7-12-93

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

OFFICE OF PREVENTION
PESTICIDES AND TOXIC SUBSTANCES

July 12, 1993

MEMORANDUM

SUBJECT: Transmittal of EFED List D Review for Thidiazuron (120301) Rereg Case #4092

FROM: Evert K. Byington, Chief
Science Analysis and Coordination Staff
Environmental Fate and Effects Division
Evert K Byington

TO: Jay Ellenberger, Chief
Generic Chemical Support Branch
Special Review and Reregistration Division

Please find attached the following documents for the completed EFED review of Thidiazuron (PC Code 120301):

1. EFGWB science review.
2. EEB science review.
3. SACS Reregistration Summary Report.
4. DERS.

If you have any questions concerning this case, please contact Betsy Grim at 305-7634 or Dennis Howard at 305-5288.

cc (with SACS Reregistration Summary Report attached)

Anne Barton
Hank Jacoby
Anthony Maciorowski
List D File
List D Cover Memo File

SACS REREGISTRATION SUMMARY REPORT
for Phase IV

July 12, 1993

FROM: Dennis Howard, PMDS, EFED Dennis Howard

THRU: Betsy Grim, SACS, EFED Betsy Grim 7-12-93

THRU: Evert K. Byington, Chief, SACS, EFED Evert K Byington

TO: Linda Deluise (Tom Myers), SRRD

Active Ingredient: List D
120301 Thidiazuron

1. Intro/History.

This summary addresses the active ingredient, thidiazuron. According to the LUIS report (dated September 9, 1992[1]), thidiazuron appears under the tradename "Dropp" (NOR-AM). Thidiazuron is a plant growth regulator used to defoliate cotton prior to harvest.

2. Use Pattern (Sites) and Application Rate.

The LUIS report for thidiazuron indicates that the active ingredient falls under the usage category of TERRESTRIAL FOOD CROP. This active ingredient is listed for use on cotton.

The maximum application rate for thidiazuron is 0.2 lb a.i./A, with two applications not to exceed a total of 0.3 lb a.i./A.

3. Registration Information.

A. **Kind of pesticide.**
Plant regulator

B. **Target organism.**
Cotton plants

[1] The cited LUIS report was not available during the preparation of the SACS Summary Report. References to the LUIS report throughout this document were taken from the EFGWB Phase IV review memorandum (dated April 28, 1993).

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C. **Method of application.**
Thidiazuron may be applied by ground or by air. There are restrictions against feeding gin trash and treated foliage to animals. Restrictions apply against planting rotational crops 2 weeks (small grains, sorghum, corn, and root crops) to 2 months (legumes, alfalfa, or leafy vegetables) following application.

D. **Formulation issues and structure.**
Thidiazuron is formulated as a wettable powder contained in water soluble bags.

Structure: *N-phenyl-N'-1,2,3-thiadiazol-5-yl urea*

4. EEB Disciplinary Summary to Highlight Special Issues.

The EEB Phase 4 review of thidiazuron is given in a memorandum dated January 12, 1993 and is based on a terrestrial food use pattern for the product. The review indicates that an acute avian dietary (quail) study [71-2(a); MRID No. 81629] was reviewed in 1981 and rated as invalid and must be repeated[2]. The EEB memo also notes that a study of the effects of chemical on the life cycle of an aquatic invertebrate [72-4(b); MRID No. 421320-02] does not meet the requirements for a chronic, flow-through toxicity test using *Daphnia magna*. The results of this test indicate statistically significant effects on daphnid length at all test concentrations, thus a maximum acceptable toxicant concentration (MATC) could not be determined. This study must be repeated at appropriate test concentrations.

The EEB noted that test concentrations in a number of studies were too low to establish the MATC, owing to the low water solubility of thidiazuron. EEB reasoned that because the tests were conducted at the highest water solubility possible under test conditions and the toxicity to the test species was low, the studies should not be rejected on the basis of inadequate test concentration. However, EEB cautioned that in the future, the registrant is expected to follow EEB recommendations on alternative means to increase the solubility of the test compound.

