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May 2008

Reregistration Eligibility Decision for Siduron

Reregistration Eligibility Decision (RED) for Siduron

List C

Case No. 3130

Approved by: _____

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Date: 5/22/08

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
DER	Data Evaluation Record
ESTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
ESA	Endangered Species Act
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)
GRAS	Generally Recognized As Safe
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.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
ppb	Parts per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

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" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for siduron. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for siduron and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket at http://www.regulations.gov under docket number EPA-HQ-OPP-2007-0973.

II. Chemical Overview

A. Regulatory History

Siduron was originally registered as a pesticide active ingredient in the United States in 1964, and this registration was transferred from E.I. Dupont de Nemours and Company to Gowan Company in 1994. Gowan Company holds the registrations for the sole technical grade and sole manufacturing use products. There are 17 additional products containing siduron as an active ingredient currently registered with the EPA.

There is only one active ingredient in Case 3130. No tolerances exist for siduron as siduron is not registered for use on food or feed crops. Table 1 presents the current active siduron registrations, and siduron is the only active ingredient in the following products.

Table 1. Supported Registrations of Siduron

Registration #	Product Name	% Active Ingredient (A.I.)
4-146	Crabgrass Preventer & Weed Killer	2.75
4-179	Crabgrass Preventer & Weed Killer	7.65
538-60	Scotts Starter Fertilizer with Crabgrass Preventer	3.1
769-840	Anderson's Proturf Starter Fertil w/ Preemergent WE	4.7
961-297	Miller Tupersan Granular	2.4
961-309	Greenfield Modern Trebl	4.6
961-319	Lebanon Crabgrass Control	3.71
7401-241	Lebanon Spring Seeding Crabgrass Preventer with Grass Food	2.54
8378-63	Ferti lome Crabgrass Preventer Plus Lawn Food	3.5
8378-64	Shaw's Starter Fertilizer with Crabgrass Control 350 Tupersan	4.7
8660-23	Shaw's Tupersan 470 Granules	6.4
8660-87	Vertagreen Crabgrass Preventer with Tupersan	3.71
9198-50	Vertagreen Fertilizer for Professional Turf with Tupersan	3.5
9198-65	Anderson's Pre-emergent Crabgrass Killer Plus Fertilizer	4.7
9198-181	The Andersons Professional Turf Products Crabgrass Preventer	3.1
10163-213	Andersons Starter Fertilizer with Preemergent Weed Control	50
10163-214	Tupersan Herbicide (Formulation Intermediary)	70
10163-216	Siduron Technical	98.5
32802-28	Seed Safe – Turf Care	3.71

A generic data call-in (DCI) was issued for siduron in 1992, and data requirements included product chemistry, ecotoxicity, acute toxicity, plant toxicity, and environmental fate studies. In 1995 a DCI was issued for outdoor, residential-use products requiring data for products used on residential grass and turf. In 1995, a DCI was issued for products used on commercial agricultural crops, tree crops and ornamental crops for agricultural reentry data.

B. Chemical Identification

Siduron is a phenylurea herbicide registered for us on annual grassy weeds in newly seeded or established plantings of cool season grasses. The chemical structure and properties of siduron are presented in Table 2 and Table 3.

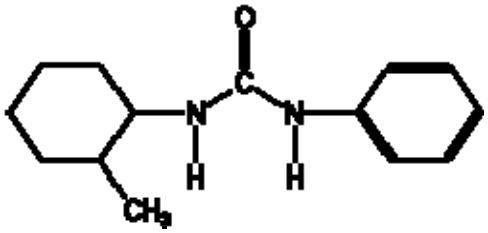
Table 2. Test Compound Nomenclature- Siduron	
Chemical Structure	
Empirical Formula	$C_{14}H_{20}N_2O$
Common Name	Siduron
OPP PC Code	035509
IUPAC name	1-(2-methylcyclohexyl)-3-phenylurea
Chemical Abstract Service (CAS) Name	*N*-(2-methylcyclohexyl)-*N'*- phenylurea
CAS Registry Number	1982-49-6

Table 3. Physiochemical Properties		
Parameter	Value	Reference
Molecular Weight	232.36 g/mol	http://www.ars.usda.gov
Water solubility (25°C)	22.3 ppm	MRID 41277101
Melting point/range	133 - 141 º C	MRID 43587001
pH at 20 °C	5.7	USDA ARS Pesticide Properties Database, May 1995
Density (25°C)	1.08 g/mol	Material Safety Data Sheet
Solubility (25°C)	22.3	MRID 41277101
Vapor pressure (25°C)	<0.0008 mm Hg; 4 x 10^{-9} Torr	Material Safety Data Sheet
Dissociation constant, pK_a (20 °C)	Does not dissociate	MRID 43587001
Octanol/water partition coefficient, Log(K_{OW})	0.431	http://www.ars.usda.gov
UV/visible absorption spectrum	---	Data Gap

C. Use Profile

Type of Pesticide:	Phenylurea herbicide
Target Pests:	Registered for control of annual grasses, annual weeds, barnyardgrass, bermudagrass, crabgrass, and foxtail.
Mode of Action:	Exact mode of action for target pests is unknown. It is believed to inhibit some aspect of cell division. It is a root growth inhibitor, perhaps acting by mitosis disruption.
Use Sites:	Registered for use on golf courses, sod farms, and residential turf.
Formulation Type:	Granular formulations and wettable powder formulations only.
Application Methods:	Granular formulations may be applied using belly grinders, push-type fertilizer spreaders, and tractor-drawn spreaders. Wettable powder formulations may be applied via chemigation, groundboom sprayer, low-pressure handwand sprayer, handgun sprayer and other hand-operated sprayers. The wettable powder formulation may also be mixed with seed, fertilizer and mulch and applied with a hydraulic seeder or hydroseeder. There are no prohibitions against aerial applications on product labels.
Application Rates:	End-use product rates range from 2 to 12 lbs a.i./A/season, with the exception of a specialty application for golf course greens permitting ½ lb of siduron per 1,000 square feet for band (perimeter) applications.
Application Timing:	Siduron is generally applied between March and May to established grass, spring-seeded grass, and grass planted the previous fall. A second treatment, to newly seeded areas, may be made in the fall. Treatments for bermudagrass encroachment may run into the summer. Spot treatment to overseeded areas in golf courses is made at seeding. The specialty application to golf course greens is made initially in March or April with subsequent applications at 4 – 5 week intervals, and the label does not specify a maximum number of applications.
Registrants:	The registrant for the sole technical grade and manufacturing use product is Gowan Company. Gowan Company also holds a registration for one end-use product. Other than Gowan Company, there are nine primary formulating registrants.

III. Summary of Siduron Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of the EPA's risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessments and supporting documents referenced in Appendix C were used to formulate the regulatory decision for the pesticidal uses of siduron.

While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket, docket number EPA-HQ-OPP-2007-0973, and may be accessed through http://www.regulations.gov/. Hard copies of these documents may also be found in the OPP public docket under this same docket number.

A. Human Health Risk Assessment

The human health risk assessment addresses potential exposure and risks from all registered uses of siduron. Siduron is registered for use on golf courses, sod farms, and for residential use, thus, occupational handler, residential handler, and post-application exposure were evaluated in the risk assessment. Siduron is not registered for use on any food commodities, but due to this chemical's persistence in the environment, the Agency did conduct a drinking water assessment. For the complete human health risk assessment, please refer to *Siduron Revised Human Health Risk Assessment, May 2008,* which is available in the public docket.

1. Toxicity of Siduron

The toxicological database is limited but sufficient for the risk assessment of siduron. Siduron has low toxicity via oral and dermal routes of exposure (Category IV and Category III respectively), is moderately irritating to the eye (Category III), and is not a dermal sensitizer. The acute toxicity data submitted for this non-food use pesticide are summarized in Table 4.

