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Reregistration Eligibility Decision for Thidiazuron

List D

Case No. 4092

Approved by: _____ Date:_____

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CARES	-------
CCA	Comparative Cholinesterase Assay
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EC	Engineering Control
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FATE5	-------
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
Lifeline	------
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/ EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TCPSA	2,3,3-trichloroprop-2-ene sulfonic acid ([chemical name] Metabolite)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

This document presents the Environmental Protection Agency's (hereafter the Agency or EPA) decision regarding the reregistration eligibility of the registered uses of thidiazuron [1-phenyl-3-(1,2,3-thidiazol-5-yl)urea]. The Agency made its reregistration eligibility determination based on its review of the required data and current guidelines for conducting acceptable studies to generate such data. The Agency has found that currently registered uses of thidiazuron are eligible for reregistration, provided that the changes specified in this document are made to the label.

Thidiazuron is a member of the phenylurea class of herbicides and is used as a growth regulator only on cotton. The first registration was in 1982. Currently, there are 22 tolerances for thidiazuron.

Dietary Risk from Food and Water

An acute dietary assessment was not performed on thidiazuron because there were no effects observed in the available toxicology studies that could be attributable to a single exposure (dose). Chronic dietary risk estimates for food and water are below the Agency's level of concern. The highest chronic exposure and risk estimates were for children 1 to 2 years old. The chronic dietary risks are less than 100% of the chronic Population Adjusted Dose (cPAD) for all population subgroups. Therefore, no mitigation is warranted at this time for dietary exposure to thidiazuron.

Occupational Risk

To address occupational exposure, short-term inhalation, and intermediate-term inhalation risks were assessed. MOEs were not calculated for dermal exposures, since no hazard concern was identified for exposures via the dermal route. For handlers, in all scenarios considered, risks were not of concern (MOEs ranged from 150 to 1,300,000 at baseline protection). Therefore, no mitigation is warranted at this time for occupational risk to thidiazuron.

Residential Risk

There are no residential uses of thidiazuron. Therefore, residential exposures are not expected and a residential exposure assessment was not conducted.

Aggregate Risk

An acute dietary assessment was not performed on thidiazuron because there were no effects observed in the available toxicology studies that could be attributable to a single exposure (dose). Therefore, no mitigation is warranted at this time for acute aggregate risk to thidiazuron. A chronic aggregate risk assessment was conducted for thidiazuron. The chronic aggregate risk looked at the combined risk from dietary exposure (food and drinking water pathways), since

there are no residential uses. Chronic risks from food exposures were below the Agency's level of concern. Therefore, no mitigation is warranted at this time for aggregate risk to thidiazuron.

Ecological Risk

Non-target terrestrial and semi-aquatic plants are at potential direct risk from thidiazuron use. Dicots are sensitive to thidiazuron, but monocots do not appear to be affected at expected environmental concentrations. Aquatic plants do not appear to be at risk. However, if terrestrial non-target plants come in contact with thidiazuron, these plants may be killed or damaged enough to prevent the plant from reproducing or successfully competing with other plants for resources. For mammals, acute risks did not exceed levels of concern, but there is a potential for chronic risk when maximum (high-end) EECs are assumed. For birds, acute risk quotients did not exceed levels of concern. Chronic risks to birds cannot be estimated due to absence of data; however such data will be required as a follow-up to this RED. To help mitigate environmental risks, specific language clarifying allowable use rates and conditions shall be required.

Endangered Species

The Agency's screening level risk assessment for listed species indicates that thidiazuron exceeds the endangered species levels of concern for endangered and threatened terrestrial and semi-aquatic dicots, and exceeds chronic levels of concern for certain mammals.

Next Steps

The Agency is issuing this RED document for thidiazuron as announced in a Notice of Availability published in the Federal Register. In the near future, EPA will issue a generic DCI for additional data necessary to confirm the conclusions of this RED for the active ingredient thidiazuron. EPA will also issue a product specific DCI for data necessary to complete product reregistration for products containing thidiazuron.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FQPA requires EPA to consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity" when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by the EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://epa.gov/pesticides/cumulative/.]

Unlike other pesticides for which EPA has considered cumulative risk based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for thidiazuron. The Agency has found no information indicating thidiazuron shares a common mechanism of toxicity with other substances. Thidiazuron does not appear to produce a toxic metabolite produced by other substances. Therefore, for the purposes of tolerance reassessment and a decision on reregistration eligibility, EPA has assumed that thidiazuron does not share a

common mechanism of toxicity with other compounds. In the future, if additional information suggests thidiazuron shares a common mechanism of toxicity with other compounds, additional testing may be required and a cumulative assessment may be necessary.

This document presents EPA's revised human health and ecological risk assessments and the reregistration eligibility decision for thidiazuron. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the revised human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information and supporting documents. The preliminary and revised risk assessments for thidiazuron are available in the Public Docket, under docket number(s) OPP-2004-0382 and on the Agency's web page, http://www.epa.gov/edockets.

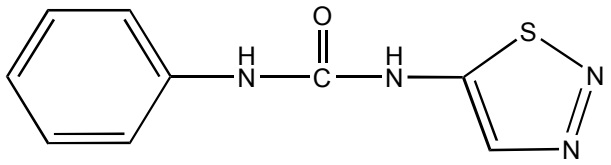
II. Chemical Overview

A. Regulatory History

Thidiazuron has been registered for use as a pre-harvest cotton defoliant or growth regulator. It removes green leaves and immature fruiting structures, which contribute to cotton staining. Currently, there are eighteen active products containing thidiazuron (one technical product) registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

B. Chemical Identification

Technical Thidiazuron



Common Name:	Thidiazuron
Trade Name:	Dropp®
Chemical Name:	1-phenyl-3-(1,2,3-thidiazol-5-yl)urea
Chemical Family:	Phenylurea herbicide

Case Number:	4092
CAS Registry Number:	51707-55-2
OPP Chemical Code:	120301
Moleculer weight:	220.25
Empirical Formula:	$C_9H_8N_4OS$
Basic Manufacturers:	Bayer CropScience LP

C. Use Profile

The following is information on the currently registered uses including an overview of use sites and application methods. A detailed table of the uses of thidiazuron eligible for reregistration is contained in Appendix A.

Type of Pesticide:	Herbicide
Target organism(s):	N/A
Mode of action:	Used as a defoliant or growth regulator by removing green leaves and immature fruiting structures, which contribute to cotton staining.
Use Sites:	Cotton (only)
Food uses:	Tolerances have been established for cottonseed, milk, eggs, meat and meat by-products of cattle, goat, hog, horse, and sheep because livestock and poultry feed on cottonseed and other by-products that may be treated with thidiazuron.
Non-Food & Residential Uses:	N/A
Public Health Uses:	N/A
Use Classification:	General Use
Formulation Types:	Thidiazuron registered formulations include wettable powders (WP) (50 percent active ingredient), soluble concentrates (SC) (12 percent active ingredient), and emulsifiable concentrates (EC) (8.4-50 percent active ingredient).

Application Methods:	Thidiazuron can be applied with aerial or ground equipment, such as groundboom sprayers.
Application Rates:	The maximum single application rate on labels when thidiazuron is the sole active ingredient is 0.2 lb. a.i. (active ingredient)/A on cotton. The maximum seasonal rate is 0.3 lb. a.i./A. (A maximum of two 0.1-0.2 lb. a.i./acre applications may be applied to mature cotton plants, not exceeding a total rate of 0.3 lb. a.i./A/season (0.337 kg a.i./ha/season)).
Application Timing:	Applications of thidiazuron to cotton are made prior to harvesting. The minimum pre-harvest interval (PHI) is 5 days and the Re-entry interval (REI) is 24 hours.

D. Estimated Usage of Pesticide

The predominant usage is in the major cotton producing areas of the Mid-South, Southeast, and Western United States. Approximately 30% of the annual U.S. cotton crop is treated with thidiazuron.

III. Summary of Thidiazuron Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for thidiazuron as presented fully in the documents "Thidiazuron: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)" written by T. Goodlow, B. Chin, and J. Dawson and "Environmental Fate and Effects Division Revised Risk Assessment for the Reregistration Eligibility Decision of Thidiazuron" written by W. Evans, A. Clem, J. Hetrick and E. Odenkirchen.

The purpose of this section is to summarize the key features and findings of the risk assessment in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in the document, they are available in the public docket (docket number OPP-2004-0382) and may also be accessed on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

A. Human Health Risk Assessment

EPA released its preliminary risk assessments for thidiazuron for public comment on May 11, 2005 (Phase 3 of the public participation process). In response to comments received, the risk assessments were updated and refined.

1. Toxicity of Thidiazuron

Further details on the toxicity of thidiazuron can be found in the revised human health risk assessment, dated August 31, 2005, as listed in the technical support documents cited in Appendix C.

a. Toxicity Profile

The available toxicity data indicate the acute oral, dermal, inhalation, and primary eye and dermal irritation toxicity of thidiazuron to be in toxicity categories III and IV. Thidiazuron is not a dermal sensitizer or a skin irritant. The acute toxicity of thidiazuron is listed in Table 1.

Both subchronic and chronic toxicity studies in rats show that thidiazuron causes decreased body weight gains and food consumption. In addition, chronic toxicity studies showed bilateral vesicle atrophy in rats, and dilated tubules of epididymis in mice. In the subchronic toxicity study, small seminal vesicles and prostate were also reported. The data from the developmental toxicity studies in rats and rabbits and of the 2-generation reproduction study indicated no increase in susceptibility of fetuses and pups to the *in utero* and/or postnatal exposure to thidiazuron.

No neurotoxicity was reported in any of the studies. Carcinogenicity studies in both rats and mice produced no treatment-related increase in tumor incidence. The standard battery of genotoxicity tests was negative. Therefore, thidiazuron has been classified as "not likely to be carcinogenic to humans."

