGINIA NORTHERN FLYING SQUIRREL, NORTHERN IDAHO GROUND SQUIRREL, MOUNT GRAHAM RED SOUIRREL, DELMARVA PENINSULA FOX SQUIRREL, CAROLINA NORTHERN FLYING SHREW, BUENA VISTA MOUSE, ALABAMA BEACH MOUSE, ANASTASIA ISLAND BEACH MOUSE, CHOCTAWHATCHEE BEACH MOUSE, PACIFIC POCKET MOUSE, PERDIDO KEY BEACH MOUSE, PREBLE'S MEADOW JUMPING MOUSE, SALT MARSH HARVEST MOUSE. SOUTHEASTERN BEACH BAT, INDIANA VOLE, AMARGOSA VOLÉ, FLORIDA SALT MARSH VOLE, HUALAPAI MEXICAN BAT, HAWAIIAN HOARY KANGAROO RAT, FRESNO BAT, LESSER (=SANBORN'S) LONG-NOSED BAT, MEXICAN LONG-NOSED BAT, OZARK BIG-EARED KANGAROO RAT, SAN BERNARDINO KANGAROO RAT, STEPHENS' KANGAROO RAT, TIPTON RABBIT, PYGMY KANGAROO RAT, MORRO BAY BAT, VIRGINIA BIG-EARED KANGAROO RAT, GIANT SNAIL, FLAT-SPIRED THREE-TOOTHED SNAIL, NEWCOMB'S PEBBLESNAIL, FLAT CAVESNAIL, TUMBLING CREEK CAMPELOMA, SLENDER RIVERSNAIL, ANTHONY'S ELIMIA, LACY ROCKSNAIL, PAINTED ROCKSNAIL, PLICATE ROCKSNAIL, ROUND MARSTONIA, ROYAL (=ROYAL SNAIL) SHAGREEN, MAGAZINE MOUNTAIN SNAIL, ARMORED SNAIL, BLISS RAPIDS

Speyeria callippe callippe Euphilotes battoides allyni Heraclides aristodemus ponceanus Callophrys mossii bayensis Neonympha mitchellii francisci Speyeria zerene hippolyta Euphydryas editha quino (=E. e. wrighti) Myotis grisescens Neotoma fuscipes riparia Glaucomys sabrinus fuscus Spermophilus brunneus brunneus Tamiasciurus hudsonicus grahamensis Sciurus niger cinereus Glaucomys sabrinus coloratus Sorex ornatus relictus Peromyscus polionotus ammobates Peromyscus polionotus phasma Peromyscus polionotus allophrys Perognathus longimembris pacificus Peromyscus polionotus trissyllepsis Zapus hudsonius preblei Reithrodontomys raviventris Peromyscus polionotus niveiventris Myotis sodalis Microtus californicus scirpensis Microtus pennsylvanicus dukecampbelli Microtus mexicanus hualpaiensis Lasiurus cinereus semotus Dipodomys nitratoides exilis Leptonycteris curasoae yerbabuenae Leptonycteris nivalis Corynorhinus (=Plecotus) townsendii ingens Dipodomys merriami parvus Dipodomys stephensi (incl. D. cascus) Dipodomys nitratoides nitratoides Brachylagus idahoensis Dipodomys heermanni morroensis Corynorhinus (=Plecotus) townsendii virginianus Dipodomys ingens Triodopsis platysayoides Erinna newcombi Lepyrium showalteri Antrobia culveri Campeloma decampi Athearnia anthonyi Elimia crenatella Leptoxis taeniata Leptoxis plicata Leptoxis ampla Pyrgulopsis ogmorhaphe Mesodon magazinensis Pyrgulopsis (=Marstonia) pachyta Taylorconcha serpenticola

Insect Insect Insect Insect Insect Insect Insect Mammal Snail Snail

Snail

Snail

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SNAIL, MORRO SHOULDERBAND Helminthoglypta walkeriana SNAIL, IOWA PLEISTOCENE Discus macclintocki AMBERSNAIL, KANAB Oxyloma haydeni kanabensis SNAIL, NOONDAY Mesodon clarki nantahala SNAIL, OAHU TREE (MANY SPECIES) Achatinella spp. SNAIL, PAINTED SNAKE COILED FOREST Anguispira picta SNAIL, SNAKE RIVER PHYSA Physa natricina SNAIL, TULOTOMA Tulotoma magnifica SNAIL, UTAH VALVATA Valvata utahensis SNAIL, VIRGINIA FRINGED MOUNTAIN Polygyriscus virginianus SPRINGSNAIL, ALAMOSA Tryonia alamosae SPRINGSNAIL, BRUNEAU HOT Pyrgulopsis bruneauensis SPRINGSNAIL, IDAHO Fontelicella idahoensis SPRINGSNAIL, SOCORRO Pyrgulopsis neomexicana LIOPLAX, CYLINDRICAL Lioplax cyclostomaformis LIMPET, BANBURY SPRINGS Lanx sp. SNAIL, CHITTENANGO OVATE AMBER Succinea chittenangoensis

Snail

Appendix VII: PRZM/EXAMS output

<u>A-VII, Part 1</u>: Modeling of Clothianidin Cotton Seed Treatment Key files:

PRZM Input:

\Sorgh-Cott_Seed050609\PE4_CottSd_050609d__przm3.inp
EXAMS Environment Input:

\Sorgh-Cott_Seed050609\PE4_CottSd_050609d__pz2ex.exa EEC Summary File:

\Sorgh-Cott_Seed050609\PE4_CottSd_050609d.out

Estimated Environmental Concentrations

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.1323	0.1312	0.1275	0.1211	0.1166	0.06649
1962	0.1155	0.1149	0.1132	0.1078	0.104	0.0823
1963	0.06702	0.06684	0.06613	0.06462	0.06347	0.05655
1964	0.09638	0.09572	0.09309	0.09089	0.08875	0.06428
1965	0.05878	0.05862	0.05795	0.05652	0.05549	0.0447
1966	0.05872	0.05836	0.05694	0.05584	0.05415	0.0408
1967	0.1943	0.1928	0.1899	0.1807	0.1737	0.1098
1968	0.1552	0.1544	0.1517	0.1454	0.1406	0.115
1969	0.09326	0.09302	0.09202	0.08985	0.08826	0.07193
1970	0.09561	0.09498	0.09253	0.09053	0.08807	0.0661
1971	0.1297	0.1288	0.1267	0.1207	0.1162	0.0837
1972	0.07513	0.07491	0.074	0.07206	0.07064	0.0608
1973	0.0766	0.07612	0.07528	0.07292	0.07039	0.0535
1974	0.04648	0.04634	0.04579	0.04459	0.0437	0.0375
1975	0.04064	0.04041	0.03986	0.03811	0.03679	0.029
1976	0.07727	0.07671	0.07544	0.07215	0.06969	0.0468
1977	0.04733	0.04722	0.04675	0.04571	0.0449	0.0400

Year Peak		96 hr	21 Day	60 Day	90 Day	Yearly
1978	1978 0.04102 0.04		0.04015	0.03838	0.03712	0.03064
1979	0.1848	0.1833	0.1782	0.1706	0.165	0.1007
1980	0.1122	0.1117	0.1103	0.1075	0.1042	0.09303
1981	0.06887	0.06869	0.06795	0.06638	0.0652	0.054
1982	0.0633	0.0629	0.06187	0.05888	0.05669	0.0449
1983	0.09264	0.09221	0.08988	0.08564	0.08241	0.05857
1984	0.06007	0.0598	0.05874	0.05646	0.05467	0.04842
1985	0.03665	0.03654	0.03613	0.03527	0.03463	0.03066
1986	0.0289	0.02879	0.02827	0.02721	0.02628	0.02222
1987	0.02088	0.02078	0.02037	0.01959	0.01895	0.01633
1988	0.04808	0.04775	0.04659	0.04575	0.04492	0.02552
1989	0.07262	0.07226	0.07075	0.06738	0.06491	0.04774
1990	0.06568	0.06532	0.0639	0.06173	0.05992	0.04736

EECs (0.1 exceedance probability), Clothianidin on Cotton Seed:

	Probability	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
ſ	0.1	0.15291	0.15208	0.14928	0.14297	0.1382	0.099933

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* * *	Record	7:											
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	3												
* * *	Record	9											
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	2	0	. 2	125		98		3 94	84	83		0	120
	3	0.	.2	125		98		3 99	83	83		0	120
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1608 0109 1609 0110 1610 0111 1611 0112 1612 .289 .343 .359 .223 .327 .376 .425 .465 .494 .014 .014 .014 .014 .014 .014 .014 .014 .014 0101 1601 0102 1602 0103 1603 0104 1604 2504 0105 1605 0106 1606 0107 1607 .500 .517 .532 .549 .567 .591 .617 .667 .705 .718 .699 .620 .496 .354 .303 .305 .014 1608 0109 1609 0110 1610 0111 1611 0112 1612 .289 .343 .359 .223 .327 .376 .425 .465 .494 .014 .014 .014 .014 .014 .014 .014 .014 .014 0101 1601 0102 1602 0103 1603 0104 1604 2504 0105 1605 0106 1606 0107 1607 .500 .517 .532 .549 .567 .591 .617 .667 .705 .718 .699 .620 .496 .354 .303 .305 .014 EPA ARCHIVE DOCUMENT 1608 0109 1609 0110 1610 0111 1611 0112 1612 .289 .343 .359 .223 .327 .376 .425 .465 .494 *** Record 10 -- NCPDS, the number of cropping periods *** Record 11 *** Record 12 -- PTITLE Clothianidin - 1 applications @ 0.0224 kg/ha Record 13

2209.80

*** Record 15 -- PSTNAM Clothianidin

*** Record 16		
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3 0.37	0.146 0.1	6 0
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1 0.335 6 33 1.51	0.137 0.0	
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3 0.343	0.147 0.0	6 0
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RUNF	TCUM	0	0							
INFL	TĊUM	1	1							
ESLS	TCUM	0	0	1.0E3						
RFLX	TCUM	0	0	1.0E5						
EFLX	TCUM	0	0	1.0E5						
RZFX	TCUM	0	0	1.0E5						

A-VII, Part 2: Modeling of Clothianidin Sorghum Seed Treatment Key files:

PRZM Input:

\Sorgh-Cott_Seed050609\PE4_SorghSd_050609c_przm3.inp

EXAMS Environment Input:

\Sorgh-Cott_Seed050609\PE4_SorghSd_050609c_pz2ex.exa **EEC Summary File**:

\Sorgh-Cott_Seed050609\PE4_SorghSd_050609c.out

Estimated Environmental Concentrations, Clothiainidin on Sorghum Seed.

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	1961 0.0118 0.0		0.01129	0.01065	0.01022	0.005551
1962	0.01585	0.01574	0.01537	0.01456	0.01402	0.01003
1963	0.01911	0.01899	0.01863	0.01772	0.01707	0.01276
1964	0.02142	0.02129	0.02097	0.02019	0.01952	0.01465
1965	0.02213	0.022	0.02165	0.02068	0.01999	0.01588
1966	0.01784	0.01775	0.01746	0.01674	0.01619	0.01401
1967	0.02386	0.02371	0.0233	0.02216	0.02139	0.01582
1968	0.01678	0.0167	0.01651	0.01609	0.01567	0.01425
1969	0.02122	0.0211	0.02084	0.01986	0.01916	0.01474
1970	0.02345	0.02334	0.02292	0.02192	0.02119	0.01655
1971	0.02237	0.02226	0.02179	0.02088	0.0202	0.01638
1972	0.01709	0.01701	0.01667	0.01638	0.01615	0.01417
1973	0.02469	0.02456	0.02394	0.02295	0.02219	0.0164
1974	0.01608	0.01605	0.01591	0.0156	0.01537	0.01369
1975	0.02232	0.0222	0.02177	0.02089	0.02015	0.0147