Table 4. Acute Toxicity Profile of Siduron

Guideline Number	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral - rat	41933402	LD_{50} > 5000mg/kg	IV
870.1200	Acute dermal - rabbit	41933403	LD_{50} > 2.0 g/kg	III
870.1300	Acute inhalation - rat	41933404	LC_{50} could not be determined, no mortality	IV
870.2400	Primary eye irritation - rabbit	41933405	Grade 2 erythema in animals at 24 hours	III
870.2500	Primary dermal irritation - rabbit	41933406	Slight erythema at 4 hour evaluation	IV
870.2600	Dermal sensitization - guinea pig	43351501	Not a dermal sensitizer	NA

The toxicity database for repeat exposure to siduron includes two dermal toxicity studies in New Zealand white rabbits. The first study, MRID 41137201, was conducted in 1989, and rabbits were dosed with siduron at eleven weeks of age, not at ten weeks as originally suggested in the preliminary human health risk assessment. Testicular effects were noted by the study authors and these included decreased testes weights, delayed germinal maturation in the testes, and atrophy of the epididymides and prostate/proprostate. This 21-day dermal toxicity study was used to establish the point of departure (PoD) for dermal exposure in the Agency's 2007 preliminary human health risk assessment for the registration eligibility decision on siduron.

A follow-up study (MRID 42107101) was conducted in 1991 to assess the reproducibility of the testicular effects noted in the 1989 dermal study. The 1991 21-day dermal toxicity test was conducted with the same species of rabbit and rabbits were dosed at the same age (as the 1989 study (11 weeks) as well as upon maturation (20 weeks). No testicular, epididymal, prostate, or serum testosterone effects were seen at any dose level in either age group.

As a follow-up to the 1991 21-day dermal toxicity study, a study was conducted in 1993 in order to assess the normal course of testicular maturation in untreated New Zealand white rabbits (MRID 42627001). This study demonstrated that the progression of testicular maturation was highly variable in sexually immature rabbits approaching puberty. Results of these studies indicate that the putative testicular effects in the 1989 study appear to be an age-related phenomenon rather than a chemical-related effect.

Within the past few months, the Agency has reexamined the pathology data from the 1989, 1991, and 1993 studies. The information presented in the 1991 and 1993 dermal studies (MRID 42107101 and 42627001) support the contention that effects observed in the 1989 study were due to the high degree of variability in testicular maturation in immature New Zealand white rabbits as they approach maturity rather than a chemical-related effect. Consequently, the Agency has concluded that the effects and endpoint previously identified for dermal exposure in the 2007 preliminary siduron human health risk assessment are not relevant for risk assessment purposes.

The Agency has also removed the 3x database uncertainty factor applied to the oral and inhalation risk assessment for the lack of an oral study that evaluated the potential testicular effects observed in immature rabbits following repeated dermal exposures since the Agency has concluded the effects observed in the 1989 study were not a chemical-related phenomenon. Please see the following document, located in the OPP Public Docket, docket number EPA-HQ-OPP-2007-0973, for further explanation:

> *Siduron: Hazard Characterization and Endpoint Selection Reflecting the Review of the Testicular Maturation in Prepubertal New Zealand White Rabbits Toxicity Study. Dated May 1, 2008.*

A metabolism study and carcinogenicity studies are not required for siduron because of siduron's classification as a non-food use chemical. It should, however, be noted that there was no evidence of mutagenicity in the in vivo and in vitro assays. Acute and subchronic neurotoxicity studies are not available for siduron; however, there were no clinical signs of any

acute, subchronic, or developmental toxicity in the literature to suggest that siduron elicits a neurotoxic effect. The Agency is not requiring additional neurotoxicity studies at this time.

2. Selection of Endpoints

Table 5 summarizes the toxicological doses and endpoints used in the human health risk assessment of siduron. Uncertainty factors were applied in estimating the reference dose (RfD) to account for extrapolation from animal to human, potential variation in sensitivity among members of the human population, and use of a short-term study for long-term risk.

Table 5. Summary of Toxicological Doses and Endpoints for Siduron

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD Level of Concern	Study and Toxicological Effects
Acute Dietary (All Populations)	An acute endpoint was not selected based on the absence of an appropriate endpoint attributable to a single dose.			
Chronic Dietary (All Populations)	NOAEL= 150 mg/kg/day	UF_A= 10X UF_H = 10X UF_s = 10X	cRfD = 0.15 mg/kg/day	Developmental toxicity study- rat (MRID 41390401) Maternal LOAEL (mg/kg/day): 750 based on decreased body weight gain (63% GD 7-9) and food consumption (19.3% GD 7-9). No developmental toxicity was observed above the limit dose.
Incidental Oral Short- (1-30 days) & Intermediate- (1-6 month) Term	NOAEL= 150 mg/kg/day	UF_A= 10X UF_H= 10X	Residential LOC for MOE = 100	Developmental toxicity study- rat (MRID 41390401) Maternal LOAEL (mg/kg/day): 750 based on decreased body weight gain (63% GD 7-9) and food consumption (19.3% GD 7-9). No developmental toxicity was observed above the limit dose.
Dermal Short- (1-30 days) & Intermediate- (1-6 month) Term	A short- and intermediate-term dermal endpoint was not selected due to the lack of systemic toxicity at 1500 mg/kg/day.			
Dermal Long-Term (>6 months)	Long- term dermal exposure is not expected for Siduron.			
Inhalation Short- (1-30 days) & Intermediate- (1-6 month) Term	NOAEL= 150 mg/kg/day 100% absorption	UF_A= 10X UF_H= 10X	Occupational and Residential LOC for MOE = 100	Developmental toxicity study- rat (MRID 41390401) Maternal LOAEL (mg/kg/day): 750 based on decreased body weight gain (63% GD 7-9) and food consumption (19.3% GD 7-9). No developmental toxicity was observed above the limit dose.
Inhalation Long-Term (>6 months)	Long- term inhalation exposure is not expected for Siduron.			
Cancer (oral, dermal, inhalation)	Inadequate Information to Assess Carcinogenic Potential.			

NOAEL = no observed adverse effect level. **LOAEL** = lowest observed adverse effect level. **UF** = uncertainty factor. **UF_A** = extrapolation from animal to human (interspecies). **UF_H** = potential variation in sensitivity among members of the human population (intraspecies). **UF_S** = use of a short-term study for long-term risk assessment. **MOE** = margin of exposure. **LOC** = level of concern. **N/A** = not applicable.

3. Exposure Pathways and Risk Estimates

Dietary Exposure

Siduron is a non-food use herbicide so there is no expectation of dietary exposures through food consumption. However, exposure to siduron in drinking water is anticipated because of the environmental fate of this chemical: siduron is highly mobile and persistent in the environment so movement to water is possible. A drinking water assessment was thus conducted for this chemical. For additional information on the environmental fate of siduron, please refer to section III B1 in this document.

Acute dietary risk was not assessed for siduron based on the absence on an appropriate endpoint attributable to a single dose of siduron. Chronic drinking water exposure was estimated with the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID^{TM}, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which the Agency has concluded will result in no adverse health effects). This dose is referred to as the reference dose (RfD). The RfD is equivalent to the NOAEL divided by the appropriate uncertainty factors.

The chronic exposure estimates for siduron in drinking water are not of concern as they are below 100% of the chronic RfD for the U.S. population and all subgroups in the two regional scenarios selected. In the Florida (surface water) scenario, the Agency estimated infant exposure to be 13% of the chronic RfD. In the Pennsylvania (surface water) scenario, the Agency estimated infant exposure to be 12% of the chronic RfD. In both of the regional (groundwater) scenarios, the Agency estimated infant exposure to be 2% of the chronic RfD.