Table 1. Acute Toxicity Data for Thidiazuron

Guideline No./ Study Type	MRID Number	Results	Toxicity Category
(870.1100) Acute Oral Toxicity- Rat	46121501	LD_{50} > 2 g/kg	III
(870.1200) Acute Dermal Toxicity- Rat	46121502	LD_{50} > 5 g/kg 2000mg/kg	IV
(870.1300) Acute Inhalation Toxicity- Rat	46121503	LC_{50} > 3.48 mg/L	IV
(870.2400) Acute Eye Irritation- Rabbit	42099601	Irritation clearing in 48 hours	IV
(870.2500) Acute Dermal Irritation- Rabbit	42099602	No dermal effects	IV
(870.2600) Skin Sensitization- Guinea Pig	46121504	Not a skin sensitizer	N/A

b. FQPA Safety Factor

The Federal Food Drug and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FFDCA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

FQPA Special Safety Factor

After evaluating hazard and exposure data for thidiazuron, EPA reduced the default 10X FQPA special safety factor to 1X. The toxicity database for thidiazuron includes acceptable developmental and reproductive toxicity studies, and there is no evidence in the developmental toxicity study of susceptibility following *in utero* exposure. Also, the Agency has a low level of concern and no residual uncertainties for the effects seen in the developmental toxicity studies after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment. Therefore, the 10X FQPA special safety factor was reduced to 1X.

c. Endocrine Effects

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, thidiazuron may be subject to additional screening and/or testing to better characterize effects related to possible endocrine disruption.

d. Toxicological Endpoints for Risk Assessment

The toxicological doses and endpoints used in the human health risk assessment for thidiazuron are summarized below in Table 2.

Table 2. Toxicity Endpoints for Human Health Risk Assessment for Thidiazuron

Exposure Scenario	Dose used in Risk Assessment (mg/kg/day); Uncertainty Factors	FQPA Safety Factor; Level of Concern for Risk Assessment	Study and Toxicological Effects (MRID)
Acute Dietary	NOT APPLICABLE. A dose and endpoint were not identified for this population group because there were no effects observed in the available toxicology studies which could be attributable to a single exposure (dose).		
Chronic Dietary (All populations)	NOAEL= 3.93 mg/kg/day UF =100 Chronic RfD = 0.0393 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD / FQPA SF = 0.0393 mg/kg/day	Dog chronic toxicity study LOAEL =11.1 mg/kg/day based on increased incidence of anemia, changes in hematological parameters and marked hemosiderosis in liver and spleen. (MRID No. 00159344)
Dermal, Short, Intermediate and Long-Term	Quantitation of dermal exposure to thidiazuron is not necessary because dermal absorption in rats was low (MRID 46261502) and no dermal or systemic toxicity is expected, based on studies with both rats and rabbits.		
Inhalation, Short-Term[a] (1-30 days)	NOAEL= 25 mg/kg/day UF: 100	0.25 mg/kg/day (target MOE of 100)	Developmental Toxicity - Rabbit LOAEL = 125 mg/kg/day based on decreased body weight gains (decreased. 70% during GD 6-29) and food consumption (decreased 19 during GD 6-8; 44% during GD 14-18). (MRID No. 46121507)
Cancer	Thidiazuron is classified as “not likely to be carcinogenic to humans".		

[a] Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation to correct for differences in exposure routes.

e. Cancer Classification

Based on the weight of evidence and lack of evidence of carcinogenicity in both rats and mice (no treatment-related increase in tumor incidences), thidiazuron is classified as “not likely to be carcinogenic to humans".

2. Dietary Exposure and Risk from Food and Water

a. Exposure Assumptions and Data

The tier 1 unrefined chronic dietary exposure assumptions and risk analysis for thidiazuron was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.02) and the Lifeline ™ Model Version 2.0, both of which use food consumption data from the United States Department of Agriculture's (USDA's) Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The assumptions of these dietary exposure assessments were tolerance level residues and 100% crop treated, with the exception of meat, meat byproducts, and fat tolerances. Existing meat, meat byproduct, and fat tolerance levels for ruminant livestock were not used in the aggregate assessment because the magnitude of the residue study suggests higher residue values than the current tolerance level. Therefore, the Agency extrapolated from the existing magnitude of residue study to obtain reasonable high end estimates of total thidiazuron residues in livestock commodities.

In order to account for possible degradates of concern for the drinking water pathway, the Agency modeled four different scenarios using FIRST, Version 1.0 (surface water) and SCI-GROW (groundwater), Version 2.3. Estimated Environmental Concentrations (EECs) from modeling showed negligible differences regardless of application timing (all at once or split in two) based on lack of thidiazuron degradation in soil. The estimated annual average (chronic) surface water concentration for the parent and both photoproducts, photo-thidiazuron and 1-cyano-3-phenylurea, was 1.0 ppb.

Estimated ground water concentrations are based on the Screening Concentration in Ground Water (SCI-GROW) (Ver. 2.3; Nov. 4, 2003) model, which is a Tier 1 assessment that provides a high-end estimate. The SCI-GROW model generates a single EDWC value of pesticide concentration in ground water used for drinking water and provides a ground water screening concentration for use in determining potential risk to human health from drinking water contaminated with a pesticide. Further, this EDWC is used in assessments of both acute and chronic dietary risk. It is not unusual for the ground water EDWC to be significantly lower than that for the surface water. The value for the chronic groundwater concentration was estimated to be 0.066 ppb. The most conservative estimate was used to assess chronic risk and included thidiazuron and both photoproducts, photo-thidiazuron and 1-cyano-3-phenylurea. The water concentration estimate used was 1.0 ppb.

The dietary exposure analyses in this assessment for thidiazuron result in dietary risk estimates for food and water that are below the Agency's level of concern for chronic dietary exposure. For the chronic analyses, the highest exposure and risk estimates were for children 1 to 2 years old. Using DEEM-FCID™, the chronic exposure for children 1 to 2 years old was 0.002867 mg/kg/day, which utilizes 7.3% of the chronic Population-Adjusted Dose (cPAD) for thidiazuron. Using the Lifeline Model, the chronic exposure for children 1 to 2 years old was 0.00254 mg/kg/day, which also utilizes 6.5% of the cPAD for thidiazuron. The results of the

chronic dietary analysis for food and water are below the Agency's level of concern and are summarized below in Table 3.

Table 3. Result of Chronic Dietary Exposure and Risk Estimates for Thidiazuron- Food and Water

Population Subgroup	PAD, mg/kg/day	DEEM-FCID		Lifeline		Water Concentration Estimates (ppb)
		Exposure, mg/kg/day	% PAD	Exposure, mg/kg/day	%PAD	
Chronic Dietary Estimates						
U.S. Population	0.0393	0.000899	2.3	0.000832	2.1	1.0
Children 1-2 yrs	**0.0393**	**0.002867**	**7.3**	**0.00254**	**6.5**	**1.0**

b. Population Adjusted Dose (PAD)

A population adjusted dose, or PAD, is the reference dose (RfD) adjusted for the FQPA safety factor. A risk estimate that is less than 100% of the chronic PAD, the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, does not exceed EPA's level of concern.

3. Residential and Other Non-Occupational Exposure

Thidiazuron is not registered for residential (home/garden) use, nor is it used in or around public buildings, schools or recreational areas where children might be exposed. Thus, there was no residential assessment developed for thidiazuron.

4. Aggregate Risk

Since there are no residential uses registered, the aggregate exposure assessment for thidiazuron considered exposures from food and drinking water only. A Tier 1 chronic dietary risk assessment was conducted, which resulted in risk estimates for food and water that are below the Agency's level of concern for all population subgroups (<8% of the cPAD).

5. Occupational Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). In the case of thidiazuron, MOEs greater than 100 do not exceed the Agency's level of concern. This MOE level of concern is derived from the standard safety factors of 10X for intraspecies variability and 10X for interspecies variability.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and for exposure following application, or post-application exposure. Application

parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose.

For more information on the assumptions and calculations of potential risk of thidiazuron to workers, see the Section 9.0 of, "Thidiazuron: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)" dated August 31, 2005.

a. Occupational Toxicity

The toxicity endpoint used in the occupational risk assessment for thidiazuron was from an oral developmental toxicity study in rabbits (MRID 46121507). The dose used in the risk assessment was a NOAEL of 25 mg/kg/day for maternal toxicity based on abortions and decreased body weight gain and food consumption at the LOAEL of 125 mg/kg/day. Inhalation absorption was assumed to be equivalent to oral absorption.

b. Occupational Handler Exposure

Occupational handler risks from inhalation were assessed for both short- and intermediate-term durations of exposure. Occupational handler risk from dermal exposure was not assessed because dermal absorption is low, and no dermal or systemic toxicity is expected from the dermal route. Chronic occupational risks were not assessed because exposure for more than 6 months is unlikely, since the cultivation and harvesting of cotton is a predominately mechanized process. The assessment of intermediate-term risks provides an upper-bound assessment of the potential risks.

Occupational handler assessments are conducted using increasing levels of personal protective measures. The Agency typically evaluates all exposures with minimal protection and then considers additional protective measures using a tiered approach (going from minimal to maximum levels of protection) until risks fall below EPA's level of concern. The lowest tier is represented by the baseline clothing scenario (i.e., single layer clothing, socks, shoes, and no respirator), followed by increasing levels of risk mitigation such as personal protective equipment (PPE) and engineering controls (EC) if the MOEs indicate a potential risk concern at the baseline scenario. In the case of thidiazuron, MOEs for every occupational exposure scenario are above 100 at baseline PPE (long-sleeved shirt, long pants, socks, shoes, and no respirator) and therefore do not exceed the Agency's level of concern. The assessment for thidiazuron as an active ingredient does not indicate a need for additional PPE, but the need for end-use product PPE will be assessed on a product-by-product basis.

c. Occupational Handler Risk Summary

Based on the use patterns, 5 major occupational handler exposure scenarios were identified as follows:

Mixing/Loading:

(1a) Liquids for Aerial;
(1b) Liquids for Groundboom/Commercial Applications;
(1c) Liquids for Groundboom/Grower Applications;
(2a) Wettable Powders for Aerial;
(2b) Wettable Powders for Groundboom/Commercial Applications;
(2c) Wettable Powders for Groundboom/Grower Applications;

Applicator:

(3) Aerial/Liquid Application;
(4a) Groundboom Application/Commercial;
(4b) Groundboom Application/Grower; and

Flaggers:

(5) Flagging for Liquid Sprays.