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	1976	0.02739	0.02723	0.02658	0.02531	0.02448	0.01846
	1977	0.03923	0.03896	0.03822	0.03628	0.03491	0.02501
	1978	0.04481	0.04452	0.04354	0.04157	0.04008	0.03015
	1979	0.02912	0.02906	0,02881	0.02828	0.02787	0.02392
	1980	0.034	0.03379	0.03304	0.03148	0.03026	0.02259
	1981	0.05496	0.05458	0.05314	0.0503	0.04837	0.03369
	1982	0.03411	0.03404	0.03375	0.03313	0.03265	0.0292
	1983	0.02347	0.02342	0.02313	0.02233	0.02185	0.01985
	1984	0.03317	0.03296	0.03215	0.0305	0.02936	0.02116
ł	1985	0.02399	0.02387	0.02345	0.02247	0.02175	0.01948
	1986	0.04074	0.04046	0.03936	0.0375	0.03619	0.02543
	1987	0.03127	0.03111	0.0306	0.0294	0.02844	0.02454
	1988	0.03282	0.03263	0.03187	0.03106	0.03037	0.02399
	1989	0.03002	0.02987	0.02926	0.02819	0.02737	0.02281
	1990	0.08521	0.08456	0.08206	0.07738	0.07427	0.04716
L		-					

EECs (0.1 exceedance probability), Clothianidin on Sorghum Seed:

Probability	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.1	0.044403	0.044114	0.043122	0.041163	0.039691	0.030055

PRZM Sorghum Seed Input File:

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stil	ll in MI	GRA 112	(East Cen	tral KS);	Metfi	le: W13	996.dvf,	(old me	tfile:	
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3 10 1.6	0.316	. 0	0	0		
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5 0.316	0.166	0.174	0			
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2 0.348	0.198	0.116	0			
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ESLS TCUM 0 0	1.0E3					
RFLX TCUM 0 0	1.0E5					
EFLX TCUM 0 0	1.0E5					
RZFX TCUM 0 0	1.0E5					

A-VII, Part 3: Modeling of Clothianidin Multiple (3) Foliar Applications on Potatoes Key files:

PRZM Input:

\Potato-ME050603\Potato_3appsLateSeasn_CAM2_Clothain_przm3.inp EXAMS Environment Input: 1

\Potato-ME050603\Potato_3appsLateSeasn_CAM2_Clothain__pz2ex.exa <u>EEC Summary File</u>: \Potato-ME050603\PE4_Potat050603b.out

Also presented, but not used in EEC calculations (same scenario, early season applications): **PRZM Input**:

\Potato-ME050603\Potato_3appsEarlySeasn_CAM2_Clothain_przm3.inp EXAMS Environment Input:

\Potato-ME050603\Potato_3appsEarlySeasn_CAM2_Clothain__pz2ex.exa <u>EEC Summary File</u>:

\Potato-ME050603\PE4_Potat050603a.out

Estimated Environmental (Dissolved Water) Concentrations, 3 Late-Season Applications of Clothianidin on Potatoes (total season rate of 0.2 lb ai per acre).

Yea	ır	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
196	1	1.724	1.366	0.6673	0.319	0.2436	0.07417
196	2	1.075	0.9373	0.926	0.8785	0.6244	0.2573
196	3	0.886	0.8829	0.8709	0.8475	0.8338	0.295
196	4	1.551	1.276	0.8146	0.7158	0.594	0.1901
196	5	0.9215	0.9174	0.9014	0.8715	0.8534	0.2737
196	6	1.074	0.8835	0.5688	0.3171	0.2485	0.08372
196	7	1.912	1.542	0.8629	0.4217	0.339	0.135
196	8	1.436	1.17	1.058	0.8564	0.6833	0.2562
196	9	2.711	2.204	1.119	0.9911	0.9744	0.3886
197	0	3.597	2.966	1.732	0.8332	0.5901	0.2334
197	1	0.554	0.4587	0.2437	0.166	0.1539	0.09006
197	2	0.7334	0.5909	0.3135	0.269	0.2637	0.1429
197	3	0.7615	0.7565	0.6145	0.3826	0.3562	0.1665
197	4	0.7417	0.7374	0.7207	0.6939	0.691	0.2288
197	5	0.3956	0.394	0.3673	0.3344	0.3291	0.1144
197		1.326	0.992	0.5041	0.4292	0.402	0.1527
197	7	0.7559	0.6312	0.4485	0.3885	0.3173	0.1412

Page 89 of 110

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1978	0.2633	0.2167	0.2086	0.2051	0.1945	0.08678
1979	1.264	1.002	0.6043	0.5278	0.4158	0.1714
1980	0.4287	0.4221	0.3907	0.3778	0.3788	0.1498
1981	0.4894	0.4268	0.3885	0.3642	0.3144	0.1554
1982	0.6695	0.5663	0.4025	0.2711	0.2643	0.1493
1983	0.8186	0.6522	0.3585	0.3035	0.2963	0.1533
1984	0.3452	0.3445	0.3412	0.33	0.3222	0.1009
1985	0.4386	0.4357	0.4247	0.3297	0.2273	0.08064
1986	0.7742	0.7697	0.7524	0.7225	0.6574	0.2203
1987	0.6753	0.5372	0.3457	0.2058	0.1859	0.1156
1988	0.4552	0.4435	0.387	0.3778	0.3645	0.1298
1989	0.2464	0.245	0.2394	0.2071	0.1497	0.07859
1990	1.761	1;.427	0.7839	0.6297	0.5937	0.2391

EECs (0.1 exceedance probability), Clothianidin on Potatoes (3 late-season applications):

Probability	Peak	96 hr	21 Day	60 Day	90 Day	Yearly	
0.1	1.8969	1.5305	1.0448	0.86999	0.81952	0.27206	

PRZM - Maine Potatoes, 3 Late-Season applications Input File:

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Estimated Environmental (Dissolved Water) Concentrations, 3 Early-Season Applications of Clothianidin on Potatoes (total season rate of 0.2 lb ai per acre). (not used in ecological risk assessment).