Residential (Non-Occupational) Exposure and Risk

The anticipated use patterns and current labeling include two short-term (1-30 days) residential handler exposure scenarios. Intermediate- (1- 6 months) and long-term exposures are not expected based on the sporadic nature of siduron application by homeowners. Residential post-application exposures are also anticipated following applications at residential sites by commercial pesticide handlers and residential handlers.

Residential handler risk estimates were calculated using a margin of exposure (MOE) approach for short- and intermediate-term inhalation risks. MOE is determined by dividing the toxicological endpoint of concern by the estimated exposure. The MOE is typically compared to the level of concern (LOC), usually the product of all of the appropriate uncertainty factors. In this case, the Agency LOC for inhalation risk is 100, so there are no risk concerns from inhalation for the residential handler scenarios because the MOEs for residential handlers are well above the Agency's LOC (2,000,000 for loading/applying granulars with a push-type spreader and 610,000 for loading/applying granulars with a belly grinder).

Incidental oral risks were estimated for toddler post-application exposure for three scenarios (hand to mouth activity on turf, object to mouth activity on turf, and incidental soil

ingestion). The incidental oral MOEs for toddlers are all above the Agency's LOC of 100, and thus, are not of risk concern (MOEs of 840, 3,330, and 250,000 respectively). In addition, the total combined incidental oral exposure risk for toddlers is not of concern for applications of siduron at the maximum labeled residential application rate of 12 lbs a.i./acre (MOE of 670). Post-application incidental ingestion of siduron granules by toddlers from pesticide-treated residential areas was not assessed because an acute dietary (oral) endpoint was not identified.

Dermal risk was not quantified for residential or occupational handler or post-application scenarios due to the lack of systemic toxicity at 1500 mg/kg/day in the 1991 21-day dermal study in rabbits (MRID 42107101). Risk is not expected as siduron is not a dermal sensitizer and is also classified as having low toxicity for the dermal pathway of exposure (Category IV).

Aggregate Exposure and Risk

The Agency also considered the potential aggregate risks from drinking water and residential routes of exposure. As mentioned earlier in the discussion of dietary exposure and risk, chronic risk of exposure to siduron in drinking water is not of concern. Since the residential risk assessments show ample margins of exposure, aggregate risk is not likely to be a concern.

Cumulative Risk Characterizing/Assessment

EPA has not identified a common mechanism of toxicity for siduron and any other substances. Siduron does not appear to produce a toxic metabolite produced by other substances.

Occupational Exposure and Risk

The occupational scenarios associated with siduron use were classified as having potential short-term and intermediate-term exposures. Long-term exposures are not expected to occur because of siduron's use pattern.

Occupational handler risk estimates were calculated using a MOE approach for inhalation risks. The Agency's LOC for inhalation risk is 100, and there are risk concerns for two of the scenarios involving mixing/loading/applying the 50% wettable powder formulation without a respirator. However, with the addition of a quarter-face dust/mist respirator, MOEs were above the Agency's LOC.

Table 6 summarizes the occupational handler short- and intermediate-term inhalation risks for siduron.

Table 6: Occupational Handler Short- and Intermediate-term Dermal Inhalation Risks					
Exposure Scenario	Crop or Target	Application Rate (lb a.i./acre)	Area Treated Daily (acres)	MOEs (LOC= 100)	
				Baseline PPE (single layer with chemical resistant gloves)	Baseline PPE plus quarter-face dust/mist respirator
Mixing/loading wettable powders for aerial applications	turf: grown for grass seed and sod	12	350	58	290
Mixing/loading wettable powders for chemigation applications	turf: grown for grass seed and sod	12	350	58	290

The Agency assumes that inhalation exposures are minimal following outdoor applications of an active ingredient with low vapor pressure. Since siduron is applied only in outdoor settings and has a very low vapor pressure (< 0.0008 mm Hg; $4x10^{-9}$ Torr), post-application inhalation exposures and risks were not assessed

Dermal exposure and risk was not quantified for occupational handler scenarios due to the lack of systemic toxicity at the highest dose tested, 1500 mg/kg/day in the 1991 21-day dermal study in rabbits. Once again, risk is not expected for this exposure pathway due to siduron's low dermal toxicity and because this chemical is not a dermal sensitizer. Post-application dermal exposures and risks were not assessed, since no toxicological endpoint of concern was identified for dermal exposures.

Endocrine Disruption

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 such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, "siduron" may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Incident Reports

There were some reports of ill effects from exposure to siduron in the available incident databases. The OPP Incident Data System (IDS) listed two reported incidents involving siduron submitted to OPP since 1992. One individual reported weakness, headache, and dizziness two hours after applying a siduron product, and this person was treated in an emergency room. In the second case, an individual inhaled the product and reported nausea, loss of hand coordination,

difficulty breathing, and slurred speech. Several cases were reported to the National Poison Control Centers (PCC) between 1993 and 2003: one case in the Occupational Class involving moderate symptoms of abdominal pain and bronchospasm; nine cases in the Non-Occupational Class were reported, but only one presented mild symptoms; and twenty-five cases were suspected of exposure in the Children's Group, where nine were followed and presented no symptoms. One incident was reported to the California Department of Pesticide Regulation since 1982, where a grower applied the product by sprinkler irrigation and reported a red and painful left eye and blurred vision.

Siduron is not on the list of the top 200 chemicals for which the National Pesticide Information Center (NPIC) received calls from 1984 to 1991, and siduron was not reported to be involved in human incidents. Out of 5,899 cases reported to the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR) from 1998 to 2003, none involved siduron.

B. Environmental Risk Assessment

Environmental fate studies are available and acceptable for the siduron risk assessment. Ecotoxicity guideline studies are available for a number of the data requirements, but data gaps exist for chronic toxicity for freshwater and marine/estuarine fish and aquatic invertebrates as well as for toxicity to aquatic vascular plants. Toxicity data from other phenylurea compounds similar to siduron were used to estimate chronic risk to fish and aquatic invertebrates and aquatic vascular plants, so the Agency is not requiring any additional ecological data at this time. No acceptable 2-generation mammalian reproduction studies were available for estimating chronic risk. Toxicity data from a rat developmental study was used to estimate mammalian chronic risk in the final ecological risk assessment instead of using surrogate data from another chemical in the phenylurea class of pesticides, which had been used previously in the preliminary assessment. The full assessment, *Ecological Risk Assessment Chapter for the Reregistration Eligibility Decision on Siduron,* dated May 2008, is available on the internet and in the public docket at www.regulations.gov (EPA-HQ-OPP-2007-0973).

1. Environmental Fate and Transport

Siduron is resistant to hydrolysis, photolysis in water and on soil, and soil metabolism under aerobic and anaerobic conditions. The primary degradate was not identified but detected at up to 8.1% of the applied radioactivity of the two soils tested, and 2-methylcyclohexylamine, a secondary degradate, accounted for 2.1% of the applied radioactivity. Siduron degrades slowly under laboratory conditions across a range of degradation routes so degradates are not expected to form in significant quantities. Siduron does however, have the potential to accumulate in soil over time because of its persistence in the environment.

The major routes of siduron dissipation include movement in soils and sediments, and dilution. Depending on the soil, site, and meteorological conditions, siduron may be transported off-site via runoff, leaching, and drift. Terrestrial field studies in California show siduron leaching 6 to 12 inches in depth in a loamy sand site and 12 to 18 inches in depth in a sandy loam

site, both under bare soil conditions. Given siduron's mobility and persistence, movement to ground water is possible. A drinking water assessment was conducted for this chemical.

2. Ecological Exposure and Risk

Ecological risk is characterized by types of effects a pesticide can potentially produce in an animal or plant, and this characterization is typically based upon registrant-submitted studies describing acute and chronic effects for different plant and wildlife species. Acceptable ecotoxicity data are available for birds, mammals, terrestrial invertebrates, and terrestrial plants for consideration in the siduron ecological risk assessment. Acute studies of fish and aquatic invertebrates are also available, but there are no studies available for chronic risk to these organisms.