Summary of Risk Estimates for Handlers

Short- and intermediate-term inhalation MOEs for occupational handler scenarios are greater than 100 at the baseline level of protection (i.e., long-sleeved shirt, long pants, shoes plus socks, and no respirator). MOEs range from 150 for mixer/loaders (aerial) to >1 million for applying with groundboom. Therefore, short- and intermediate-term occupational risk is below EPA's level of concern.

For more information, see the Occupational Exposure/Risk Pathway (Section 9.0) in the Thidiazuron: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) dated August 31, 2005.

d. Occupational Post-application Risk

EPA did not quantify occupational post-application risks to agricultural workers following application to cotton, because there were no dermal toxicological endpoints of concern identified, and because post-application inhalation exposure is expected to be negligible once sprays have dried.

6. Cumulative Assessment

Risks summarized in this document are those that result only from the use of thidiazuron.

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for thidiazuron and any other substances. Therefore, for the purposes of this action, EPA has assumed that thidiazuron does not share a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

7. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), and the California Pesticide Illness Surveillance Program. The following databases have been consulted for the poisoning incident data on the active ingredient thidiazuron.

Relatively few incidents of illness have been reported due to thidiazuron. Since 1992, OPP IDS has only reported 5 incidents as a result of thidiazuron exposure, which all show similar symptoms such as skin rash, nausea, and weakness. However, no medical treatment was required.

The PCC database reported no incidents from 1993-1998; from 1999-2001, there was one report of a child exposed. However, there were no symptoms reported and the child was not seen at a health care facility. NIOSH SENSOR data from 1998-2002 reported a single thidiazuron exposure incident due to drift from an aerial application in 1998. There were no poisoning reports due to thidiazuron in California from 1982- 2002, according to the California Department of Pesticide Regulation (CDPR). Additionally, there were no incidents of poisoning or other human health effects related to thidiazuron found in scientific literature. Relatively few incidents of illness have been reported due to thidiazuron; as a result, no recommendations based on incident occurrence are warranted.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for thidiazuron is presented below. Thidiazuron's use as a cotton defoliant resulted in potential environmental risks to non-target plants (both terrestrial and semi-aquatic dicots) and mammals (herbivores and insectivores) foraging on short grass and broadleaf forage, as well as foraging on small insects, when maximum (high-end) EECs are assumed. More detailed information associated with the environmental risk from the use of thidiazuron can be found in the Environmental Fate and Effects Division's Revised Risk Assessment for the Reregistration Eligibility Decision of Thidiazuron for Use on Cotton, dated September 15, 2005. The complete environmental risk assessment is not included in this RED, but may be accessed in the OPP Public Docket (docket number OPP-2004-0382) and on the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

1. Environmental Exposure

a. Environmental Fate and Transport

The environmental fate database is sufficient to characterize the environmental exposure associated with thidiazuron use. However, EPA intends to issue a data call-in (DCI) following the issuance of this RED to require submission of additional data for the parent compound and potential degradates (photodegradates) as well as spray drift data to address areas of uncertainty. These data are expected to confirm the conclusions of this environmental risk assessment.

In soil, thidiazuron is persistent, as evidenced by laboratory and field half-lives of approximately one year. It has intermediate soil adsorption coefficients. Such persistence and intermediate mobility would allow some year-to-year accumulation and the potential for runoff from application sites to occur. Based on its solubility, vapor pressure, and other laboratory evidence, thidiazuron is non-volatile. In addition, based on its relatively low octanol/water partitioning coefficient, thidiazuron is not expected to bioconcentrate.

When thidiazuron reaches surface water, photolysis is expected to be the major route of transformation; other degradative processes are essentially negligible by comparison. Aqueous photolysis rapidly yields two photoproducts. One of the photodegradates (photothidiazuron) is a structural isomer of the parent, while the other has a substantially altered chemical structure (1-cyano-3-phenylurea). Only photothidiazuron was included in the risk assessment. Ground water is not impacted by these degradates because all field studies show that the parent is long-lived in soil (half-lives of the order of one year) with only minimal evidence of photolysis.

b. Aquatic Organism Exposure

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. Surface water models are used to estimate exposure to freshwater aquatic animals. Available monitoring data are generally not

from studies targeted on small water bodies and primary streams, where many aquatic animals are found. The Agency used modeling to derive estimated environmental concentrations (EECs) for thidiazuron and its degradate, photothidiazuron. The modeling results used in risk calculations for thidiazuron are detailed in the EFED chapter.

Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. Therefore, the EEC values used to assess exposure to aquatic animals are not the same as the values used to assess human dietary exposure from drinking water sources.

Thidiazuron is assumed to be introduced to surface waters via runoff and spray drift. The Estimated Environmental Concentrations (EECs) used to determine the risk quotients (RQs) were estimated by modeling for surface water in a farm pond scenario. Based on the intermediate range of its adsorption coefficients and the supplemental field evidence, leaching should not be a major route of dissipation. Resulting concentrations for the parent compound plus photothidiazuron are below in Table 4.

Table 4. Estimated Environmental Concentrations (EECs) of Thidiazuron and Photothidiazuron in Surface Water (ppb)

Peak	96-hour Average	21-day Average	60-day Average	90-Day Average
11	11	9.7	8.6	8.2

c. Terrestrial Organism Exposure

The Agency assessed exposure to terrestrial organisms by first predicting the amount of thidiazuron residues found on animal food items and then determining the amount of pesticide consumed based on typical food consumption by various species of birds and mammals. The amount of residues on animal feed items is based on the Fletcher nomogram and the current maximum application rate for thidiazuron. Residues may be compared directly with dietary toxicity data or converted to an oral dose, as is the case for small mammals. Current labels allow a maximum single application of 0.2 lbs a.i./A (active ingredient/Acre) and up to 0.3 lbs a.i./A applications per season for a total seasonal maximum rate of 0.3 lbs a.i./A. Accordingly, all thidiazuron labels allow two applications. The sum of these is a maximum of 0.3 lbs a.i./A/yr (0.2 lb a.i./A for the first application and up to 0.1 lb a.i./A for the second application).

(1) Birds

For birds, toxicant concentrations (EECs) on food items following multiple applications were predicted based on Agency models.

(2) Mammals

The exposure route emphasis for mammals is on uptake through the diet via food items. The residue estimates are based on a nomogram that relates food item residues to a pesticide's application rate. Residues may be compared directly with dietary toxicity data or converted to an oral dose, as is the case for small mammals. For mammals, the residue concentration is converted to daily oral dose based on fractions of body weight consumed daily, as estimated through mammalian allometric relationships.

d. Non-target Terrestrial Plant Exposure

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to pesticides from runoff, spray drift, or volatilization. Volatilization was not included in the assessment. Semi-aquatic areas are those low-lying wet areas that may be dry at certain times of the year. The Agency's runoff exposure estimate is characterized as "sheet runoff" (one treated acre to an adjacent acre) for dry areas, or as "channelized runoff".

2. Environmental Effects (Toxicity)

a. Toxicity to Aquatic Organisms

(1) Freshwater and Estuarine/Marine Fish

An acute freshwater fish toxicity classification for thidiazuron cannot be definitively established because no mortality or signs of intoxication were observed at the highest concentration tested 19 and 32 mg/L. Thidiazuron can be considered practically non-toxic for risk assessment purposes.

A chronic toxicity study was submitted for freshwater fish early life-stage (fathead minnow) for parent thidiazuron. The NOAEC of the parent was 5,700 μg/L based on hatchability, fry survival, and total survival (MRID 421320-02). A chronic full life cycle test was not submitted for freshwater fish or marine/estuarine fish.

(2) Freshwater and Estuarine/Marine Invertebrates

Acute freshwater invertebrate data for the parent thidiazuron resulted in an LC50 of 5,700 μg/L and a NOAEC of 1200 ug/L. Therefore, this LC50 value classifies the parent compound as moderately toxic to freshwater invertebrates. Acute freshwater invertebrate studies on the major degradates were also submitted and showed LC50 > 12,000 ug/L.

Acute marine invertebrate studies show that the mysid shrimp and the eastern oyster embryo/larvae LC50s are 3,240 and 5,384 μg/L, and NOAECs are 1400 and 1.06 ug/L, respectively. This classifies thidiazuron as moderately toxic to marine acute invertebrates. No studies were submitted for any of the metabolites. In addition, no invertebrate full-life-cycle toxicity studies were submitted to the Agency.

A chronic daphnid toxicity study showed a LOAEC of <100 μg/L based on length. Even though a definitive NOAEC could not be obtained, the 21-day EC10 was found to be 720 μg/L. No chronic data were submitted for marine invertebrates.

b. Toxicity to Aquatic Plants

Aquatic plant testing was conducted on the parent compound thidiazuron. The EC50 was determined to be >24,000 μg/L for the vascular plant (*Lemna gibba*) based on frond count as the most sensitive parameter. The NOAEC and EC05 were determined to be 8,600 and 570 μg/L, respectively. Non-vascular plant data were submitted for the green alga, blue-green algae, and the marine diatom. The most sensitive of these non-vascular plants was the marine diatom with an EC50 of 850 μg/L, a NOAEC of 110 μg/L, and EC05 of 56 μg/L. No data are currently available for the freshwater diatom.

Additional non-vascular plant data (green alga) was submitted for three degradates and metabolite. All these studies were considered as Tier 1 studies and classified as supplemental because they were conducted for 3 days instead of 5 days as required by the Agency. Acute toxicity values for aquatic plants are shown in Table 5.

Table 5. Acute Toxicity of Thidiazuron to Aquatic Plants

Species	%a.i.	EC50, (μg/L)	NOAEC/EC05 (μg/L) a.i.	MRID, Author, Year
Vascular Plant				
Duckweed *(Lemna gibba)*	99.5	>24,000	8600 / 570	46203506 Desjardins, D. et.al., 2003.