1

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.3482	0.2872	0.1545	0.09481	0.08092	0.0235
1962	1.295	1.012	0.5936	0.2589	0.1825	0.05534
1963	0.3113	0.2568	0.1462	0.1011	0.08956	0.03542
1964	0.5951	0.4709	0.2156	0.09972	0.07656	0.03785
1965	0.1767	0.1464	0.08944	0.08718	0.0857	0.03828
1966	0.2177	0.1791	0.1112	0.06434	0.04923	0.01888
1967	0.8761	0.6878	0.3167	0.1635	0.1277	0.04216
1968	0.626	0.4814	0.3067	0.1478	0.1206	0.05812
1969	0.4637	0.3738	0.2499	0.1634	0.1605	0.07485
1970	0.3406	0.2807	0.1748	0.103	0.08933	0.03209
1971	0.1608	0.13	0.07052	0.03782	0.03017	0.0146
1972	0.5606	0.4466	0.236	0.1409	0.1304	0.04179
1973	1.013	0.8645	0.4668	0.194	0.1345	0.04566
1974	0.2222	0.1745	0.09848	0.04523	0.05114	0.02713
1975	0.2789	0.2162	0.1581	0.09072	0.06574	0.02508
1976	0.7299	0.5415	0.3566	0.211	0.1517	0.04655
1977	0.9034	0.7046	0.3655	0.1621	0.1366	0.04084
1978	1.045	0.8107	0.3973	0.1855	0.1319	0.0384
1979	0.291	0.2276	0.1105	0.07115	0.06625	0.02443
1980	0.3427	0.2689	0.1594	0.0989	0.07176	0.02245
1981	1.567	1.208	0.5591	0.2554	0.204	0.05849
1982	1.153	0.8849	0.4415	0.2092	0.1498	0.04806
1983	1.039	0.81	0.3967	0.2238	0.16	0.04856
1984	0.4936	0.4339	0.276	0.1686	0.116	0.03474
1985	0.3447	0.2688	0.1648	0.08152	0.05725	0.02219
1986	0.4391	0.3442	0.2435	0.1368	0.09703	0.03895
1987	0.4224	0.3277	0.1546	0.0872	0.06748	0.02623
1988	0.2059	0.171	0.1	0.0688	0.05963	0.02454
1989	1.129	0.9124	0.4429	0.2082	0.1522	0.04455
1990	0.6473	0.5462	0.2832	0.1925	0.1389	0.0526

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EECs (0.1 exceedance probability), Clothianidin on Potatoes (3 early-season applications):

Probability	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.1	1.1506	0.90965	0.46441	0.22252	0.16045	0.057842

A-VII, Part 4: Modeling of Clothianidin Single Broadcast Application on Potatoes

Key files:

PRZM Input:

\Potato-ME050603\Potato-ME050603_przm3.inp

EXAMS Environment Input:

file accidently erased.

EEC Summary File:

\Potato-ME050603\PRZM-EX_Clothia__ME-pota_050603.out

Estimated Environmental (Dissolved Water) Concentrations, Single Broadcast Application of Clothianidin on Potatoes (0.2 lb ai per acre).

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.2231	0.1845	0.09903	0.06274	0.05418	0.01881
1962	0.7117	0.5549	0.3207	0.1375	0.1025	0.02948
1963	0.2015	0.1666	0.09126	0.06408	0.05414	0.01986
1964	0.4242	0.3351	0.1519	0.06894	0.05222	0.0263
1965	0.1264	0.1049	0.05629	0.05474	0.05374	0.02582
1966	0.3711	0.2921	0.1412	0.06944	0.04954	0.02017
1967	0.6129	0.4804	0.2197	0.1116	0.08552	0.0286
1968	0.474	0.3633	0.2326	0.1052	0.08629	0.04188
1969	0.2534	0.2041	0.1382	0.1144	0.1123	0.0509 0
1970	0.3432	0.2676	0.1335	0.07968	0.05932	0.02479
1971	0.1121	0.0895	0.03978	0.02953	0.02292	0.01046
1972	0.9208	0.7848	0.4528	0.208	0.1467	0.04245
1973	0.6694	0.573	0.3088	0.1284	0.093	0.02942
1974	0.1813	0.1542	0.08526	0.04857	0.04353	0.01845
1975	0.2153	0.1678	0.1024	0.06877	0.05715	0.01849

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Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1976	0.4494	0.3327	0.1909	0.1425	0.1126	0.03168
1977	0.8565	0.704	0.4107	0.1784	0.1446	0.03915
1978	0.6003	0.4653	0.2226	0.1182	0.08528	0.0251
1979	1.462	1.146	0.5582	0.2348	0.1668	0.04719
1980	0.2655	0.2081	0.1207	0.07378	0.05843	0.02056
1981	0.5374	0.4143	0.2053	0.09594	0.0941	0.02895
1982	0.6782	0.52	0.2593	0.1199	0.1032	0.03184
1983	1.96	1.663	0.7721	0.3887	0.2911	0.07907
1984	1.63	1.317	0.6756	0.3527	0.2437	0.06934
1985	0.1981	0.1542	0.09328	0.04886	0.03854	0.01571
1986	0.3212	0.2515	0.1793	0.09807	0.06883	0.02555
1987	0.3038	0.238	0.1196	0.0761	0.05546	0.01915
1988	0.1695	0.1407	0.08183	0.051	0.04252	0.01601
1989	0.6522	0.5267	0.2567	0.1198	0.09591	0.03015
1990	0.8788	0.6943	0.3398	0.1805	0.136	0.04075

EECs (0.1 exceedance probability), Clothianidin on Potatoes (single soil application):

Probability	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.1	1.40788	1.10988	0.54766	0.23212	0.16479	0.050529

PRZM - Maine Potatoes, Single Soil application Input File:

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*** Record 19 STITLE "Conant Silt Loam MLRA M-14	6. Aroos	took County	ME"	
*** Record 20	10, 111000	cook county	,	
100 0 0	1 0	0 0 0	0 0	
*** Record 26				:
0 0 0 *** Record 30			· .	
4 188	×			
*** Record 33				·
4	0 0 4 4		0	
1 10 1.25 0.0009320.000932	0.341	· 0	0	0
0.1 0.341	0.121	4.64	10	
2 16 1.25	0.341	0	0	0
0.0009320.000932	0			
$\begin{array}{cccc} 1 & 0.341 \\ 3 & 64 & 1.4 \end{array}$	0.121 0.266	4.64	0 0	0
0.0009320.000932	0.200	0	U ,	0
1 0.266	0.116	0.174	. 0	
4 10 1.6	0.261	0 .	0	0
0.0009320.000932 1 0.261	0 0.111	0.116	0	
***Record 40	0.111	0.110	0	
0				
YEAR 10		YEAR	10	YEAR
1 1				
7 YEAR				
PRCP TCUM 0 0				
RUNF TCUM 0 0		• • •		
INFL TCUM 1 1 ESLS TCUM 0 0 1	L.0E3			
	L.0E5			
	L.0E5			
	L.0E5			1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 - 1997 -

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<u>A-VII, Part 5</u>: Modeling of Clothianidin Applications on Grapes Key files:

		lication		··· .	• . •	_	
Year	Pe: 1961	ak 96 0.3591	hr 21 0.3566	Day 60 0.3471	0 Day 90 0.2483	Day Y 0.196	early 0.05984
	1962	0.3283	0.3267	0.3204	0.3095	0.3024	0.273
	1963	0.4117	0.4096	0.4039	0.389	0.3787	0.3413
	1964	0.7305	0.7253	0.7128	0.6831	0.5726	0.3703
	1965	0.6354	0.633	0.6237	0.6048	0.5917	0.5161
	1966	0.4772	0.4758	0.4702	0.4584	0.4498	0.3998
	1967	0.4198	0.4183	0.4125	0.4017	0.3937	0.353
	1968	0.6528	0.6487	0.6343	0.6066	0.5303	0.3454
	1969	0.5791	0.577	0.5693	0.5532	0.5418	0.4678
	1970	0.7082	0.7046	0.69	0.5455	0.4876	0.4188
	1971	0.6843	0.6813	0.6693	0.6462	0.631	0.5385
	1972	0.6943	0.6905	0.6752	0.612	0.5387	0.4541
	1973	0.6226	0.6204	0.6114	0.5932	0.5808	0.4979
	1974	0.5757	0.5722	0.5587	0.5504	0.4928	0.3927
· · . •	1975	0.5356	0.5337	0.5271	0.5122	0.5017	0.4438
· .	1976	0.9341	0.9273	0.901	0.855	0.8284	0.4682
	1977	1.11	1.104	0.9178	0.722	0.7075	0.6234
	1978	1.094	1.089	1.067	1.024	0.9963	0.8705
	1979	0.8193	0.8169	0.8113	0.7922	0.7771	0.6566
	1980	0.5436	0.5423	0.5389	0.5287	0.5189	0.4494
	1981	0.5538	0.5512	0.541	0.521	0.5076	0.4328
	1982	0.7249	0.7209	0.7079	0.6938	0.6819	0.4359
	1983	0.6602	0.6581	0.6495	0.6317	0.6188	0.542
	1984	0.4877	0.4862	0.4802	0.4675	0.4582	0.4005
	1985	0.3812	0.3801	0.3753	0.3653	0.3581	0.3231
	1986	1.071	1.063	0.7046	0.4136	0.3675	0.2942

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1987	1.062	1.056	1.032	0.9852	0.9551	0.7716
1988	0.5861	0.5847	0.5785	0.5647	0.5541	0.48
1989	0.5323	0.529	0.516	0.4917	0.4767	0.418
1990	0.5133	0.5114	0.5037	0.4884	0.4776	0.4145

Selected EECs:

EECs (0.1 exceedance probability), Clothianidin on Grapes (two soil application):

Probability	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.1	1.0701	1.0623	0.91612	0.84872	0.82327	0.65328

EECs for Grapes, single soil application:

Year		96 hr	21 Day	60 Day 9	90 Day `	•
1961	1 0.112	0.1109	0.1071	0.1005	0.09658	0.06849
1962	2 0.6985	0.6933	0.6733	0.6351	0.6114	0.4358
196	3 0.6572	0.6537	0.6447	0.6183	0.601	0.4715
1964	4 0.4537	0.4519	0.4447	0.4304	0.4206	0.3423
196	5 0.3508	0.3492	0.343	0.3307	0.3224	0.2594
1966	6 0.2953	0.2939	0.2884	0.2776	0.2702	0.2132
1967	7 0.2605	0.2592	0.254	0.2439	0.2375	0.187
1968	8 0.2424	0.2411	0.2373	0.2298	0.2236	0.1746
1969	9 0.2464	0.2452	0.2407	0.235	0.2306	0.1814
1970	0 0.2421	0.2408	0.2357	0.226	0.2197	0.1713
197 ⁻	1 0.2324	0.2311	0.2261	0.2167	0.2107	0.165
1972	0.2329	0.2317	0.228	0.2188	0.2125	0.1645
1973	3 0.5062	0.5026	0.4888	0.4638	0.4482	0.33
1974	4 0.356	0.3545	0.3482	0.3359	0.3275	0.2615
197	5 0.2931	0.2917	0.2861	0.2754	0.2684	0.2141
1970	6 0.2658	0.2648	0.2621	0.2526	0.246	0.1947
197	7 0.2515	0.2501	0.2449	0.235	0.2284	0.1784

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							a é
	1978	0.2422	0.2413	0.2368	0.2293	0.223	0.1729
	1979	0.2332	0.2319	0.227	0.2183	0.2121	0.1641
	1980	0.2257	0.2244	0.2201	0.212	0.2061	0.1601
	1981	0.2242	0.2229	0.218	0.2087	0.2027	0.1556
	1982	0.2198	0.2186	0.2137	0.2047	0.1989	0.1549
	1983	0.6086	0.6041	0.5864	0.5551	0.5359	0.3914
	1984	0.3957	0.394	0.3872	0.3735	0.364	0.2883
-	1985	0.3062	0.3047	0.2993	0.2882	0.2805	0.2201
	1986	0.3021	0.3004	0.2941	0.2816	0.2742	0.2128
	1987	0.2604	0.259	0.2544	0.2446	0.2378	0.1856
	1988	0.2412	0.2399	0.2347	0.2249	0.2184	0.1698
	1989	0.2297	0.2285	0.2236	0.2142	0.208	0.1608
	1990	0.2393	0.2379	0.2327	0.2234	0.2169	0.1667
						•	
Prol	abilit Y	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
	0.1	0.59836	0.59395	0.57664	0.54597	0.52713	0.38649