The Risk Quotient (RQ) approach is used to estimate the potential for adverse effects associated with the use of siduron. The basis of the RQ approach is a comparison of the exposure concentrations to toxicity endpoints. Specifically, estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values to calculate RQs. RQs are then compared to the Agency's LOCs, and if the RQs exceed the LOCs, the Agency presumes there is a potential to affect species in that taxa. Laboratory environmental fate, laboratory ecological effects, and use data provide the basis for these risk quotients. Risk characterization provides additional information on the likelihood of adverse effects by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies. Table 6 summarizes EPA's levels of concern and associated risk presumptions.

Table 6. 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	0.5	0.5	1
Acute Endangered Listed Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	Not Assessed

A. Terrestrial Organisms

Siduron is mobile and persistent in the environment in terrestrial systems, so it is appropriate to model terrestrial dietary residues. Terrestrial exposure for animals was modeled using TREX, which calculates the dietary and dose-based estimated environmental concentration (EEC) for birds and mammals. TerrPlant was used to model terrestrial plant exposure.

Birds

The acute oral toxicity of siduron to the Northern bobwhite quail (*Colinus virginiana*) was assessed in a single-dose study with a 14-day observation period. No mortalities were observed in either the control or treatment groups. With the resulting LD_{50} >2250 mg a.i./kg-bw, siduron can be classified as practically non-toxic to birds on an acute oral exposure basis. Sub-acute dietary toxicity studies of siduron on the mallard duck and the Northern bobwhite quail were also considered for the risk assessment. These studies yielded LD_{50} values of >2250 ppm a.i. for the mallard duck study and >5620 ppm a.i. for the bobwhite quail study and mortality was not observed at these highest doses tested, so siduron may be classified as practically non-toxic to birds on an acute dietary basis.

Avian LD_{50} values were adjusted to account for bird weight, and these adjusted values were compared to the EECs for each siduron use scenario. Most of the siduron use scenarios yielded EECs below the weight adjusted avian LD_{50} values, which indicates that acute risk is not expected for these scenarios. The EECs for small birds feeding on short grass and broadleaf plants/small insects for the 12 lb a.i/acre scenario are above the adjusted LD_{50} values (>3280.03 mg/kg-bw and >1845.02 mg/kg-bw respectively), and several of the EECs for the specialty golf-course use (22 lbs a.i./acre) are above the adjusted LD_{50} values. Although some siduron uses result in values that exceed the Agency's LOC, this is not necessarily indicative of risk since there were no mortalities at the highest level tested.

A dietary reproduction study of the bobwhite quail was considered in order to assess the risk associated with chronic avian exposure to siduron. The study yielded a LOAEC of 6250 ppm a.i. and a NOEAC of 2800 ppm a.i, and when compared to the control, there were no treatment related effects on any of the reproductive parameters measured. The RQ values exceed the chronic LOC of 1.0 for specialty applications to golf course greens for species that consume short grasses, tall grasses, or broadleaf plants/small insects (RQs of 4.09, 1.87, and 2.30 respectively) and the LOC is minimally exceeded for the 12 lb a.i./A application rates for birds that consume short grass (RQ = 1.03). Although the RQ values suggest chronic risk to birds may exist for these scenarios, it is important to note the RQ values only exceed the LOC by a small margin.

Mammals

The acute LD_{50} (>5000 mg a.i/kg-bw) for mammals is based on an acute oral toxicity study (rat). There were no mortalities observed at this highest level which suggests siduron is practically non-toxic to mammals on an acute oral basis.

Mammalian LD_{50} values were adjusted to account for mammal weight, and these adjusted values were compared to the EECs for each siduron use scenario. Most of the siduron uses yielded EECs below the weight adjusted mammalian LD_{50} values, which indicates that acute risk is not expected for these scenarios. The only acute LOC exceedences for mammals were for the specialty application to golf course greens, where the RQs for mammals weighing 15g and 35g and consuming short grass slightly exceed the Agency's LOC of 0.5 (0.99 and 0.86 respectively). While this use presents values that exceed the Agency's LOC, this is not necessarily indicative of risk since there were no mortalities at the highest level tested.

Since no two-generation reproduction study was submitted for siduron, the NOAEL value for a two-generation study on another phenylurea chemical (linuron) was examined in the preliminary ecological assessment from October 2007 for estimating chronic mammalian risk. However, in registrant-submitted comments to the Agency, it was noted that toxicity data was available for siduron from a developmental study. The data from the developmental study were used in the final ecological risk assessment instead of the surrogate approach. Using the data from the developmental study, the chronic LOC of 1 is still exceeded for all uses for species consuming short grass, tall grass, and broadleaf plants/small insects with RQs values of 3.82, 1.75, and 2.15 respectively. Although the RQ values suggest chronic risk to mammals may exist for these scenarios, it is important to note the RQ values only exceed the LOC by a small margin.

Non-Target Insects

Acute contact honeybee studies indicate that siduron is practically non-toxic to honey bees (LD_{50} =120 µg/bee). However, due to the high application rates associated with some siduron uses and use patterns, EECs are expected to be higher than the LD_{50}. Therefore, the risk of direct adverse effects to terrestrial invertebrates is possible.

Terrestrial Plants

Tier II seedling emergence studies demonstrate the potential for siduron to affect terrestrial monocot and dicot plants. The NOAELs were 0.19 and 1.5 lbs a.i./A for dicots (pea) and monocots (onion) respectively, which is well below the typical, and labeled, application rates for siduron. Risk is expected for non-target terrestrial plants based on the seedling emergence studies and given siduron's likely mechanism of action and use pattern, as discussed earlier in Section IIC. Vegetative vigor studies have not been submitted for siduron, and the Agency is not requiring these studies because the Tier II studies provide adequate information for the risk assessment of siduron at this time.

B. Aquatic Organisms

Tier II modeling (PRZM/EXAMS) was used to generate estimated environmental concentrations (EECs) for siduron in surface water reflecting actual use patterns. The Tier II aquatic exposure modeling scenario assumptions for siduron are as follows: a 10-hectare field is treated using the maximum application pattern, and that this area borders a 1 hectare pond that is 2 meters deep having no outlet. While such assumptions adequately estimate typical use for siduron on sod farms, they are highly conservative for residential/homeowner settings. Golf course adjustment factors were used to account for the area of golf courses actually treated with siduron.

Limited monitoring data on the concentrations of siduron in surface water were available for assessment. The frequency and length of sampling, however, were not sufficient to represent the temporal and special requirements for regulatory purposes. The modeling for water concentration was thus conducted with the purpose of supplementing the monitoring data.

Data are limited but sufficient for the assessment of acute risk to aquatic organisms. No aquatic chronic toxicity tests were submitted and none were found in the open literature, so toxicity endpoints were extrapolated using acute-to-chronic ratios (ACRs) or from other phenylurea compounds. The Agency is thus not requiring the registrant to conduct chronic studies on siduron since the extrapolated data is sufficient for the risk assessment at this time.

Freshwater Fish

Acute toxicity of siduron to freshwater fish was assessed using 96-hour acute toxicity studies on the rainbow trout (*Oncorychus mykiss*) and the bluegill sunfish (*Lepomis macrochirus*). The most sensitive 96-hr LC_{50} reported was for rainbow trout, with a value of 8,100 ppb a.i, but the acute 96 hr no observed adverse effects concentration (NOAEC) for freshwater fish was considered to be 2,590 ppb a.i. since no mortality or sub-lethal effects were observed at or below this concentration. The RQ values for each of the siduron application scenarios range between 0.05 and 0.1. Based upon the slope of the dose-response curve and since the Agency's LOC was only exceeded by a narrow margin, acute risk to freshwater fish is not expected.