Table 5. Acute Toxicity of Thidiazuron to Aquatic Plants (continued)

Species	%a.i.	EC50, (μg/L)	NOAEC/EC05 (μg/L) a.i.	MRID, Author, Year
Nonvascular Plants				
Green algae *(Selenastrum capricornutum)*	99.3	>150	150	45638221, Jenkins, 1998.[a]
Blue-green algae *(Anabaena flos-aquae)*	99.5	6000	2800 / 1800	46203504, Desjardins, D. et.al., 2003.[a]
Marine diatom *(Skeletonema costatum)*	99.5	860	110/56	46203505, Desjardins, D. et.al., 2003.
Thidiazuron Photometabolite (AE F132347)				
Nonvascular Plants				
Greeen Algae *(Scenedesmus subspicatus)*	97.4	980	220 / 310	46203510, Desjardins, D. et.al., 2003.[a]
Thidiazuron Urea Metabolite (AE F132345)				
Nonvascular Plants				
Greeen Algae *(Scenedesmus subspicatus)*	91 w/w ai	3400	1300 / 1200	46203517, Desjardins, D. et.al., 2003. [a]
Thidiazuron Photodegradate (AE C421200)				
Nonvascular Plants				
Green Algae *(Scenedesmus subspicatus)*	98.4	70000	49,000 / 53,000	46203513, Desjardins, D. et.al., 2003. [a]

[a] Since the study duration was for 3 days instead of 5, the study can only be classified as a Tier 1 study.

c. Toxicity to Terrestrial Organisms

(1) Birds

Thidiazuron is classified as practically non-toxic to birds and no sub-lethal effects or other treatment related effects were observed in any of the studies. No avian chronic testing data was submitted to the Agency for thidiazuron.

(2) Mammals

Thidiazuron is classified as a category III compound (moderately toxic) for mammals based on an acute oral LD_{50} value of 2000 mg/kg-body weight. However, minimal adverse effects (anemia, blood related effects and decreased body weight) were demonstrated in the

mammalian subchronic toxicity and pre-natal developmental toxcicity studies. See Table 6 for endpoints.

Table 6. Summary of Subchronic and Chronic Toxicity Endpoints for Mammals

Toxicity Study	Test Species	% a.i.	NOAEL/LOAEL (mg/kg-bwt)	MRID
Subchronic				
52-week Oral Toxicity	Dog	98.8	3.93/11.1	00159344
Chronic (reproductive)				
Prenatal Developmental Toxicity	Rat	99.4	100/300	00077127
Prenatal Developmental Toxicity	Rabbit	99.5	25/125	46121507
2-generation Reproductive	Rat	99.5	Parental = 35.4/108.5 Repro = 108.5/ND* Offspring = 35.4/108.5	46209601

*ND= Not Determined

The results from a 2-generation rat study were used to assess chronic risks to mammals. The NOAEL for both parental and offspring toxicity in this study was 400 ppm diet and the LOAEL for these endpoints was 1200 ppm diet. Table 7 discusses the data that support the chronic toxicity data used in assessing the risks to mammals.

Table 7: Mammalian Developmental and Chronic Toxicity to Thidiazuron

Test Type	% a.i.	NOAEC (mg ai/kg-diet)	LOAEC (mg ai/kg-diet)	Effects	MRID #, Author, Year
EPA PC Code: 120301 - Thidiazuron Technical SN 49537					
2-generation reproductive (rat)		400 ppm (35.4/39.8 mg/kg/day [M/F])	1200 ppm (108.5/121.1 mg/kg/day [M/F])	Delayed sexual maturity, disrupted estrous cycling	46209601
3-generation reproductive (rats)	100	200 ppm (10 mg/kg bw/da)	600 (30 mg/kbw/da)[a]	Decreased F3 litter size at 200 ppm.	429589-01, Rees, S.J., 1992. (Core-Supplementary)

[a] Based on decrease epidermal sperm counts.

d. Toxicity to Non-Target Insects

Acute contact toxicity studies to honeybees revealed contact LD_{50}s of greater than 100 μg ai /bee for thidiazuron technical and greater than 98.1 μg ai /bee for the SC42 water miscible suspension concentrate 500 g/L. In addition, a 72-hour acute oral toxicity test was conducted for the SC42 water miscible suspension concentrate 500 g/L in accordance with OECD guidelines.

This study resulted in an oral contact LD_{50} greater than 197.8 μg ai/bee. These results classify thidiazuron as practically non-toxic to non-target insects. Based on thidiazuron's use pattern, minimal risk is expected to non-target insects.

e. Toxicity to Terrestrial Plants

Since thidiazuron is used as a defoliant on cotton to inhibit regrowth and removal of both mature and juvenile leaves in cotton, non-target terrestrial plant data are required. Several non-guideline studies evaluating thidiazuron phytotoxicity were submitted and two are summarized below.

Combined tier I and II testing for seedling emergence and vegetative vigor (MRID #s 459085-01 and 459215-01) for the SC42 formulated product have been submitted. The seedling emergence tests indicated negative growth responses to plant emergence for onion and oat by more than 25% at the maximum single application label rate of 0.2 lb a.i./A. This would indicate that a need exists for tier II testing for these two monocot species. All other tested species showed an EC_{25} above the maximum single application rate which mean no further data are required for seedling emergence for those species.

Similar results were shown in vegetative vigor tests. Negative growth responses below the EC_{25} level were indicated for all the monocots at the maximum single application rate. This indicates that tier II testing will need to be performed for these monocot species. All of the dicot plants were tested at the tier II level with the exception of turnip and cabbage and since these plants are not among the most sensitive dicots tested, further testing will not be required. The results from these tests are shown in Table 8.

Table 8: Terrestrial Plant Toxicity Summary for Thidiazuron SC 42

Study Type		Most sensitive Crop	EC25 / NOEC or EC05 (lb ai/A)	Least sensitive Crop / Active Ingredient	EC25 / NOEC or EC05 (lb ai/A)
Seedling Emergence	Monocot	Onion & oat	<0.1783 / <0.1783	Corn & wheat	>0.1783 / 0.1783
	Dicot	Turnip	0.0152 / 0.0031	Tomato	>0.1783 / >0.1783
Vegetative Vigor	Monocot	Onion, corn, & oat	>0.1783 / <0.1783	Wheat	> 0.1783 / 0.1783
	Dicot	Lettuce	0.0011 / 0.00005	Turnip & cabbage	>0.1783 / <0.1783

3. Ecological Risk Estimation (RQs)

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to EECs based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of thidiazuron products, the Agency calculates an RQ, which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD50) or the median lethal concentration (LC50). These RQ values are then compared to the Agency's levels of concern (LOCs), given in Table 9 , which indicate whether a pesticide, when used as directed, may have the potential to cause adverse effects on non-target organisms. When the RQ exceeds the LOC for a particular category (e.g., endangered species), the Agency presumes a potential risk of concern to that category. These potential risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 9. EPA's Levels of Concern and Associated Risk Presumptions.

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.	0.5	0.5	1
Acute Restricted Use - there is potential for acute risk, but may be mitigated through restricted use classification.	0.2	0.1	N/A
Acute Endangered Species - endangered species may be adversely affected; regulatory action may be warranted.	0.1	0.05	1
Chronic Risk - there is potential for chronic risk; regulatory action may be warranted.	1	1	N/A

For a more detailed explanation of the ecological risks posed by the use of thidiazuron, refer to the "Environmental Fate and Effects Division's Revised Risk Assessment for the Reregistration Eligibility Decision of Thidiazuron for Use on Cotton", dated September 15, 2005.

a. Risk to Aquatic Organisms

(1) Fish and Aquatic Invertebrates

Acute risks to all freshwater and marine fish and invertebrates are below all levels of concern established by the Agency's screening level assessment for thidiazuron. The acute risk quotients ranged from <0.0003 (marine fish) to 0.002 (freshwater fish and estuarine

invertebrates).

Chronic risks to all freshwater and marine fish and invertebrates are below all levels of concern established by the Agency's screening level assessment for thidiazuron. Chronic risk quotients ranged from 0.002 (freshwater fish) to >0.1 (freshwater invertebrates). Although there may be some uncertainty with respect to chronic risk to freshwater and marine invertebrates because a definitive NOAEC value could not be obtained, it is possible to estimate chronic risk based on a 21-day EC_{10} value which was obtained in the chronic freshwater invertebrate study. The 21-day EC_{10} value was 720 μg/L based on the length of the test organisms. Using this generated EC_{10} value, the definitive 21-day RQ value of 0.015 is well below the chronic level of concern.

b. Risk to Aquatic Plants

An aquatic plant risk assessment for acute risk to non-target plants (non-endangered and endangered) was conducted with endpoints from the most sensitive aquatic plant. The acute risk quotient for non-target plants was determined by dividing the peak concentration of thidiazuron in surface water by the EC50 value for the most sensitive aquatic plant species. The acute endangered species risk quotient was determined by dividing the peak concentration of thidiazuron in surface water by the NOAEC. As a result, the acute risk quotients for the non-endangered and endangered species were well below all established levels of concern for aquatic plants.

Aquatic plants do not appear to be at risk; however, semi-aquatic dicots, not monocots, are at potential direct and indirect risk. The Agency does not conduct chronic risk assessments for plants. Preliminary data indicate that there may be potential aquatic plant risks from the photoproducts of thidiazuron. The Agency intends to call in additional data in order to assess the risk.

c. Risk to Non-target Terrestrial Organisms

(1) Birds

There are no exceedences for any acute, acute restricted use, endangered species, or chronic LOCs for birds. Acute RQs from two applications of thidiazuron (for a seasonal maximum of 0.3 lb a.i./A) range from less than 0.013 to 0.001. Avian chronic risks cannot be quantitatively evaluated at this time because chronic data were not submitted. However, available data showing that chronic levels of concern for mammals are exceeded and that thidiazuron is persistent in the field suggest that there is also potential for chronic risk to birds should they be of equal or greater sensitivity than mammals.