In summary, the EEB Phase 4 review calls for the following outstanding requirements to be fulfilled:

Must be repeated to fulfill requirements
- 72-4(b) - Life-Cycle Aquatic Invertebrate
- 71-2(a) - Acute Avian Dietary (Quail)

5. EFGWB Disciplinary Summary to Highlight Special Issues.

The EFGWB Phase 4 review of thidiazuron was submitted on April 28, 1993 and is based on a terrestrial food use pattern for the product. The review indicates that the data are insufficient to allow a comprehensive environmental fate assessment for thidiazuron at this time. The EFGWB reports four data requirements for which no studies are known to have been submitted and for which data for terrestrial food uses either is required (two spray drift studies) or reserved

[2] The EEB review of this study was not available in the file at the time of preparation of this summary report.

(a long term terrestrial field dissipation study and a field rotational crop accumulation study).

A number of studies have been submitted that do not satisfy the data requirements and do not appear to be salvageable with submission of additional information or limited data. These studies will need to be repeated, but in the meantime, the submitted data can be used for supplemental purposes. Such data requirements include requirements no. 161-2, 161-3, 164-1, and 165-1. Two other data requirements (162-1 and 163-1) can be fulfilled if the registrant submits data to augment the original studies. For 162-1, acceptable aerobic soil metabolism data (laboratory) are needed for thiadiazol-labeled thidiazuron to fulfill the data requirement. For 163-1, acceptable leaching data are required for aged thidiazuron residues.

The EFGWB memorandum notes that the registrant requested a waiver of the accumulation in fish requirement (165-4) on the basis that the reported octanol/water partition coefficient is low and because the estimated environmental concentration is low in comparison to the aquatic LC_{50} value for daphnia[3]. EFGWB agreed to waive the requirement, provided that the K_{ow} is valid and that the EEB does not need this information (EEB concurs with this waiver).

The EFGWB Phase 4 review is summarized as follows:

Must be submitted to fulfill requirements (no known studies)
- 201-1 - Spray Drift, Droplet Spectrum
- 202-1 - Spray Drift, Field Spray Drift Evaluation

Must be repeated to fulfill requirements
- 161-2 - Photodegradation in Water
- 161-3 - Photodegradation in Soil
- 164-1 - Dissipation-Field, Terrestrial (Soil)
- 165-1 - Accumulation Studies, Confined Rotational Crops

Must be supplemented to fulfill requirements
- 162-1 - Metabolism-Lab, Aerobic Soil
- 163-1 - Mobility Studies, Leaching and Adsorp./Desorp.

Reserved
- 164-5 - Dissipation-Field, Long Term Terrestrial
- 165-2 - Accumulation Studies, Field Rotational Crops

6. Integrating Paragraph to Highlight Special Issues.

Based on the EFED's data review of thidiazuron for terrestrial crop use patterns, the outstanding required studies are as follows:

Must be submitted to fulfill requirements (no known studies)
- 201-1 - Spray Drift, Droplet Spectrum

[3] Waiver request not in file at time of preparation of SACS Summary Report.

- 202-1 - Spray Drift, Field Spray Drift Evaluation

Must be repeated to fulfill requirements
- 161-2 - Photodegradation in Water
- 161-3 - Photodegradation in Soil
- 164-1 - Dissipation-Field, Terrestrial (Soil)
- 165-1 - Accumulation Studies, Confined Rotational Crops
- 72-4(b) - Life-Cycle Aquatic Invertebrate
- 71-2(a) - Acute Avian Dietary (Quail)

Must be supplemented to fulfill requirements
- 162-1 - Metabolism-Lab, Aerobic Soil
- 163-1 - Mobility Studies, Leaching and Adsorp./Desorp.

Reserved
- 164-5 - Dissipation-Field, Long Term Terrestrial
- 165-2 - Accumulation Studies, Field Rotational Crops

No records of requests for low volume/minor use waivers appeared in the file. There are no special studies requiring justification for OMB.

It should be noted that some growth regulators have been found to qualify for a reduced data requirement set by being classified as "biochemical pesticides." To qualify as a "biochemical pesticide" the material must operate on target organisms via a non-toxic mode of action and must either be naturally occurring or be essentially identical to a naturally occurring chemical. If the registrant wishes thidiazuron to be considered as a biochemical, the official request must contain substantiating information on the mode of action and the natural occurrence of this chemical.