Since no chronic toxicity data were submitted for siduron, a chronic study of diuron was used for the assessment (MRID 00141636). Diuron is a phenylurea with a similar chemical structure and mechanism of action as siduron, so the diuron ACR of 538 was used as a conservative ACR factor for extrapolating a siduron early life stage NOAEC from the most acutely sensitive siduron endpoint (rainbow trout). The NOAEC was established at 15 ppb a.i., and this was used to calculate the chronic RQ values for each siduron use scenario. All uses of siduron exceed the chronic LOC (RQ > 1) for freshwater fish with RQ values ranging from 5.1 to 55.6, so chronic risk to freshwater fish is expected.

Freshwater Aquatic Invertebrates

Acute toxicity of siduron to freshwater invertebrates was assessed using a study in the waterflea (*Daphnia magna*), which resulted in a 48-hour EC_{50} > 13,700 ppb a.i., the highest concentration tested in the study. The RQ values for each of the siduron application scenarios range between 0.05 and 0.1. Based upon the slope of the dose-response curve and since the Agency's LOC was only exceeded by a narrow margin, acute risk to freshwater aquatic invertebrates is not expected.

There was no reproduction NOAEC for the waterflea, and a NOAEC could not be extrapolated using another phenylurea because there was no definitive acute 48-hour EC_{50} value. However, based on the sensitivity pattern of the waterflea to siduron and other phenylureas and the range in reproduction NOAEC values, the lowest phenylurea waterflea reproduction value of 6 ppb was used for siduron as a conservative estimate of its reproductive effects level and this was used to calculate the chronic RQ values for each siduron use scenario. All uses of siduron exceed the chronic LOC (RQ > 1) for freshwater aquatic invertebrates, with RQs ranging from 15.1 to 139.7, so chronic risk to freshwater aquatic invertebrates is expected.

Marine/Estuarine Fish

An acute toxicity study of the Sheepshead minnow (*Cyprinodon variegates*) resulted in a 96-hr LC_{50} of 12,300 ppb, indicating that siduron is slightly toxic to estuarine/marine fish upon acute exposure. The 96-hr NOAEC was 6,300 ppb a.i since there was no mortality or sub-lethal effects observed at or below this concentration. The RQ values for each of the siduron application scenarios range between 0.05 and 0.1. Based upon the slope of the dose-response curve and since the Agency's LOC was only exceeded by a narrow margin, acute risk to marine/estuarine fish is not expected.

Since no chronic toxicity data were submitted, the diuron ACR of 538 was used to extrapolate a conservative early life stage Sheepshead minnow NOAEC using the siduron Sheepshead minnow acute value. The NOAEC was established at 23 ppb a.i., and this was used to calculate the chronic RQ values for each siduron use scenario. All uses of siduron exceed the chronic LOC (RQ > 1) for marine/estuarine fish with RQ values ranging from 3.3 to 36.3, so chronic risk to marine/estuarine fish is expected.

Marine/Estuarine Aquatic Invertebrates

The acute study on the oyster resulted in a 48-hr EC_{50} estimated to be greater than 10,800 ppb a.i., which classifies siduron as no more than slightly toxic to Eastern oyster larvae. The 48-hr NOAEC was 10,800 ppb a.i. The RQ values for each of the siduron application scenarios range between 0.06 and 0.13. Based upon the slope of the dose-response curve and since the Agency's LOC was only exceeded by a narrow margin, acute risk acute risk to marine/estuarine aquatic invertebrates is not expected.

Since no chronic toxicity data were submitted, the NOAEC was extrapolated from the marine/estuarine invertebrate *M. bahia*. The NOAEC was established at 4.6 ppb a.i., and this was used to calculate the chronic RQ values for each siduron use scenario. All uses of siduron exceed the chronic LOC (RQ > 1) for marine/estuarine aquatic invertebrates with RQ values ranging from 16.9 to 115.9, so chronic risk to marine/estuarine aquatic invertebrates is expected.

Aquatic Plants

A growth and reproduction study of non-vascular aquatic plants (green algae) resulted in a 5 day EC_{50} of 220 ppb a.i. with an associated NOAEC of 24 ppb a.i, . There was no toxicity data submitted for vascular aquatic plants, but by comparing siduron to chemicals with a similar aquatic algae toxicity profile, the Agency determined that vascular plants may be up to 10 times more sensitive to siduron than non-vascular plants. The toxicity endpoint for freshwater aquatic plants was extrapolated using this information, which yielded an EC_{50} = 21.0 ppb.

The RQs calculated for freshwater non-vascular plants (algae) slightly exceed the Agency's LOC for several application scenarios, and the RQ values above the Agency's LOC range from 1.28 to 3.82. Based on the extrapolated toxicity value for freshwater vascular aquatic plants, the RQ values exceed the LOC for all of the use scenarios (RQs range from 3.74 to 40.01). Acute risk is expected for aquatic plants.

Table 7 presents a summary of the most sensitive endpoints and RQ values used in the siduron risk assessment.

Table 7: Most Sensitive Endpoints Used in the Siduron Risk Assessment and Highest RQ Values

Environment	Taxa	Type of Risk	Type of Endpoint	Endpoint	Units	RQ
Aquatic	Freshwater Fish	Acute	LC_{50}	8,100	ppb a.i.	0.10
		Chronic	NOAEC	15	ppb a.i.	55.63
	Freshwater Invertebrates	Acute	EC_{50}	>13,700	ppb a.i.	0.06
		Chronic	NOAEC	6	ppb a.i.	139.72
	Estuarine/Marine Fish	Acute	LC_{50}	12,300	ppb a.i.	0.07
		Chronic	NOAEC	23	ppb a.i.	36.28
	Estuarine/Marine Invertebrates	Acute	EC_{50}	6,500	ppb a.i.	0.13
		Chronic	NOAEC	4.6	ppb a.i.	182.24
	Plants	Acute	EC_{50}	21.0	ppb a.i.	40.01
Terrestrial	Avian	Acute	LD_{50}	> 2,250	mg a.i./kg-bw	8.05
		Chronic	NOAEC	2,800	mg a.i./kg-diet	4.09
	Mammalian	Acute	LD_{50}	>5,000	mg a.i./kg-bw	0.99
		Chronic	NOAEC	150	mg a.i./kg-bw	3.82
	Plants	Acute	EC_{25}	0.18	lb a.i./A	15.4
		Listed	NOAEL	0.19	lb a.i./A	24.32

Endangered Species

The Agency's screening-level assessment indicates the possibility of direct effects to listed aquatic plants, terrestrial and semi-aquatic monocot plants, semi-aquatic dicot plants, and insects. In addition affects to birds and mammals are expected for chronic exposure. While the RQ values for freshwater fish and marine/estuarine invertebrates exceed the listed-species LOC, based on the slope of the dose response curve, acute exposure to siduron is not likely to adversely affect these taxonomic groups. Potential indirect effects to any species dependent upon a species that experiences effects from use of siduron cannot be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the endangered species act.

Incident Reports

There are no reports of ecological incidents for siduron in the Environmental Incident Information System (EIIS) database.

IV. Risk Management and Reregistration 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 required to support reregistration of products containing siduron 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 products containing siduron.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing siduron. The Agency has determined that siduron products are eligible for reregistration provided the risk mitigation measures outlined in this document are adopted and label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of siduron that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of siduron, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Requirements for Reregistration

Siduron products are eligible for reregistration provided that registrants comply with the requirements outlined in this document including the following: (1) submit required data and (2) implement risk mitigation measures.

1. Required Data

Siduron products are eligible for reregistration provided that registrants submit data as required by the product-specific data call-ins that EPA intends to issue as a result of this RED (see Section V). The generic database supporting the reregistration of siduron uses has been reviewed and determined to be adequate to support a reregistration eligibility decision. However, the Agency is now requiring a UV/visible absorption spectrum study for all pesticide chemicals as additional characterization of the active ingredient's properties.