(2) Mammals

Acute RQs are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). Chronic mammalian RQs are calculated using the most sensitive NOAEC from the 2-generation rat study and the residue concentration expected on food items from Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994) listed in the ecological risk assessment. There are no exceedences of any acute LOCs for mammals as all RQs were <0.03.

Chronic RQs for mammals did exceed LOCs, with RQs ranging from 1.8 (15-g mammal feeding on short grass) to 0.01 (1000-g mammal feeding on large insects). Potential effects at predicted maximum and mean residues for single applications were also evaluated. No RQ exceeds the chronic level of concern when considering mean predicted residues (See Table 10).

Table 10. Mammalian Chronic Risk Quotient Calculations for Spray Applications (NOAEL = 35.4 mg/kg-bw/da)

Animal Body Weight (g)	% Body Weight Consumed	Scenario	Predicted Maximum Residue Levels		Predicted Mean Residue Levels	
			EEC (mg/kg-diet)	Chronic RQ	EEC (mg/kg-diet)	Chronic RQ
15	95	Short grass	67	1.8 *	23.73	0.64
		Broadleaf forage, small insects	37	1.0 *	12.33	0.33
		Large insects	4.2	0.1	1.96	0.05
35	66	Short grass	67	1.2 *	23.73	0.44
		Broadleaf forage, small insects	37	0.7	12.33	0.23
		Large insects	4.2	0.08	1.96	0.04
1000	15	Short grass	67	0.3	23.73	0.10
		Broadleaf forage, small insects	37	0.2	12.33	0.05
		Large insects	4.2	0.02	1.96	0.01

* indicates an exceedence of Chronic Level of Concern (LOC).

d. Risk to Non-Target Insects

Available data from a honeybee acute contact toxicity study indicated that technical thidiazuron and formulated product are practically nontoxic to the honeybee. The two other non-target insect OECD studies showed no significant effects at the highest maximum single rate (0.2 lb ai/A); therefore there is little concern for non-target insects. Thidiazuron use on cotton is predicted to pose minimal risk to non-target insects.

e. Risk to Non-target Terrestrial Plants

Thidiazuron poses potential risks to terrestrial plants based on the results of a screening-level assessment. The risk quotients exceed the levels of concern for non-endangered and endangered plants adjacent to treated sites as well as plants inhabiting semi–aquatic sites. This is especially true for dicots for both single and multiple applications. The RQs resulting from single applications at the maximum label rates range from 0.39 to 9.09 for non-endangered plants (Table 11) and up to as high as 52.63 for endangered plants (See Table 12).

Tier I testing data for vegetative vigor indicated negative growth response (<25%) in one of the four monocots (onion) and five of the six species of dicots that were tested. Accordingly, Tier II studies are required for all low dose herbicides with maximum use rates of 0.5 lbs ai/A or less and any pesticide showing a negative response equal to or greater than 25% in Tier I tests. Recently submitted data combined Tier I and II testing for seedling emergence and vegetative vigor (MRID #s 45908501 and 45921501) for the SC42 formulated product, which have indicated that a need exists for Tier II testing for both onion and oat. Currently, EPA does not perform chronic risk assessments for terrestrial and semi-aquatic plants.

Adverse effects in terrestrial plants from thidiazuron applied at current labeled rates are expected, particularly in dicots (not monocots). As a result, if non-target plants come in contact with thidiazuron, they may be killed or damaged enough to prevent the plant from reproducing or successfully competing with other plants for resources.

Table 11. Terrestrial Plant Risk Quotients for Single Applications

Plant Group (non-Endangered / Endangered)	Type of Plant Study	Type of Plant (monocot / dicot)	Most Sensitive EC_{25} (Non-Endangered) or NOAEC / EC_{05} (Endangered)	Risk Quotient Range (Plants Adjacent to Treated Sites)	Risk Quotient Range (Plants in Semi-Aquatic Areas)
Non-endangered	Seedling Emergence	Monocot	<0.1783	>0.03 - >0.07	>0.17 - > 0.22
		Dicot	0.0152	0.39 - 0.79	1.97 - 2.63*
	Vegetative Vigor	Monocot	>0.1783	<0.01 - <0.06	<0.01 - <0.06
		Dicot	0.0011	1.82 - 9.09*	1.82 - 9.09*

* Exceeds terrestrial plant Levels of Concern (LOC)

4. Ecological Incidents

There are no reports or incidents of wildlife poisonings associated with thidiazuron in the Ecological Incident Information System (EIIS) data base.

5. Endangered Species Concerns

The screening level ecological risk assessment results in a determination that use of thidiazuron will have no direct acute effects on fresh water or marine/estuarine fish and invertebrates, insects, aquatic plants, terrestrial and semi-aquatic monocots, avian species, and mammals. However, the Agency's level of concern for direct effects to endangered and threatened terrestrial and semi-aquatic plants, and for direct chronic effects to mammals is exceeded for the use of thidiazuron on cotton. In addition, the Agency can not quantitatively predict potential chronic risks to birds; however, if avian species are as sensitive, or more sensitive than mammals, a potential effect could be of concern for avian species. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of thidiazuron, can not be precluded based on the screening level ecological risk assessment.

a. Risk to Endangered Species

The screening level risk assessment for listed species indicates that thidiazuron exceeds the endangered species LOCs for the following combinations of analyzed uses and species: (1) use of thidiazuron on cotton indicates that the chronic LOC of 1.0 is exceeded for 15 g mammals foraging on short grass and broadleaf forage and small insects. Chronic mammalian RQs range up to 1.8; and (2) use of thidiazuron on cotton results in an exceedence of the LOC for terrestrial and semi-aquatic plants.

County-level location data for listed species (terrestrial plants and mammals) were compared with county-level information on crop production to identify coarse overlaps of listed species with the proposed labeled use areas of thidaizuron. More information on the number of species at potential risk can be found in the Environmental Fate and Effects Division Revised Risk Assessment for the Reregistration Eligibility Decision of Thidiazuron for Use on Cotton, dated September 15, 2005.

In addition to these potential direct effects, there may be potential for indirect effects to taxa of listed that are dependent upon a taxa that may experience effects from the use of this pesticide. Potential risks to endangered species identified in the Environmental Fate and Ecological Risk Assessment and reflected in this RED for thidiazuron are based solely on EPA's screening level ecological risk assessment and do not constitute "may effect" findings under the Endangered Species Act.

Table 12: Acute Endangered Terrestrial Plant Risk Quotient Calculations For Single Spray Applications of thidiazuron

Scenario Toxicity Threshold, NOEC or EC05 (lb ai/ac)			Plants Adjacent to Treated Sites			Plants in Semi-aquatic Areas		
			Total Drift (lb ai/ac)	Total Loading (Sheet runoff + Drift) (lb ai/ac)	RQ[a]	Total Drift (lb ai/ac)	Total Loading (Channel runoff + Drift) (lb ai/ac)	RQ[a]
Cotton - Ground Applications (0.2 lbs ai/ac/app)								
Seed Emergence	Monocot	0.1783	N/A	0.006	0.03	N/A	0.04	0.22
	Dicot	0.0111	N/A	0.006	0.54	N/A	0.04	3.60*
Vegetative Vigor	Monocot	0.1783	0.002	N/A	0.01	0.002	N/A	0.01
	Dicot	0.00019	0.002	N/A	10.53*	0.002	N/A	10.53*
Cotton - Aerial Applications (0.2 lbs ai/ac/app)								
Seed Emergence	Monocot	0.1783	N/A	0.012	0.07	N/A	0.03	0.17
	Dicot	0.0111	N/A	0.012	1.08*	N/A	0.03	2.70*
Vegetative Vigor	Monocot	0.1783	0.01	N/A	0.06	0.01	N/A	0.06
	Dicot	0.00019	0.01	N/A	52.63*	0.01	N/A	52.63*

[a] Indicates acute risk to endangered plants.

6. Risk Characterization

Thidiazuron has a limited use pattern. It is used exclusively as a cotton defoliant to facilitate the uniform removal of both mature and juvenile leaves prior to machine harvesting. Thidiazuron is only applied during the cotton harvesting period, which is typically in late August and early September. All labels indicate that citrus trees are particularly sensitive to thidiazuron. Product labels indicate that the areas potentially at direct and/or indirect risk from the application of thidiazuron are the cotton agronomic environments. In the case of mixed products, the risk assessment was conducted to focus on the fraction of the application rate contributed by thidiazuron (only) instead of the sums of both active ingredients.

The main ecological risk concerns, based on toxicity testing with typical end-use products containing thidiazuron as the only active ingredient and the small amount of data on three transformation products, are the following: (1) Non-target terrestrial and semi-aquatic dicots (not monocots) are at potential direct risks, whereas aquatic plants do not appear to be at risk. If non-target plants come into contact with thidiazuron, these plants may be killed or damaged enough to prevent the plant from reproducing or successfully competing with other plants for resources. (2) Mammals are at potential chronic risk, but not acute risk. (3) Potential acute risks to birds are below all levels of concern. However, potential chronic risk to birds cannot be determined, due to the absence of chronic data.

The risk assessment for terrestrial plants was based on RQs calculated from toxicity studies using a typically formulated end-use product (TEP) Thidiazuron SC42. However, it appears that no surfactants or other adjuvants were added to the product during the studies and all labels clearly state the addition of adjuvants has been shown to improve the performance. Therefore, the risk to terrestrial non-target plants may be greater than thidiazuron RQs indicate.

Acute risk quotients for mammals did not exceed levels of concern (LOCs). However, chronic risk quotients for mammals did exceed LOCs for 15g mammals foraging in short grass, broadleaf forage, and on small and large insects when maximum (high-end) EECs are assumed. Potential effects at predicted maximum and mean residues for single applications were also evaluated. No RQ exceeds the chronic level of concern when considering mean predicted residues.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data to support reregistration of products containing thidiazuron as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all uses of thidiazuron.