If you have any questions concerning this case, please contact Dennis Howard at 305-5288 or Betsy Grim at 305-7634.

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

28 APR 1993

Chemical: Thidiazuron
PC Code: 120301
Case no: 4092
DP Barcode: 184066,184064,
170798, 167595, 166723
EFGWB nos: 93-0134, 93-0136
92-0185, 91-0791, 91-0185

MEMORANDUM

Subject: Thidiazuron - List D Phase 4 Review

From: Arnet W. Jones, Agronomist
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Through: Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Paul J. Mastradone, Ph.D., Chief, Review Section #1
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

To: Kathy Davis, Product Manager #52
Special Review and Reregistration Division (H7508W)

Enclosed is the Phase 4 review package for List D chemical Thidiazuron. The package includes DERs for nine studies and Table A which provides details concerning all applicable environmental fate data requirements.

I. Use Pattern

According to the LUIS report (09/02/92), Thidiazuron (N-phenyl-N'-(1,2,3-thiadiazyl) urea) is a cotton defoliant (ground or aerial application) used to remove cotton leaves prior to harvest. The only product (Dropp 50 WP) is formulated as a wettable powder and is contained in water soluble bags. It can be applied by ground or air at a maximum rate of 0.2 lb a.i./A, with two applications not to exceed a total of 0.3 lb a.i./A. There are restrictions against feeding gin trash and treated foliage to animals. Also, there are restrictions against planting rotational crops of 2 weeks (small grains, sorghum, corn, and root crops) to 2 months (legumes, alfalfa, or leafy vegetables) following application. The usage category is **Terrestrial Food.**

2. Status of Environmental Fate Data Requirements

The status of the environmental fate data requirements for thidiazuron for terrestrial food crop use is summarized below:

Environmental Fate Data Requirements		Status	MRID Number
Degradation			
161-1	Hydrolysis	Fulfilled (AWJ 04/28/93)	42069203
161-2	Photodegradation in water	Not Fulfilled (JAH 12/06/89; AWJ 04/28/93)	41188201 41364910
161-3	Photodegradation on soil	Not Fulfilled (AWJ 04/28/93)	41364902 00156241
161-4	Photodegradation in air	Not Submitted[1]	
Metabolism			
162-1	Aerobic soil	Partially Fulfilled (AWJ 04/28/93)	41950101
162-2	Anaerobic soil	Fulfilled (AWJ 04/28/93)	41945201
Mobility			
163-1	Leaching, Adsorption/ Desorption	Partially Fulfilled (AWJ 04/28/93)	41364909
163-2	Volatility-lab	Not Submitted[1]	
163-3	Volatility-field	Not Submitted[1]	
Dissipation			
164-1	Soil	Not Fulfilled (AWJ 04/28/93)	41761105
164-5	Soil, long-term	Reserved[2]	
Accumulation			
165-1	Confined rotational crops	Not Fulfilled (AWJ 04/28/93)	00030793 41364907 41364908
165-4	Fish	Waived[3]	
Spray Drift			
201-1	Droplet size spectrum	Not submitted[4]	
202-1	Drift field evaluation	Not submitted[4]	

Footnotes:

[1] Based on the vapor pressure reported in EFGWB 's One-Liner Database (3 x 10^{-11} mm Hg), volatility does not appear to be an important route of dissipation. Therefore, this study is not required at this time.

[2] The long-term soil dissipation study (164-5) is reserved until evaluation of an acceptable soil dissipation study (164-1).

[3] See Waiver Request below.

[4] This study is required when aerial applications (rotary and fixed wing) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. These data are required for all herbicides which are applied aerially.

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3. Environmental Fate Summary

There are insufficient data for a comprehensive environmental fate assessment for thidiazuron at this time. Preliminary data indicate that mineralization to CO_2 and adsorption to soil may be major routes of dissipation. These data, however, were derived from European soils which are not representative of the compound's typical use sites (i.e. U.S. cotton soils). Additional data from U.S. cotton soils are needed to assess fully the environmental fate of thidiazuron. The following assessment is based on all available information.