2 Risk Mitigation

Products containing siduron are eligible for reregistration provided the specific labeling requirements required in Table 7 are reflected on the siduron labels.

C. Regulatory Rationale

The Agency has determined that siduron is eligible for reregistration provided that the requirements for reregistration outlined in this document are implemented. Provided that registrants comply with the requirements of this RED, EPA believes that siduron will not present risks inconsistent with FIFRA.

1. Human Health and Ecological Risk

EPA has conducted human health and ecological risk assessments for siduron to support the reregistration eligibility decision. In its assessments, EPA concluded that most risk estimates are below the Agency's level of concern, but also identified some potential risks that, if left unmitigated, may pose risks or adverse effects to humans or the environment.

All human health risk estimates are below the Agency's level of concern with the exception of inhalation risk from mixing/loading wettable powders for chemigation. To mitigate this risk, the Agency is requiring a NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P, or HE filter.

In EPA's ecological risk assessment, several exceedances were estimated from use of siduron, specifically concerning acute risk to non-target plants and chronic risk to fish and aquatic invertebrates. To mitigate these ecological risks, the Agency is requiring language to reduce spray drift; requiring an environmental hazard statement addressing the toxicity of siduron to fish and aquatic invertebrates; limiting band-treatments to golf courses to 6 applications per year; advising users that non-target plants can be adversely affected by siduron; and prohibiting aerial application of siduron.

Although there are also some exceedances of the LOC for birds and mammals, the RQs for these taxonomic groups only slightly exceeded the Agency's LOC. However, based on the slope of the dose-response curves from the bird and mammal studies, unacceptable risk is not expected. In addition, the potential for risk is based on the assumption that birds and mammals are feeding exclusively within golf courses, sod farms, and residential properties that use siduron on turf. To the extent that those birds and mammals do not reside exclusively and permanently within the area, exposure will be less and risk is presumably less.

2. Endangered Species

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 (ESA) 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 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, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for the pesticidal use of siduron result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Risk findings are based solely on EPA's qualitative assessment for siduron and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of siduron "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

3. Endocrine Screening

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 such endocrine effects as the Administrator may designate."* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, "siduron" may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

V. What Registrants Need to Do

The Agency has determined that the products containing siduron are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table 8. The Agency intends to issue a Data Call-In (DCI) requiring product-specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of the pesticidal use of siduron has been reviewed and determined to be substantially complete. The human health risk assessment identified a data gap for UV/Visible Light Absorption, guideline number 830.7050. This is a new data requirement which is being required of all pesticide chemicals as additional characterization of the active ingredient's properties.

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 8.

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 a pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure 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 Registrations Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements will be issued in the near future.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is specified in Table 8. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 8 describes how language on the labels should be amended.

Table 8: Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 8: Summary of Labeling Changes for Siduron (PC 035509)		
Manufacturing Use Products		
Description	Amended Labeling Language	Placement on Label
For all Manufacturing Use Products	"Only for formulation into an ***herbicide*** for the following use(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	"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(s)."	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."	Precautionary Statements
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED[1] for Granular Formulations	"Personal Protective Equipment (PPE)" "All loaders, applicators and other handlers must wear: > Long-sleeve shirt and long pants, > Shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for Wettable Powder Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators and other handlers must wear: > Long-sleeve shirt and long pants, > Chemical-resistant gloves, > Shoes plus socks." "In addition, for chemigation: All mixers and loaders must wear: > NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

	any N, R, P, or HE filter."	
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." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals 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."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"This product is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply where runoff is likely to occur. Do not contaminate water when disposing of equipment washwaters or rinsate."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours."	Directions for Use, Under Agricultural Use Requirements Box

Agricultural Pesticides (WPS)		
Entry Restrictions for products having occupational uses on the label not subject to the WPS	***Entry Restriction for non-WPS uses applied as a liquid:*** *:* "Do not enter or allow others to enter the treated area until sprays have dried." ***Entry Restriction for non-WPS uses applied as a solid)*** *:* "Do not enter or allow others to enter the treated area until dusts have settled." ***Note to registrants-if the label requires watering in add this statement:*** "If watering in is required after the application, do not enter or allow others to enter the treated areas (except those involved in the watering) until the watering-in is complete and the surface is dry." ***Note to registrants-if the label requires soil incorporation add this statement:*** "If soil incorporation is required after the application, do not enter or allow others to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete."	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"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 plants, soil, or water, is: > Coveralls > Waterproof gloves > Shoes plus socks	Direction for Use Agricultural Use Requirements box

General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	"Aerial application is prohibited." "Non-target plants can be adversely affected by this product." <u>Golf Course Greens (band-treatment)</u> "For band-treatments: Do not make more than 6 applications of siduron (of one product or combinations of products) to golf course greens per year."	Directions for Use
Spray Drift (for products applied as a spray only)	**"Spray Drift Requirements"** **"Wind Direction and Speed"** "Do not apply when the wind speed exceeds 10 miles per hour at the application site." **"Temperature Inversion"** "Do not apply into a temperature inversion or under stable atmospheric conditions." **"Droplet Size"** "Apply as a medium or coarser spray (ASABE standard 572)." **"Release Height"** "Do not apply with a nozzle height of greater than 4 feet above the ground or crop canopy."	Spray Drift

End Use Products Intended for Residential Use		
Application Restrictions	"Do not apply this product in a way that will contact any person, pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions	Liquid: "Do not allow people or pets to enter the treated area until sprays have dried." Solid: "Do not allow people or pets to enter the treated area until dusts have settled." ***Note to registrants-if the label requires watering in add this statement:*** "If watering in is required after the application, do not enter or allow people or pets to enter the treated areas (except those involved in the watering) until the watering-in is complete and the surface is dry." ***Note to registrants-if the label requires soil incorporation add this statement:*** "If soil incorporation is required after the application, do not enter or allow people or pets to enter the treated area (except those persons involved in the incorporation) until the incorporation is complete."	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Appendix A. Use Patterns Subject to Reregistration of Siduron (PC Code 035509)

Use Site	Application Timing	Maximum Application Rate	Formulation[2]	Maximum Number of Applications per Year	Minimum Application Interval	Application Equipment /Type
TERRESTRIAL NON-FOOD & OUTDOOR RESIDENTIAL USES						
sod farms, golf courses, residential areas, parks, turf	at seeding	6 lb. a.i./acre	granular	1	NA	push-type spreader, tractor-drawn spreader, belly grinder
			wettable powder	1	NA	groundboom, low pressure handwand, handgun, chemigation
	at seeding	6 lb. a.i./acre followed 30 days later by 3 lb. a.i./acre	granular	2	30 days	push-type spreader, tractor-drawn spreader, belly grinder
			wettable powder	2	30 days	groundboom, low pressure handwand, handgun, chemigation
	fall plantings/ established turf	12 lb. a.i./acre	granular	1	NA	push-type spreader, tractor-drawn spreader, belly grinder
			wettable powder	1	NA	groundboom, low pressure handwand, handgun, chemigation
golf course greens	established turf	12 in. band application of 1 lb. per 1,000 sq. ft.	wettable powder	6	30 days	single nozzle sprayer

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

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the siduron case covered by this RED. It contains generic data requirements that apply siduron 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 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is 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 lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