The Agency has completed its assessment of the dietary, occupational, and ecological risk associated with the use of pesticide products containing the active ingredient thidiazuron. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient thidiazuron, the Agency has sufficient information on the human health and ecological effects of thidiazuron to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that thidiazuron containing products are eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted; and (ii) label amendments are made to reflect these measures.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for thidiazuron. During the public comment period on the risk assessments, which closed on July 11, 2005, the Agency received comments from four commentors, Bayer CropScience, Siemer and Associates, and two private citizens. The comments pertained to the importance of particular uses and urged the Agency to consider how it regulated these commodities. These comments in their entirety are available in

the public docket (OPP-2004-0382) at http://www.epa.gov/edockets. An individual response to these comments is being prepared by EPA and will be made available in the public docket (OPP-2004-0382).

The RED and technical supporting documents for thidiazuron are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number OPP-2004-0382. The public may access EPA Dockets at http://www.epa.gov/edockets. In addition, the thidiazuron RED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to thidiazuron is within its own "risk cup." An aggregate assessment was conducted for exposures through food and drinking water. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for thidiazuron meet FQPA safety standards.

b. Determination of Safety to the U.S. Population Including Infants and Children

The Agency has determined that the established tolerances for thidiazuron, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population, infants and children or any subgroup from the use of thidiazuron. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of thidiazuron. As discussed in Chapter 3, the total acute dietary (food alone) risk was not assessed, since no appropriate acute endpoint was identified. Also, the chronic dietary risk estimates for food (only) as well as food and water are both below the Agency's level of concern.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of thidiazuron, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and the possibility of increased dietary exposure due to the specific consumption patterns of infants and children. The FQPA Safety Factor has been reduced to 1X for thidiazuron because: (1) there are no concerns and no indication of quantitative or qualitative increased susceptibility

of rats or rabbits to *in utero* or postnatal exposure; and 2) the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures to infants and children.

c. Endocrine Disruptor Effects

EPA is required under the 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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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). The available data on thidiazuron indicated that there was no toxicologically significant evidence of endocrine disruption effects.

d. Cumulative Risks

Risks summarized in this document are those that result only from the use of thidiazuron. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not assumed that thidiazuron shares a common mechanism of toxicity with other compounds. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Reassessment Summary

a. Tolerances Currently Listed Under 40 CFR §180.403

The existing tolerances for residues of thidiazuron [1-phenyl-3-(1,2,3-thidiazol-5-yl)urea] are established under 40 CFR §180.403. Although additional data are required to confirm the existing tolerances in/on the following commodities, the Agency has no dietary or drinking water risk concerns associated with these tolerances and considers them reassessed (see Table 13).

Table 13. Tolerance Reassessment Summary for Thidiazuron.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerances Listed Under 40 CFR §180.403(a)			
Cattle, fat	0.2	0.4	Proposed tolerances are considered reassessed and will be confirmed upon the submission of additional data (see Regulatory Rationale).
Cattle, meat	0.2	0.4	
Cattle, meat byproducts	0.2	0.4	
Cotton, undelinted seed	0.4	0.3	Available residue data from crop field trials provide sufficient information to reduce the tolerance.
Cotton, hulls	0.8	Revoke	A processing study was performed for cottonseed meal, oil, and hulls. Cottonseed hull residues are not expected to exceed the current recommended RAC tolerance of 0.3 ppm for cottonseed. Therefore, it is recommended that the current 0.8 ppm tolerance for cottonseed hulls be revoked.
Egg	0.1	Revoke	Cottonseed meal is a common feeding source for poultry. Thidiazuron residues in a cottonseed meal processing study demonstrated that tolerances are no longer required on eggs as there is no reasonable expectation of finite residues.
Goat, fat	0.2	0.4	Proposed tolerances are considered reassessed and will be confirmed upon the submission of additional data (see Regulatory Rationale).
Goat, meat	0.2	0.4	
Goat, meat byproducts	0.2	0.4	
Hog, fat	0.2	0.4	
Hog, meat	0.2	0.4	
Hog, meat byproducts	0.2	0.4	
Horse, fat	0.2	0.4	
Horse, meat	0.2	0.4	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Horse, meat byproducts	0.2	0.4	
Milk	0.05	0.05	
Poultry, fat	0.2	Revoke	Cottonseed meal is a common feeding source for poultry. Thidiazuron residues in a cottonseed meal processing study demonstrated that tolerances are no longer required on poultry as there is no reasonable expectation of finite residues.
Poultry, meat	0.2	Revoke	
Poultry, meat byproducts	0.2	Revoke	
Sheep, fat	0.2	0.4	Proposed tolerances are considered reassessed and will be confirmed upon the submission of additional data (see Regulatory Rationale).
Sheep, meat	0.2	0.4	
Sheep, meat byproducts	0.2	0.4	
Tolerances To Be Proposed Under 40 CFR §180.403(a)(2)			
Cotton, gin byproduct	Not established	24	Available residue data from crop field suggest that a tolerance of 24 ppm be established for cotton gin byproducts.

b. Codex Harmonization

No CODEX maximum residue levels (MRLs) have been established or proposed for thidiazuron. Therefore, issues of compatibility between CODEX MRLs and U.S. tolerances do not exist.

D. Regulatory Rationale

The Agency has determined that thidiazuron is eligible for reregistration, in compliance with FIFRA, provided that: the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in section 3 below.

1. Labeling Requirements

The environmental risks for thidiazuron were based on a screening-level assessment for both terrestrial and aquatic environments. The assessment was performed for geographic areas where the highest use rates and expected exposures are likely to occur. Results show some concerns for acute risks to aquatic plants, terrestrial and wetland/riparian plants (which are not unexpected due to the herbicidal nature of the compound), as well as some chronic risks to mammals when maximum EECs are assumed. In order to address the risks identified in this screening-level assessment, registrants will be required to decrease the maximum labeled use

rate from 0.2 lbs ai/acre to 0.125 lbs ai/acre under normal conditions of use, with an annual maximum application of 0.3 lbs ai/acre. However, under certain circumstances such as during periods of rank growth/high fertilizer conditions, extreme weather conditions (such as extended periods of rain and/or low temperatures - 60^{o} to 65^{o} degree Fahrenheit), as well as on full-season cotton varieties, the higher rate (0.2 lbs ai/acre) may be used but total seasonal use may not exceed 0.3 lbs ai/acre.

2. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing thidiazuron. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

3. Endangered Species Considerations

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary. If the Agency determines use of thidiazuron "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to thidiazuron at levels of concern.

EPA is not requiring specific label language at the present time relative to threatened and endangered species. If in the future specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

4. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of thidiazuron as summarized in this document, the Agency concludes that no drift mitigation measures are needed for thidiazuron. In the future, thidiazuron product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that thidiazuron is eligible for reregistration provided that: (i) label changes outlined in this document are adopted as outlined in the Label Summary Table in Section C (Table 15) below. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring label amendments, product specific data and additional generic confirmatory (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of thidiazuron for the above eligible uses has been reviewed and determined to be substantially complete. However, the data listed below (Table 14) are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 14. Data Requirements for the Reregistration Eligibility Decision on Thidiazuron

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Avian Chronic Tests on the Mallard Duck and Bobwhite Quail	850.2300	71-4A
Tier 2 Terrestrial Plant Toxicity (seedling emergence) on Onion and Oat	850.4225	123-1A
Residue Analytical Method – Livestock	860.1340	171-4D
Storage Stability Data – Plant and Livestock	860.1380	171-4E

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Meat, Milk, Poultry, and Eggs – (Additional data for the ruminant feeding study are required).	860.1480	171-4J

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA and to be eligible for reregistration, manufacturing use product (MUP) labeling must be revised to comply with all current EPA regulations, PR Notices, and applicable policies. Currently, there are only a few label language statements needed for reregistration eligibility for thidiazuron. Therefore, the labeling must bear the following statements contained in Table 15.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

In order to be eligible for reregistration, all thidiazuron product labels must be amended to incorporate the risk mitigation measures outlined in Section IV of this document. (See Table 15).

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the required language outlined in Section IV and V of this document. The following table (Table 15) describes how language on the labels should be amended.

Table 15: Summary of Labeling Changes for Thidiazuron

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into an herbicide for the following uses(s) [fill blank only with those uses that are being supported by MP registrant.]"	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"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 Pollution 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."	Directions for Use
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED for all Formulations	"Personal Protective Equipment (PPE) All mixers, loaders and applicators must wear: -Long sleeved shirt, -Long pants, and -Shoes and socks."	Precautionary Statements – Immediately following Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
	See Engineering Controls for Requirements."	
Engineering Controls for Aerial Application	Enclosed Cockpits "Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the WPS for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements - Immediately following PPE and User Safety Requirements
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements – Immediately following the PPE Requirements
User Safety Recommendations	"**USER SAFETY RECOMMENDATIONS"** "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/ PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing." [Note: Glove statements can be removed if the acute toxicity testing of the end use product does not require gloves]	Precautionary Statements – Immediately following Engineering Controls

Description	Amended Labeling Language	Placement on Label
Environmental Hazards	"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate." "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion control practices will reduce this product's contribution to surface water contamination." "This chemical has properties and characteristics associated with chemicals detected in ground water. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination."	Precautionary Statements immediately following the User Safety Recommendations
Restricted Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval of 24 hours."	Directions for Use – Agricultural Use Requirements box
Early Reentry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice of 93-7	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: For all end-use products: -coveralls, -chemical-resistant gloves made of any waterproof material, - shoes plus socks."	Directions for Use, Agricultural Use Requirements Box
Application Restrictions	The following label recommendations must be reflected in the directions for use:	