An acceptable study indicates that thidiazuron is stable to hydrolysis at pH 5, 7, and 9. Supplemental studies indicate that it photodegrades rapidly in water and on soil ($t_{\frac{1}{2}}$ = <1 hr). The principal soil photodegradation product was the isomer 1-phenyl-3-(1,2,5-thiadiazol-3-yl)urea. In an aerobic soil metabolism study conducted in a German sandy loam which partially fulfilled the data requirement, thidiazuron metabolized with a half-life of 111 days. At the end of the 1-year study, $^{14}CO_2$ and bound residues comprised 21.2% and 44.7% of the applied radioactivity, respectively, indicating that mineralization to CO_2 and adsorption to soil may be routes of dissipation. Data regarding the formation and decline of degradation products containing the thiadiazol moiety are needed to understand more completely the aerobic soil metabolism of the compound. Thidiazuron was stable in an acceptable anaerobic soil metabolism ($t_{\frac{1}{2}}$ = >>90 days). It was slightly mobile to relatively immobile in acceptable batch equilibrium studies (K_{ads} were 4.36, 16.2, 7.33, and 18.78 on sand, loamy sand, sandy loam, and clay loam soils, respectively); adsorption was related to soil organic matter content and cation exchange capacity. Aged leaching data are needed to assess the mobility of degradation products. In a supplemental study conducted for 9 months, thidiazuron did not dissipate from the upper 8 cm of a Florida sand and did not leach significantly (low concentrations of parent were detected at 15-30 cm; it was not detected deeper than 30 cm). In two supplemental studies, small amounts of thidiazuron accumulated in confined rotational crops.

4. Accumulation in Fish (165-4) - Waiver Request

The registrant (NOR-AM) has requested a waiver of this data requirement based on the low octanol/water partition coefficient and because the estimated environmental concentration (<4 ppb) is low in comparison to the aquatic LC_{50} value for daphnia (10 ppb).

The octanol/water partition coefficient (K_{ow}) reported by NOR-AM to the Product Manager (but not validated by HED/Product Chemistry), 58.3 (log K_{ow} = 1.77), indicates that thidiazuron has low potential to bioaccumulate in fish. Accordingly, EFGWB agrees to waive the accumulation in fish data requirement (165-4) at this time provided that the K_{ow} is valid and that Ecological Effects Branch does not need this information.

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR THIDIAZURON

Chemical Code : 120301 Reviewer: A. W. Jones, EFED/EFGWB

Pesticide Type: Defoliant (Growth Regulator) Date: 04/28/93

Uses (LUIS 09/02/92): Terrestrial Food

		Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
PRODUCT CHEMISTRY					
160-5.	Chemical ID				No[1]
DEGRADATION-LAB:					
161-1.	Hydrolysis	42069203	(AWJ;04/28/93)	Satisfies	No
Photodegradation:					
161-2.	In Water	41188201 41364910	(JAH;12/06/89)	DNS/NSalv/Supp	Yes[2]
161-3.	On Soil	41364902 00156241	(AWJ;04/28/93) (AWJ;04/28/93)	DNS/NSalv/Supp DNS/NSalv/Supp	Yes[2]
161-4.	In Air	None			NA[f]
METABOLISM-LAB:					
162-1.	Aerobic Soil	41950101	(AWJ;04/28/93)	Partially	Yes[3]
162-2.	Anaerob. Soil	41945201	(AWJ;04/28/93)	Satisfies	No
162-3	Anaerob. Aqua.	None			NA[f]
162-4.	Aerobic Aqua.	None			NA[f]

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR THIDIAZURON

		Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
MOBILITY STUDIES:					
163-1.	Leaching and Adsorp./Desorp.	41364909	(AWJ;04/28/93)	Partially	Yes[4]
163-2.	Volatil.(Lab)	None[e]			NA[f]
163-3.	Volatil.(Field)	None[e]			NA[f]
DISSIPATION-FIELD:					
164-1.	Terrestr.(Soil)	41761105	(AWJ;04/28/93)	DNS/NSalv/Supp	Yes[5]
164-2.	Aquat.(Sediment)	None[e]			NA[f]
164-3.	Forestry	None[e]			NA[f]
164-4.	Combin./Tank Mix	None[e]			NA[f]
164-5.	Long Term Terr	None[e]			Reserved[6]
ACCUMULATION STUDIES:					
165-1.	Conf. Rot. Crops	00030793	(AWJ;04/28/93)	DNS/NSalv/Supp	Yes[7]
		41364907	(AWJ;04/28/93)	DNS	Yes[7]
		41364908	(AWJ;04/28/93)	DNS	Yes[7]
		41364903		Study Withdrawn[b]	
		41364905		Study Withdrawn[b]	
165-2.	Field Rot. Crops	None[e]			Reserved[8]