Clothianidin, Grapes, inputs, 2 foliar applications:

CAgrapes "California central valley grapes, MLRA-17, metfile: W93193.dvf (old: Met18.met_or Met17.met), *** Record 3: 0.7 0.55 0 17 З *** Record 6 -- ERFLAG 4 *** Record 7: 0.28 0.2 10 354 1 1 2 *** Record 8 ् 1 *** Record 9 1 0.25 100 70 3 84 79 82 0 200 *** Record 9a-d 1 26 0101 1601 0102 1602 0103 1603 0104 1504 1604 0105 1605 0106 1606 0107 1507 1607 .360 .410 .428 .444 .459 .478 .493 .511 .514 .517 .491 .472 .463 .462 .471 .471 0108 1608 0109 1609 0110 1610 0111 1611 0112 1612 .470 .470 .479 .481 .483 .489 .274 .293 .309 .322 *** Record 10 -- NCPDS, the number of cropping periods 30 *** Record 11 010261 150861 310861 1 010262 150862 310862 1

010263 150863 310863 1 010264 150864 310864 1 010265 150865 310865 1 010266 150866 310866 1 010267 150867 310867 1 010268 150868 310868 1 010269 150869 310869 1 010270 150870 310870 1 010271 150871 310871 1 010272 150872 310872 1 010273 150873 310873 1 010274 150874 310874 1 010275 150875 310875 1 010276 150876 310876 1 010277 150877 310877 1 010278 150878 310878 1 010279 150880 310880 1 010281 150881 310881 1 010281 150881 310881 1 010283 150883 310883 1 010284 150884 310884 1 010285 150885 310885 1 010286 150886 310886 1 010287 150887 310887 1 010284 150884 310884 1 010285 150885 310885 1 010286 150886 310886 1 010287 150887 310887 1 010288 150888 310888 1 010288 150888 310888 1 010289 150889 310889 1 010290 150890 310890 1 *** Record 12 PTITLE Clothianidin - 2 applications @ 0.1121 kg/ha	
*** Record 13 60 1 0 0	
*** Record 15 PSTNAM	
Clothianidin	
*** Record 16 160861 0 2 0.00.1121 0.99 0.01	
300861 0 2 0.00.1121 0.99 0.01	
160862 0 2 0.00.1121 0.99 0.01	
300862 0 2 0.00.1121 0.99 0.01 160863 0 2 0.00.1121 0.99 0.01	
300863 0 2 0.00.1121 0.99 0.01	
160864 0 2 0.00.1121 0.99 0.01	
300864 0 2 0.00.1121 0.99 0.01	
300865 0 2 0.00.1121 0.99 0.01 160866 0 2 0.00.1121 0.99 0.01	
300866 0 2 0.00.1121 0.99 0.01	
160867 0 2 0.00.1121 0.99 0.01	
300867 0 2 0.00.1121 0.99 0.01	
160868 0 2 0.00.1121 0.99 0.01 300868 0 2 0.00.1121 0.99 0.01	
160869 0 2 0.00.1121 0.99 0.01	
300869 0 2 0.00.1121 0.99 0.01	
160870 0 2 0.00.1121 0.99 0.01	
300870 0 2 0.00.1121 0.99 0.01 160871 0 2 0.00.1121 0.99 0.01	
300871 0 2 0.00.1121 0.99 0.01	
160872 0 2 0.00.1121 0.99 0.01	
300872 0 2 0.00.1121 0.99 0.01	
160873 0 2 0.00.1121 0.99 0.01 300873 0 2 0.00.1121 0.99 0.01	
160874 0 2 0.00.1121 0.99 0.01	
300874 0 2 0.00.1121 0.99 0.01	
160875 0 2 0.00.1121 0.99 0.01	

	,		
300875 0 2 0.00.1121 0. 160876 0 2 0.00.1121 0. 300876 0 2 0.00.1121 0. 300877 0 2 0.00.1121 0. 300877 0 2 0.00.1121 0. 300878 0 2 0.00.1121 0. 300878 0 2 0.00.1121 0. 300879 0 2 0.00.1121 0. 300879 0 2 0.00.1121 0. 300880 0 2 0.00.1121 0. 300880 0 2 0.00.1121 0. 300881 0 2 0.00.1121 0. 300881 0 2 0.00.1121 0. 300882 0 2 0.00.1121 0. 300883 0 2 0.00.1121 0. 300885 0 2 0.00.1121 0. 300886 0 2 0.00.1121 0. 300887 0 2 0.00.1121 0. 300888 0 2 0.00.1121 0. 300889 0 2 0.00.1121 0. 300890 0 2 0.00.1121	99 0.01 99 0.01	Ο Ο	
1 0.1 0.55 0.4 *** Record 30			
4 188 *** Record 33			
2 1 10 1.84 0.21	0	0	0
0.0009320.000932 0.1 0.21 0.1	0 0.72	0	
2 330 1.6 0.28 0.0009320.000932	0 0	0	0
30 0.28 0.15 ***Record 40	0.16	0	ĺ
0	YEAR	10	
1	*		
7 YEAR PRCP TCUM 0 0 RUNF TCUM 0 0 INFL TCUM 1 1 ESLS TCUM 0 0 1.0 RFLX TCUM 0 0 1.0)E3)E5		