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

Data Supporting Guideline Requirements for the Reregistration of Siduron			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
TOXICOLOGY			
PRODUCT CHEMISTRY			
830.6302	Color	All	43587001
830.6304	Physical state	All	43587001
830.6313	Stability	All	43587001
830.6314	Oxidation/reduction potential	All	43587001
830.7000	pH	All	43587001
830.7200	Melting Point	All	43587001
830.7300	Density	All	41933401
830.7370	Dissociation Constants in Water	All	43587001
830.7550	Octanol Water Partition Coefficient	All	43587001
830.7840	Solubility	All	41277101
830.7950	Vapor Pressure	All	41620601
ECOLOGICAL EFFECTS			
850.2100	Avian Acute Oral Toxicity	All	40991601
850.2200	Avian Dietary Toxicity – Quail	All	40991602
850.2200	Avian Dietary Toxicity – Duck	All	40991603
850.2300	Avian Reproduction - Quail	All	43883301
850.1010	Freshwater Invertebrate Toxicity	All	43327902
850.1075	Freshwater Fish Toxicity Rainbow Trout	All	43324501
850.1075	Estuarine/Marine Fish LC_{50}	All	43327902
850.1025	Estuarine/Marine Invertebrate – Mollusk	All	43385401
850.1035	Estuarine/Marine Invertebrate – Mysid	All	45868301
850.4550	Algal Plant Toxicity – Freshwater alga	All	42111002
TOXICOLOGY			
870.1100	Acute Oral Toxicity - Rat	All	41933402
870.1200	Acute Dermal Toxicity – Rabbit/Rat	All	41933403
870.1300	Acute Inhalation Toxicity – Rat	All	41933404
870.2400	Primary Eye Irritation - Rabbit	All	41933405
870.2500	Primary Dermal Irritation - Rabbit	All	41933406
870.3100	Subchronic Oral Toxicity: 90-Day Study Rodent	All	41623601
870.3200	21-Day Dermal – Rabbit/Rat	All	42627001, 41137201, 42107101

Data Supporting Guideline Requirements for the Reregistration of Siduron			
New Guideline Number	**Study Description**	**Use Pattern**	**Citation(s)**
870.3700A	Developmental Toxicity – Rat	All	41390401
870.5900	Mammalian Cytogenetics CHO/HPRT Assay	All	40991611
870.5550	Unscheduled DNA Synthesis in Mammalian Cells in Culture	All	41050503
870.5385	Mammalian Chromosome Aberration	All	41126701
ENVIRONMENTAL FATE			
835.1240	Adsorption/Desorption	All	41811303
835.2120	Hydrolysis	All	41050501
835.2240	Photodegradation - Water	All	41811301
835.2410	Photodegradation - Soil	All	41811302
835.4100	Aerobic Soil Metabolism	All	43846701
835.4200	Anaerobic Soil Metabolism	All	41618201
835.6100	Terrestrial Field Dissipation	All	42535801
850.1730	Accumulation in Fish	All	41811305

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket EPA-HQ-OPP-2007-1160. This docket may be accessed in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov.

These documents include:

HED Document:
Siduron Revised Human Health Risk Assessment for the Reregistration Eligibility Decision. Dated July 1, 2008.

Siduron: Hazard Characterization and Endpoint Selection Reflecting the Review of Testicular Maturation in Prepubertal New Zealand White Rabbits Toxicity Study. May 1, 2008.

Siduron: Chronic Aggregate (Dietary Drinking Water Only) Exposure and Risk Assessment for the Reregistration Eligibility Decision. Dated August 22, 2007.

EFED Documents:
Ecological Risk Assessment Chapter for the Reregistration Eligibility Decision on Siduron. Dated May15, 2008.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

00020661 Todd, G.C.; Kehr, C.C.; West, H.C.; et al. (1972) The Acute Toxicity of EL-103 in Mice, Rats, Rabbits, Cats, Dogs, Quail, Ducks, Chickens, and Fish. (Unpublished study received Mar 13, 1973 under 1471-97; prepared in cooperation with Bionomics, Inc., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006422-F)

00041685 Hamelink, J.L.; Kehr, C.C. (1976) The Acute Static Toxicity of Two Formulations of Compound 75503, EL-103, to Fathead Minnows (Studies 1012-6, 1013-6, 1014-6). (Unpublished study received Feb 18, 1977 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:095855-I)

00041694 Hamelink, J.L.; Todd, G.C.; Brannon, D.R.; et al. (1978) Acute Toxicity of Compound 75503 (EL-103) to Daphnia magna: Study 5058-77. (Unpublished study received Jun 1, 1978 under 1471- 109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:097102-C)

00090083 Sauter, S.; Meyerhoff, R.D.; Todd, G.C.; et al. (1981) The Toxicity of Tebuthiuron (EL-103, Compound 75503) in Water to Rainbow Trout in a 45-day Embryo-larvae Study: Study F14580. Includes method AM-AA-CA-J024-AB-755 dated Jan 26, 1981. (Unpublished study received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246375-A)

00090084 Sauter, S.; Meyerhoff, R.D.; Todd, G.C.; et al. (1981) The Toxicity of Tebuthiuron (EL-103, Compound 75503) in Water to Fat- head Minnows in a 33-day Embryo-larvae Study: Study F08381. Includes method AM-AA-CA-JO24-AB-755 dated Jan 26, 1981. (Unpublished study received Dec 10, 1981 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:246375-B)

00138700 Grothe, D.; Meyerhoff, R.; Todd, G.; et al. (1983) The Toxicity of Tebuthiuron (EL-103, Compound 75503) to Daphnia magna in a 21- day Static Renewal Full Life-Cycle study: C02882. (unpublished study received Jan 19, 1984 under 1471-109; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, IN.; CDL:252491-D)

00141636 Call, D.; Brooke, L.; Kent, R. (1983) Toxicity, bioconcentration, and metabolism of five herbicides in freshwater fish. Prepared by Univ. of Wisconsin, Center for Lake Superior Environmental studies for the Environmental Protection Agency; available from the National Technical Information Service. 113 p.

00142932 Hall, C. (1985) 48-Hour EC50 to Daphia magna: [Linuron]: Haskell Laboratory Report No. 103-85. Unpublished study prepared by Haskell Laboratory for Toxicology and Industrial Medicine. 5 p.

40094602 Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publication 137. US Fish and Wildlife Service, Washington, D.C. 106 p.

40098001 Mayer, F.; Ellersieck, M. (1986) Manual of Acute Toxicity: Interpretation and Data Base for 410 Chemicals and 66 Species of Freshwater Animals. US Fish & Wildlife Service, Resource Publication 160. 579 p.

40445501 Wetzel, J. (1986) Static Acute 96-hour LC50 of Linuron (INZ-326- 118) to Rainbow Trout (Salmo gairdneri): Rept. No. HLR 525-86. Unpublished study prepared by Dupont Haskell Laboratory. 12 p.

40991601 Grimes, J.; Jaber, M. (1988) Siduron (H # 17,409): An Acute Oral Toxicity Study with the Bobwhite: Final Report: Project No. 112-209. Unpublished study prepared by Wildlife International Ltd. 19 p.

40991602 Grimes, J.; Jaber, M. (1988) Siduron (H # 17409): A Dietary LC50 Study with the Bobwhite: Project No. 112-203; Dupont HLO No. 750-88. Unpublished study prepared by Wildlife International Ltd. 27 p.

40991603 Grimes, J.; Jaber, M. (1988) Siduron (H # 17409): A Dietary LC50 Study with the Mallard: Project No. 112-204. Unpublished study prepared by Wildlife International Ltd. 27 p.

40991611 Bentley, K. (1989) Mutagenicity Evaluation of IN Z1318-70 in the CHO/HRPT Assaya: Project ID: Haskell Laboratory Report No. 770-88. Unpublished study prepared by E.I.du Pont de Nemours and Co., Inc. 19 p.

40991612 Reynolds, V. (1989) Mutagenicity Testing of IN Z1318-70 in the Salmonella typhimurium Plate Incorporated Assay: Project ID: Haskell Laboratory Report No. 820-88. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 27 p.

41050501 Chrzanowski, R. (1989) Hydrolysis of Carbon 14|-Siduron in ph 5,7, and 9 Buffer Solutions: Proj. ID AMR-1280-88. Unpublished study prepared by E.I. du Pont de Nemours & Co., Inc. 31 p.