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR THIDIAZURON

		Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
ACCUMULATION STUDIES (continued):					
165-3.	Irrigated Crops	None[e]			NA[f]
165-4.	Fish	41364904			Waived[9]
165-5.	Aqua. Non-target Organisms (Field)	None[e]			NA[f]
GROUNDWATER MONITORING:					
166-1.	Small Prospect.	None[e]			NA[f]
166-2.	Small Retrosp.	None[e]			NA[f]
166-3.	Large Retrosp.	None[e]			NA[f]
SURFACE WATER:					
167-1.	Field Runoff	None[e]			NA[f]
167-2.	Surf. Monitoring	None[e]			NA[f]
SPRAY DRIFT:					
201-1.	Droplet Spect.	None[e]			Yes[10]
202-1.	Field Spray Drift Eval.	None[e]			Yes[10]

KEY DEFINITIONS:

a) Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row may possibly satisfy or partially satisfy the data requirement, or could possibly be salvageable to do so. Therefore, the study should be reviewed in Phase V.

b) Study Withdrawn = placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that another study will be submitted.

c) DNS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

d) DNS/Salv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

e) None = placed in the first column to indicate that the registrant did not list any studies or addendums in their Phase II and/or III responses for the given data requirement. In addition, EFGWB has no record of any studies or study/addendum combinations satisfying or partially satisfying the data requirement.

f) NA = placed in last (4th) column to indicate that the data requirement is not applicable to the uses listed in the LUIS report.

g) SWBSubmitted = placed in the final (4th) column to indicate that one or more studies will be submitted by the registrant as indicated in their Phase III response.

FOOTNOTES:

1. Except where noted, the following product chemistry information was obtained from the EFGWB one-liner database.

Molecular formula:	$C_9H_8N_4SO$
Molecular weight:	220.25
Melting point:	Not available
Vapor Pressure:	3×10^{-11} Torr
Solubility (water):	31 mg/L (reported in hydrolysis study - MRID no. 42069203)
Octanol/water partition coefficient:	58.3 (reported by SRRD Product Manager based on telephone conversation with registrant [NOR-AM]).

2. The two MRIDs noted are the original photodegradation in water study and a supplement which identified a photoproduct obtained in the original study. The photolysis in water (161-2) data requirement remains unfulfilled because the supplement submitted did not correct two of the major problems which led to

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rejection of the original study. A new photodegradation in water study is needed. See DER for details.

3. The MRID noted fulfills the aerobic soil metabolism data requirement for phenyl-labeled thidiazuron. Acceptable aerobic soil metabolism data are needed for thiadiazol-labeled thidiazuron to fulfill the data requirement.

4. The MRID noted fulfills the leaching and adsorption/desorption data requirement for unaged thidiazuron. Acceptable leaching data are required for aged thidiazuron residues.

5. Terrestrial field dissipation data are needed from two sites in the U.S. where thidiazuron is typically used. See DER for details.

6. The long-term field dissipation study is reserved pending the results of the terrestrial field dissipation studies.

7. Accumulation in confined rotational crops data are needed for crops typically grown in rotation with cotton. The study should be conducted in typical U.S. cotton soils.

8. Accumulation in field rotational crops data are reserved pending the results of accumulation in confined rotational crops studies.

9. The accumulation in fish data requirement is waived at this time because the reported octanol/water partition coefficient (58.3) indicates that thidiazuron has low potential to accumulate in fish. See memorandum and other documents in this package for details.

10. Droplet size spectrum and drift field evaluation data are required when aerial applications (rotary and fixed wing) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. These data are required for all herbicides which are applied aerially.