10 1

YEAR

EFLX TCUM 0 0 1.0E5 RZFX TCUM 0 0 1.0E5

Clothionidin Granes inputs 1 soil application:
<u>Clothianidin, Grapes, inputs, 1 soil application:</u> CAgrapes
"California central valley grapes, MLRA-17, metfile: W93193.dvf (old: Met18.met or Met17.met), *** Record 3:
0.7 0.55 0 17 1 3
*** Record 6 ERFLAG
4
*** Record 7:
0.28 0.2 1 10 1 2 354
*** Record 8
*** Record 9
1 0.25 100 70 3 84 79 82 0 200
*** Record 9a-d
0101 1601 0102 1602 0103 1603 0104 1504 1604 0105 1605 0106 1606 0107 1507 1607 .360 .410 .428 .444 .459 .478 .493 .511 .514 .517 .491 .472 .463 .462 .471 .471
.023 .023 .023 .023 .023 .023 .023 .023
0108 1608 0109 1609 0110 1610 0111 1611 0112 1612
.470 .479 .481 .483 .489 .274 .293 .309 .322
.023 .023 .023 .023 .023 .023 .023 .023
*** Record 10 NCPDS, the number of cropping periods
30 *** Record 11
010261 150861 310861 1
010262 150862 310862 1
010263 150863 310863 1
010264 150864 310864 1
010265 150865 310865 1
010266 150866 310866 1
010267 150867 310867 1
010268 150868 310868 1
010269 150869 310869 1 010270 150870 310870 1
010271 150871 310871 1
010272 150872 310872 1
010273 150873 310873 1
010274 150874 310874 1
010275 150875 310875 1
010276 150876 310876 1
010277 150877 310877 1 010278 150878 310878 1
010279 150879 310879 1
010280 150880 310880 1
010281 150881 310881 1
010282 150882 310882 1
010283 150883 310883 1
010284 150884 310884 1
010285 150885 310885 1
010286 150886 310886 1 010287 150887 310887 1
010288 150888 310888 1
010289 150889 310889 1
010290 150890 310890 1
*** Record 12 PTITLE
PE4_Grape_050608d - 1 applications @ 0.2242 kg/ha
*** Record 13 30 1 0 0
30 1 0 0

F

** Record 15		М		
PE4_Grape_0 *** Record 16	150608d			
010261 01	0.00.2242	2 0.99 0.0		
010262 0 1		2 0.99 0.0		
010263 0 1 010264 0 1		2 0.99 0.0 2 0.99 0.0		
010265 0 1		2 0.99 0.0		
010266 01		2 0.99 0.0		
010267 01		2 0.99 0.0 2 0.99 0.0		
010269 01		2 0.99 0.0		
010270 01		2 0.99 0.0		
010271 01 010272 01		2 0.99 0.0 2 0.99 0.0		
010272 01		2 0.99 0.0		
010274 01		2 0.99 0.0		
010275 0 1 010276 0 1		2 0.99 0.0 2 0.99 0.0		
010278 01		2 0.99 0.0 2 0.99 0.0	-	
010278 01	0.00.2242	2 0.99 0.0	1	
010279 0 1		2 0.99 0.0		
010280 01		2 0.99 0.0 2 0.99 0.0		
010282 01	0.00.224	2 0.99 0.0	1	
010283 0 1		2 0.99 0.0		
010284 01 010285 01		2 0.99 0.0 2 0.99 0.0		
010286 01	0.00.224	2 0.99 0.0	1	
010287 01				
010288 01 010289 01		2 0.99 0.0 2 0.99 0.0		
010290 01	0.00.2242	2 0.99 0.0		
** Record 17				
0 1 *** Record 19	0 STITLE			
'San Joaquin	loam, Hyd	grp C"		
*** Record 20 340		0 0 2 0	000	
*** Record 26		υσχι	0 0 0	
0 0	0			
*** Record 27 1 0.1	irrigatio			
*** Record 30		.4		
4 188				
*** Record 33 2				
	1.84 0.2	21 0	0	0
	20.000932		-	
0.1 2 330	0.21 0.		0 0	0
	20.000932		U	Ő
	0.28 0.1	5 0.16	0	
***Record 40 0				
YEAR	10	YEAR	10	
1 .	· .			
1 7 YEAF	2			
PRCP TO	CUM 0 0)		
		1.0E3		
	UM 0 0			

10 1

YEAR

US EPA ARCHIVE DOCUMENT

EFLX TCUM 0 0 1.0E5 RZFX TCUM 0 0 1.0E5

PE4 Input screens

w03940 dvf	Methie	8	CAM
NUC STREET		, 0	
MScottonC.txt	PRZM scenario	0.0224	Incorp: Depth (cm) App. Rate (kg a.i./ha)
pond298.exv		1.00	App: Efficiency (fraction)
	• Pond C Default	0.00	Spray Drift (fraction)
		26-04	Application Date (day-mon)
Runoff Now: 🦳 I	Monthly 🤇 Överall 🥌 None	Contractor Sector	
PE4_CottSd_0506	09d Output filename	ji inum	per of Applications Intervals
Clothianidin Chemical name		1 IPSCND (Record 17)	
249.7	— Molecular Weight	Set Hydrolysi	s More PRZM Parameters
2.85E-16	Henry's Law Const. (atm m^3/n	iol)	
4.27E-10		I Write Ber	nthic pore water concentrations
300	Solubility (mg/L)	34	Aq. Photolysis half-life (days
we now - 5+ 1+ 1 Prog 2000000000 -	- Ka	1488	Water half-life (days)
188	— Koc	81	Benthic half-life(days)
STADARS		744	Soil half-life (days)

Figure 14. PE4 Input screen for clothianidin cotton seed treatment.

PE4 Input screen for clothianidin cotton seed treatment.