	General Use Rate Information (*under normal conditions*) for Cotton: 0.125 lbs ai/A Maximum application rate of 0.3 lbs ai/A/year Maximum of 2 applications, but not to exceed 0.3 lbs ai/A/year. General Use Rate Information (*under variable conditions*) for Cotton: (*See section IV- A for more detailed information)* Maximum application rate of 0.2 lbs ai/A Maximum application rate of 0.3 lbs ai/A/year Maximum of 2 applications, but not to exceed 0.3 lbs ai/A/year. *Additional language and application rates **(in bold)** to be added to existing end-use product labels containing only the active ingredient Thidiazuron:* **For cutout and mature cotton under normal weather patterns, use (*insert product name*) at 0.05 to 0.10 lb. active ingredient per acre. The 0.05 lb. rate is most effective when used in a tank mix with other cotton defoliant products.** **Increased rates of (*insert product name*) above 0.10 lb. of active ingredient per acre may be needed to defoliate and control regrowth during periods of rank growth/high fertilizer conditions, extreme weather conditions, such as extended periods of rain and/or low temperatures (60°–65°F), and on full-season cotton varieties.**	

<table>
<tr>
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<table>
<tr><th>To Achieve an Application Rate of:</th><th>Use This Amount of Product</th><th>At the Indicated Rate, One Gallon of Product Will Treat:</th></tr>
<tr><td>0.07 lbs. ai/Acre</td><td>2.3 fluid oz/A</td><td>56 Acres</td></tr>
<tr><td>0.17 lbs. ai/Acre</td><td>5.4 fluid oz/A</td><td>23.5 Acres</td></tr>
</table>
Additional language (in bold) to be added to existing products that contain a mixture of Thidiazuron and Diuron:
TANK MIX OF (insert product name) plus other cotton defoliant products.
The tank mix of (insert product name) plus other cotton defoliant products is recommended to improve overall defoliation, and as an aid in accelerating the opening of mature, unopened cotton bolls. Best activity will be obtained where the tank mix is applied to mature cotton plants. Do not apply tank mix before sufficient unopened bolls have matured to produce the desired cotton yield.
For cotton produced in non-arid conditions, apply (insert product name) at a rate of 3.2 to 6.4 fluid ounces per acre plus other cotton defoliant products at a rate of 21 to 42 fluid ounces per acre.
For cotton produced in arid conditions, apply (insert product name) at a rate of 6.4 to 16 fluid ounces per acre plus other cotton defoliant products at a rate of 21 to 42 fluid ounces per acre.
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<tr>
<td>Application Restrictions for Drift</td>
<td>Thidiazuron products can not be applied by air within ½ mile of lettuce or 5 miles downwind of the point of application when citrus is in flush (burst of new growth, as in springtime) in the Rio Grande valley of Texas. Ground applications are restricted to 100 feet away from lettuce and ½ mile downwind from the point of application for citrus.

(In general, a decrease in droplet size or increase in wind speed at the time of application will result in risk to non-target organisms. Alternatively, if droplet size is coarser or wind speeds are lower, exposures due to drift would be reduced).</td>
<td>Directions for Use, Agricultural Use Requirements Box</td>
</tr>
</table>

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.

Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Appendices

Appendix A: Use Patterns Subject to Reregistration for Thidiazuron (Case 4092)

Use Site	Formulation	Max. Single App. Rate	Unit	Max # App. Per Crop Cycle/Yr	Max App. Rate Per Crop Cycle/Yr	Min. Restriction Interval (Days)	Reentry Interval (REI)	Preharvest Interval (PHI)	Restriction Comments
Cotton	Wettable Powder (WP) [50% a.i.] Soluble Concentrate (SC) [12% a.i.] Emulsifiable Concentrate (EC) [8.4 - 50% a.i.]	0.125 *[for end-use products under normal conditions] 0.2 *[for end-use products under variable conditions]	Lbs ai/acre	2 per season	0.3 lbs ai/acre	N/A	24 hours	Minimum PHI= 5 days	*Refer to Label Changes Summary Table in the Thidiazuron RED.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case 0153 covered by this IRED. It contains generic data requirements that apply to methyl parathion in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

    A. Terrestrial food
    B. Terrestrial feed
    C. Terrestrial non-food
    D. Aquatic food
    E. Aquatic non-food outdoor
    F. Aquatic non-food industrial
    G. Aquatic non-food residential
    H. Greenhouse food
    I. Greenhouse non-food
    J. Forestry
    K. Residential
    L. Indoor food
    M. Indoor non-food
    N. Indoor medical
    O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**			
830.1550	61-1	Product Identity and Composition	All	45915701
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	45915701
830.1620	61-2B	Description of Production Process	All	45915701
830.1670	61-2B	Formation of Impurities	All	45915701
830.1700	62-1	Preliminary Analysis	All	45915701
830.1750	62-2	Certification of limits	All	45915701
830.1800	62-3	Enforcement Analytical Method	All	45915701
830.6302	63-2	Color	All	45934001
830.6303	63-3	Physical State	All	45934001
830.6304	63-4	Odor	All	45934001
830.6313	63-13	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	All	45934001
830.6314	63-14	Oxidation/Reduction: Chemical Incompatibility	All	45934001
830.6315	63-15	Flammability	All	N/A
830.6316	63-16	Explodability	All	45934001
830.6317	63-17	Storage Stability	All	45934001; Study (1 year) in progress and must be submitted to the Agency upon completion.
830.6319	63-19	Miscibility	All	N/A
830.6320	63-20	Corrosion Characteristics	All	45934001; Study (1 year) in progress and must be submitted to the Agency upon completion.
830.7000	63-12	pH	All	45934001

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
830.7050	None	UV/Visable Absorption	All	45934001
830.7100	63-18	Viscosity	All	N/A
830.7200	63-5	Melting Point	All	45934001
830.7220	63-6	Boiling Point	All	N/A
830.7300	63-7	Relative Density	All	45934001
830.7370	63-10	Dissociation Constants in Water	All	41364901
830.7550	63-11	Octanol/Water Partition Coefficient	All	41364906
830.7840	63-8	Water solubility: column elution method; shake flask method	All	41364906 and 41786202
830.7950	63-9	Vapor Pressure	All	94246001
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity		099189
850.2200	71-2A	Avian Dietary Toxicity - Quail		0081629, 46203502
850.2200	71-2B	Avian Dietary Toxicity - Duck		00066169
850.2300	71-4	Avian Reproduction –Avian chronic tests on the Mallard Duck and Bobwhite Quail		**Data Gap;** Avian Chronic Tests (Mallard Duck and Bobwhite Quail) are required.
850.1075	72-1A	Fish Toxicity- Bluegill		42069201
850.1075	72-1C	Fish Toxicity- Rainbow Trout		42069202, 46203511, 46203515
850.1010	72-2A	Invertebrate Toxicity		099189, 00066167, 46203509, 46203503, 46203516
850.1075	72-3A	Estuarine/Marine Toxicity - Fish		41846101
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk		42132001
850.1035 850.1045	72-3C	Estuarine/Marine Toxicity - Shrimp		41846101
850.1300	72-4A	Freshwater Fish- Early Life Stage		42270301

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle		42132002
850.1500	72-5	Life Cycle Fish		N/A
850.4100	122-1A	Terrestrial Toxicity; Seedling Emergence		41821301
850.4150	122-1B	Terrestrial Plant Toxicity; Vegetative Vigor		41819101
850.5400	122-2	Aquatic Plant Growth		N/A
850.4225	123-1A	Seed Germination and Seedling Emergence (Tier 2)		45908501; **Data Gap-(onion and oat)**
850.4250	123-1B	Vegetative Vigor (Tier 2)		45921501
850.4400	123-2	Aquatic Plant Growth (Tier2)		46203504
850.3020	141-1	Honey Bee Acute Contact		46203501, 46203518
850.3030	141-2	Honey Bee Residue on Foliage		N/A
TOXICOLOGY				
	81-1	Acute Oral Toxicity		46121501
870.1200	81-2	Acute Dermal Toxicity-Rat		46121502
870.1300	81-3	Acute Inhalation Toxicity-Rat		46121503
870.2400	81-4	Primary Eye Irritation-Rabbit		42099601
870.2500	81-5	Primary Skin Irritation- Rabbit		42099602
870.2600	81-6	Dermal Sensitization- Guinea pig		46121504
870.6100	81-7	Acute Delayed Neurotoxicity - Hen		N/A
870.6100	82-5A	90-Day Neurotoxicity- Hen		N/A
870.6200	81-8	Acute Neurotox. Screening Battery-Rat		N/A
870.6200	82-7	90-Day Neurotox. Screening Battery-Rat		N/A
870.6300	83-6	Developmental Neurotoxicity Study		N/A
870.3100	82-1A	90-Day Feeding - Rodent		46121505, 46121506, 46121509

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
870.3150	82-1B	90-Day Feeding - Non-rodent		No subchronic oral study is required at this time, since the toxicological data requirements for 90-day feeding study in non-rodents are satisfied by the 1-yr. feeding study in dogs.
870.3200	82-2	28-Day Dermal Toxicity- Rat		46261501
870.3250	82-3	90-Day Dermal		N/A
870.3465	82-4	90-Day Inhalation-Rat		N/A
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent (Dog)		00159344
870.4200	83-2B	Oncogenicity - Mouse		46346001
870.3700	83-3A	Developmental Toxicity - Rat		00077126, 00077127
870.3700	83-3B	Developmental Toxicity - Rabbit		46121507, 46252001, 46241001
870.3800	83-4	2-Generation Reproduction - Rat		46209601
870.4300	83-5	2-year Combined Chronic/Oncogenicty- Rat		00159346, 46345201
870.5100	84-2	Mutagenicity-Gene Mutation- bacterial		46121508
870.5265	None	Reverse Gene Mutation Assay		46121508
870.5300	84-2	Mutagenicity-Gene Mutation-mammalian		41761102
870.5375	84-2B	Mutagenicity- Structural Chromosomal Abberations		46121510
870.5385	84-2	Micronuleus Assay		070129
870.5550	84-2	Unscheduled DNA Synthesis Assay		41761103
None	84-4	Other Genotoxic Effects		N/A
870.7485	85-1	General Metabolism- Rat		42529001
870.7600	85-2	Dermal Penetration		46261502
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.1500	235	Biological Monitoring		N/A; No residential uses