File Edit			
w14607.dv	🕂 🔟 Metfilefróm scenario	2 0	AM
MEpotatoC.	txt PRZM scenario	0	Incorp. Depth (cm)
 A state particular statements 	en de la companya de	0.0747	App. Rate (kg a.i./ha)
pond298.e:	EXAMS environment	0.99	App. Efficiency (fraction)
Field size: 🔿	IR 📀 Pond 🦳 Default	0.01	Spray Drift (fraction)
		02-09	Application Date (day-mon
	Monthly C Overall C None	3 Number o	of Applications Intervals
PE4_Potat0506	03 4 Output filename		
Clothianidin	Chemical name	1 IPSCND (Record 17)	
249,7	Molecular Weight	Set Hydrolysis	More PRZM Parameters
2.85E16	Henry's Law Const. (atm m^3/mol)		
4.27E-10	Vapour Pressure (torr)	Write Benthic pore water concentrations	
	Solubility (mg/L)	34	Aq. Photolysis half-life (day
300		A	Water half-life (days)
300	— Ка	1488	AA Green ugu une (GGAA)
300		1488 81	Benthic half-life(days)

Figure 16. PE4 Input screen for clothianidin on potatoes, 3 late-season applications totalling 0.2 lb ai/ acre.

PE4			
File Edit			
w13996.dv	f — Metfilefrom scenario	8 🛶 🛛	CAM
KSsorghumC	bit 🖵 PRZM scenario	1.91	Incorp. Depth (cm)
Laco -		0.0224	App. Rate (kg a.i./ha)
pond298.ex	EXAMS environment	1.00	App. Efficiency (fraction)
Field size: 🔿 1	R 📀 Pond 🤄 Default	0 .00	Spray Drift (fraction)
Bupoff flow: C Monthly C Riverall @ None		15-05	Application Date (day-mon)
	Monthly C Overall 🤍 None	1 Number	of Applications Intervals
Clothianidin	Output filename		
Clothianidin	Chemical name	1 — IPSCND (Record 17)	
249.7	Molecular Weight	Set Hydrolysis	More PRZM Parameters
2.85E-16	Henry's Law Const. (atm m^3/mo	· · · · · · · · · · · · · · · · · · ·	
4.27E-10	Vapour Pressure (torr)	Write Benthic pore water concentrations	
300	Solubility (mg/L)	34	Aq. Photolysis half-life (days
		1488	Water half-life (days)
188	Koc	81	Benthic half-life(days)
		744	Soil half-life (days)
Run PRZM/EX	AMS		

Figure 15. PE4 Input screen for clothianidin sorghum seed treatment.

DE4				
File Edit				
w14607.dv	Metfilefrom scenario	1 -	CAM	
MEpotatoC.t	At PRZM scenario	0	Incorp. Depth (cm)	
		0.224	App. Rate (kg a.i./ha)	
pond298.exv EXAMS environment Field size: C IR • Pond C Default Runoff flow: C Monthly C Overall • None		0.99	App. Efficiency (fraction)	
		0.01	Spray Drift (fraction)	
		30-05	Application Date (day-mon	
		1 Number	of Applications Intervals	
dan danan karana kutuk	iaME-pota_ Output filename		DCCND (Depend 17)	
Clothianidin	Chemical name	IPSCND (Record 17)		
249.7	Molecular Weight	Set Hydrolysis	More PRZM Parameters	
2.85£16	2.85E16 Henry's Law Const. (atm m^3/mol		Write Benthic pore water concentrations	
4.27E-10	Vapour Pressure (torr)			
300	Solubility (mg/L)	34	Aq. Photolysis half-life (day	
	Kd	1:488	Water half-life (days)	
1.88 :	Koc	81	Benthic half-life(days)	
		744	Soil half-life (days)	
Bun PRZM/EX	ALC			

Figure 18. PE4 Input screen for clothianidin on potatoes, single soil application of 0.2 lb ai/ acre.

PE4			
File. Edit			
w14607.dv	f 🛁 Metfilefrom scenario	2	ЗАМ
MEpotatoC.t	xt PRZM scenario	0.	Incorp. Depth (cm)
	EXAMS environment	0.0747	App. Rate (kg a.i./ha)
pond298.ex	EXAMS environment	0,99	App. Efficiency (fraction)
Field size: 🔿 J	R 🤄 Pond 🕥 Default	0.01	Spray Drift (fraction)
		13-06	Application Date (day-mor
的同时间是明白	Monthly C Overall 🧐 None	3. Number	of Applications Intervals
PE4_Potat05060	03a Output filename		
Clothianidin	Chemical name	1	PSCND (Record 17)
249.7	Molecular Weight	Set Hydrolysis	More PRZM Parameters
2.85E16	Henry's Law Const. (atm m^3/mol). 	
4.27E-10	Vapour Pressure (torr)	I Write Benthi	c pore water concentrations
300	Solubility (mg/L)	34	Aq. Photolysis half-life (day
- MARTINESSAN AND ALLEY	Kđ	1488	Water half-life (days)
188	Koc	81	Benthic half-life[days]
		744	Soil half-life (days)
Run PRZM/EX	AMS		

Figure 17. PE4 Input screen for clothianidin on potatoes, 3 early-season applications totalling 0.2 lb ai/ acre (yielded lower EECs than with 3 late-season applications, therefore not used in the ecological risk assessment).

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PE4			
File Edit			
w93193.dvf 🛁 Metfile from scenario		2 CAM	
CAgrapesC.	xt PRZM scenario	0	Incorp. Depth (cm)
		0.1121	App. Rate (kg a.i./ha)
pond298.ex	EXAMS environment	0.99	App. Efficiency (fraction)
Field size: 🤇 1	R 🖲 Pond 🕤 Default 📋	0.01	Spray Drift (fraction)
Runoff flow: C Monthly C Overall 🖲 None		16-08	Application Date (day-mon)
		2 Number of Applications Intervals	
PE4_Grape_050608c Output filename Clothianidin Chemical name		1	
249.7	Mölecular Weight	Set Hydrolysis	More PRZM Parameters
2.85E-16	Henry's Law Const. (atm m^3/mol)		
4.27E-10	Vapour Pressure (torr)	I Write Benthi	c pore water concentrations
30 4	Solubility (mg/L)	34	Ag. Photolysis half-life (days)
unan ang ang ang ang ang ang ang ang ang	Kd	1488	Water half-life (days)
188	Koc	81	Benthic half-life(days)
		744	Soil half-life (days)
Run PRZM/EX	AMS		

Figure 19. PE4 Input screen for clothianidin on grapes, 2 late-season applications totalling 0.2 lb ai/ acre.