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
875.2100	132-1A	Foliar Residue Dissipation		N/A; No residential uses
875.2200	132-1B	Soil Residue Dissipation		N/A; No residential uses
875.2400	133-3	Dermal Passive Dosimetry Exposure		N/A; No residential uses
875.2500	133-4	Inhalation Passive Dosimetry Exposure		N/A; No residential uses
None	231	Estimation of Dermal Exposure at Outdoor Sites		N/A; No residential uses
None	232	Estimation of Inhalation Exposure at Outdoor Sites		N/A; No residential uses
ENVIRONMENTAL FATE				
None	160-5	Chemical Identity		N/A
835.2120	161-1	Hydrolysis		42069203
835.2240	161-2	Photodegradation - Water		41188201, 41364910, 43075202, 44436901
835.2410	161-3	Photodegradation - Soil		00156241, 41364902, 44436901
835.2370	161-4	Photodegradation - Air		N/A
835.4100	162-1	Aerobic Soil Metabolism		41950101, 46119601
835.4200	162-2	Anaerobic Soil Metabolism		41945201
835.4400	162-3	Anaerobic Aquatic Metabolism		42666101
835.4300	162-4	Aerobic Aquatic Metabolism		N/A
835.1240	163-1	Leaching/Adsorption/Desorption		41364909
835.1410	163-2	Laboratory Volatilization		N/A
835.8100	163-3	Volatility- Field		N/A
835.6100	164-1	Terrestrial Field Dissipation		41761105, 44454001
835.6200	164-2	Aquatic Field Dissipation		N/A
835.6300	164-3	Forestry Dissipation		N/A
860.1950	165-4	Bioaccumulation in Fish		N/A
None	165-5	Bioaccumulation- Aquatic Nontarget		N/A
835-7100	166-1	Ground Water- Small Scale Prospective		N/A

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole

REQUIREMENT			USE PATTERN	CITATION(S)
840.1100	201-1	Spray Droplet Size Spectrum		SDTF data
840.1000	201-4	Background for Pesticide Aerial Drift (Evaluation)		N/A
840.1200	202-1	Spray Drift Field Deposition (Evaluation)		SDTF data
RESIDUE CHEMISTRY				
860.1100	171-2	Chemical Identity		N/A
860.1300	171-4A	Nature of Residue - Plants		94246026, 94246037, 94246027, 94246038, 94246028, 94246039
860.1300	171-4B	Nature of Residue - Livestock		42529002, 42529003, 42778001, 42778002
860.1340	171-4C	Residue Analytical Method - Plants		94246030, 94246029, 94246040, 41950102 [Pending methods for MRIDs 44558701 and 44143601].
860.1340	171-4D	Residue Analytical Method - Livestock		**Data Gap;** Animal analytical methods have been unsuccessful in simultaneously quantifying thidiazuron, 4-hydroxy thidiazuron, and phenylurea; unacceptable MRID 43869001.
860.1380	171-4E	Storage Stability Data- Plant and Livestock		**Data Gap;** Unacceptable- MRID 46298404 and 42847601.

Data Supporting Guideline Requirements for the Reregistration of Thiabendazole				
REQUIREMENT			**USE PATTERN**	**CITATION(S)**
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg		**Data Gap; 43781901 (upgradable).** Additional data for the ruminant feeding study are required: storage stability data, raw data to support findings in the study, and an analytical enforcement method that simultaneously quantifies residues of thidiazuron and its two livestock metabolites. Also, the poultry feeding study requirement has been waived; 43940701.
860.1500	171-4K	Crop Field Trials		94246031, 94246041, 94246033, 94246042, 46341001
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed		43940701, 44143601
860.1850	165-1	Confined Accumulation in Rotational Crops Study		44415501
860.1900	165-2	Field Accumulation in Rotational Crops Study		46298401

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding Federal Holidays, from 8:30 am to 4 pm.

The docket contains the risk assessments and related documents as of October 31, 2005. The availability announcement will be published in the Federal Register. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the internet at the following site: www.epa.gov/pesticides/reregistration. The following list details all documents related to the Thidiazuron RED.

Health Effects Documents:

1. DP Barcode D244574. Alex Clem. September 24, 2004. Drinking Water Assessment.

2. Felicia A. Fort. September 29, 1995. HED Metabolism Committee Decision following the 9/18/95 meeting.

3. MRID 43781901. DP Barcode D220968. Stephen Funk. February 15, 1996. Thidiazuron: Response to the Phase 4 Review Magnitude of the Residue in Ruminants.

4. DP Barcode D319302. Toiya Goodlow. August 31, 2005. Thidiazuron: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED), Phase 3-Public Comments.

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7. Felecia A. Fort. September 8, 1995. Thidiazuron Metabolism.

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9. MRID No. 46298401. DP Barcode D294543. Toiya Jimerson. November 8, 2004. Magnitude of Residue in Rotational Crops Following Cotton Treated with DROPP® SC.

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11. MRID No. 44558701. DP Barcode D246804. Sherrie L. Mason. January 21, 1999. Independent Laboratory Validation of Analytical Method AW/02/96 for the Analysis of Thidiazuron and Photo-thidiazuron in/on Cottonseed Commodities.

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14. DP Barcode D316043. Toiya Jimerson. May 2, 2005. Thidiazuron: Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision- Revised.

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Ecological Fate and Effects Documents:

1. DP Barcode D244574. Alex Clem. August 24, 2004. Thidiazuron (PC120301): Drinking Water Assessment

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision (Bibliography) for Thidiazuron

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77126	Reprotox GmbH (1981) Thidiazuron (SN 49 537): Teratology Study in the Rat: Reprotox Order No. 413/A. Rev. final rept. (Unpub- lished study received May 29, 1981 under 2139-122; submitted by Nor-Am Agricultural Products, Inc., Naperville, Ill.; CDL: 070129-B)
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46121510 Gudi, R.; Brown, C. (2001) In Vitro Mammalian Chromosome Aberration Test: Final Report. Project Number: AA39KC/341/BTL, SPGT341. Unpublished study prepared by Bioreliance. 37 p.

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46203503 Blankinship, A.; Palmer, S.; Kendall, T.; et. al. (2003) Thidiazuron: A 48-Hour Static Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report. Project Number: 149A/151, C032042. Unpublished study prepared by Wildlife International, Ltd. 40 p.

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46203506 Desjardins, D., Kendall, T., and Krueger, H. 2003. Thidiazuron: A 7-Day Static-Renewal Toxicity Test with Duckweed (*Lemna gibba*). Unpublished study performed by Wildlife International, Ltd., Easton, Maryland. Laboratory Study No. 149A-154. Study sponsored by Bayer CropScience, Frankfurt am Main, Germany. Experimental start date April 1, 2003 and experimental termination date April 8, 2003. The final report issued May 6, 2003.

46203509 Blankinship, A.; Palmer, S.; Kendall, T.; et al. (2003) AE F132347: A 48-Hour Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report. Project Number: C032043, 149A/155. Unpublished study prepared by Wildlife International, Ltd. 41 p.

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46261502 Artus-Jacenko, L. (2004) Thidiazuron: In Vivo Dermal Absorption Study in the Male Rat. Project Number: C040234, SA/02427. Unpublished study prepared by Bayer Cropscience. 156 p.

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46346001 Wason, S. (2004) Carcinogenicity Study of Thidiazuron in the C57BL/6 Mouse by Dietary Administration. Project Number: SA/01333. Unpublished study prepared by Bayer Cropscience. 1687 p.

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94246038 Bruhl, R. (1990) Nor-Am Chemical Company Phase 3 Reformat of MRID 00064749. Thidiazuron: Residues of SN 49 537 in Cotton By-Products: Lab. Project ID: PA 49 537.61/2; M8/2. Prepared by Schering AG. 20 p.

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Appendix E. Generic Data Call-In

Appendix E.
The generic data call-in will be posted at a later date.

Appendix F. Product Specific Data Call-In

Appendix F.
The product specific data call-in will be posted at a later date.

Appendix G: Batching

EPA'S BATCHING OF THIDIAZURON PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing Thidiazuron as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing

Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Eighteen products were found which contain Thidiazuron as an active ingredient. These products have been placed into four batches and a no batch group in accordance with the active and inert ingredients and type of formulation. Furthermore, recent decisions by the OPP Registration Division were used to develop this batching approach.

Batch #	EPA Reg. No.	Percent Active Ingredient
1	51036-402	98.3
	72167-28	98.0
	73631-4	97.0
2	264-622	50.0
	34704-859	50.0
	51036-401	50.0
	72167-30	50.0
	73631-3	50.0
3	264-700	41.0
	34704-871	42.4
	51036-430	42.4
4	264-634	12.0
	34704-872	12.0
	51036-429	12.0
	72167-47	12.0
No Batch	400-505	8.4
	264-821	30.3
	264-661	50.0

Appendix H. List of Registrants Sent This Data Call-In

United States Environmental Protection Agency
Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 4092, Thidiazuron

Co. Number	Company Name	Agent for	Address	City and State	Zip
264	BAYER CROPSCIECNCE		2 T.W. Alexander Drive	Research Triangle Park	NC 27709
400	CROMPTON MANUFACTURING COMPANY, INC.		74 Amity Road	Bethany	CT 065243402
34704	LOVELAND PRODUCTS, INC.		P.O. Box 1286	Greeley	CO 80632
51036	MICRO-FLO COMPANY LLC		530 Oak Court Drive	Memphis	TN 38117
72167	NATIONS AG II, LLC		4680 Monticello Avenue, 181-174	Williamsburg	VA 23188
73631	SRM CHEMICAL, LTD. CO.		1436 Second Street, Suite 331	NAPA	CA 94558

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf.
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf.
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf.
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf.
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf.
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf.
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf.
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf.
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf.

8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program--Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

   Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

b. EPA Form No. 8570-4, Confidential Statement of Formula

c. EPA Form No. 8570-27, Formulator's Exemption Statement

d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

a. Registration Division Personnel Contact List

I. b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

c. Antimicrobials Division Organizational Structure/Contact List

d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

f.. 40 CFR Part 158, Data Requirements for Registration (PDF format)

g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides.

You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.

2. Detailed Label Usage Information System (LUIS) Report.