41050503 Bentley, K. (1989) Assessment of IN Z1318-70 in the in vitro Unscheduled DNA Synthesis Assay in Primary Rat Hepatocytes: Proj. ID 53-89. Unpublished study prepared by Dupont Haskell Laboratory. 16 p.

41126701 Vlachos, D. (1989) In vitro Evaluation of IN Z1318-70 for Chromo- some Aberrations in Human Lymphocytes: Project ID: 175-89: Medical Research No. 8532-001. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 22 p.

41137201 Brock, W. (1989) Repeated Dose Dermal Toxicity: 21-Day Study with IN Z1318-70 in Rabbits: Project ID: Haskell Laboratory Report No. 165-89. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 214 p.

41277101 Hoffman, R. (1988) Determination of the Water Solubility of Siduron, Z1318: Lab Project Number: Z1318/C. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 15 p.

41390401 Rickard, L. (1989) Teratogenicity Study of IN Z1318-70 (Siduron) in the Rat: Lab Project Number: 136-89: 8532-001. Unpublished study prepared by E. I. du Pont de Nemours and Co. 179 p.

41390401 Rickard, L. (1989) Teratogenicity Study of IN Z1318-70 (Siduron) in the Rat: Lab Project Number: 136-89: 8532-001. Unpublished study prepared by E. I. du Pont de Nemours and Co. 179 p.

41418801 Boeri, R. (1987) Static Acute Toxicity of Haskell Sample Number 16, 035 to the Mysid, Mysidopsis bahia: Lab Project Number: D1187: HLO 725-87. Unpublished study prepared by Enseco Inc. 16 p.

41418803 Drottar, K. (1986) Acute Toxicity of H-16,035 to the Sheepshead Minnow (Cyprinodon variegatus): Rev.: Project No. 86342-0400- 2130: HLO 43-87. Unpublished study prepared by Environmental Science and Engineering, Inc. 37 p.

41618201 Rhodes, B. (1990) Anaerobic Soil Metabolism of ?Carbon 14|-Siduron: Lab Project Number: AMR-1520-89. Unpublished study prepared by E.I. du Pont de Nemours and Co. 51 p.

41620601 Barefoot, A. (1990) Vapor Pressure of Siduron: Lab Project Number: AMR-1850-90. Unpublished study prepared by E.I. du Pont de Nemours and Co. 18 p.

41632601 Sherman, H. (1964) Ninety-Day Feeding Study with 1-2-Methyl Cyclo- hexyl-3-Phenylurea INZ-1318: Lab Project Number: 41/64. Unpublished study prepared by E. I. du Pont de Nemours & Company, Inc. 29 p.

41811301 Estigoy, L.; Shepler, K. (1990) Sunlight Photodegradation of Carbon 14-Phenyl(U) Siduron in a Buffered Aqueous Solution at Ph 7 by Natural Sunlight: Lab Project Number: 217W-1: 217W: 612-90-100- 03-28B-01. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory, Inc. 78 p.

41811302 Estigoy, L.; Shepler, K. (1990) Photodegradation of Carbon 14-Phenyl(U) Siduron in/on Soil by Natural Sunlight: Lab Project Number : 218W-1: 218W: 613-90-100-03-28J-02. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory, Inc. 83 p.

41811303 Kesterson, A. (1990) Soil Adsorption/Desorption of Phenyl(U)-Carbon 14 Siduron by the Batch Equilibrium Method: Lab Project Number: 430: 1290: AMR-1787-90. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 63 p.

41811305 Fackler, P. (1990) Siduron-Bioconcentration and Elimination of Carbon 14-Residues by BlueGill (Lepomis macrochirus): Lab Project Number: 654-89-100-03-19G-10: 10934-0190-6121-140: 90-8-3415. Unpublished study prepared by Springborn Laboratories, Inc. 57 p.

41933401 Keeler, D. (1988) Siduron: Product Identity and Composition and Physical and Chemical Characteristics: Lab Project Number: Z1318 Unpublished study prepared by E. I. DuPont de Nemours and Co. Inc. 40 p.

41933402 Summers, J. (1990) Acute Oral Toxicity Study With INZ-1318-70 in Male and Female Rats: Lab Project Number: HLR 735-88. Unpublished study prepared by E. I. DuPont de Nemours and Co. 9 p.

41933402 Summers, J. (1990) Acute Oral Toxicity Study With INZ-1318-70 in Male and Female Rats: Lab Project Number: HLR 735-88. Unpublished study prepared by E. I. DuPont de Nemours and Co. 9 p.

41933403 Brock, W. (1988) Acute Dermal Toxicity Study of IN Z1318-70 in Rabbits: Lab Project Number: 8532-001: 638-88. Unpublished study prepared by E. I. Dupont de Nemours and Co., Inc. 11 p.

41933404 Malek, D. (1989) Acute Inhalation Toxicity Study with IN Z1318-70 (Milled) in Rats: Lab Project Number: 8532-001: 135-89. Unpublished study prepared by E. I. DuPont de Nemours and Co., Inc. 4 p.

41933405 Brock, W. (1988) Primary Eye Irritation Study with IN Z1318-70 in Rabbits: Lab Project Number: 8532-001: 622-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 18 p.

41933406 Brock, W. (1988) Primary Dermal Irritation Study with IN Z1318-70 in Rabbits: Lab Project Number: 8532-001: 662-88. Unpublished study prepared by E. I. du Pont de Nemours and Co., Inc. 10 p.

41965020 Burgess, D. (1988) Chronic Toxicity of UMP-488 to Daphnia magna Under Flow-through Test Conditions: Final Report: Lab Project Number: 36737. Unpublished study prepared by Analytical Bio- Chemistry Labs., Inc. 336 p.

42046003 Baer, K. (1991) Static, Acute, 48-Hour EC50 of DPX-14740-165 (Karmex DF) to Daphnia magna: Lab Project Number: 508-91: MR-9145- 001. Unpublished study prepared by E. I. du Pont de Nemours and Co. 26 p.

42061801 Ward, T.; Boeri, R. (1991) Static Acute Toxicity of DPX-Z326-198 (Linuron) to the Sheepshead Minnow, Cyprinodon variegatus: Lab Project Number: MR-9118-001: 9127-DU: 567-91. Unpublished study prepared by Envirosystems, Inc. in coop. with Dupont Haskell Labs. 32 p.

42061803 Ward, T.; Boeri. R. (1991) Static Acute Toxicity of DPX-Z326-198 (Linuron) to the Mysid, Mysidopsis bahia: Lab Project Number: MR-9118-001: 9128-DU: 515-91. Unpublished study prepared by EnviroSystems, Inc., in coop. with Dupont Haskell Labs. 31 p.

42061804 Pierson, K. (1991) Flow-Through, 80-Day Toxicity of DPX-Z326-198 to Embryo and Larval Rainbow Trout, Oncorhynchus mykiss: Lab Project Number: MR-9118-001: 538-91. Unpublished study prepared by Dupont Haskell Labs. 426 p.

42107101 Malek, D. (1991) Repeated Dose Dermal Toxicity: 21-Day Study with IN Z1318-70 (Siduron) in Male Rabbits: Lab Project No: 108-91: 8816-001. Unpublished study prepared by E.I. du Pont de Nemours and Co., Haskell Lab. 369 p.

42111001 McKelvey, R.; Kuratle, H. (1991) Influence of Siduron on Seed Germination, Seedling Emergence, and Vegetative Vigor of Several Terrestrial Plants: Lab Project Number: AMR 2036-91. Unpublished study prepared by E.I. du Pont de Nemours and Co. 196 p.

42132002 Blakemore, G. (1991) Chronic Toxicity of Thidiazuron to Daphnia magna Under Flow-through Test Conditions: Final Report: Lab Project Number: 39114: 507-AW. Unpublished study prepared by ABC Labs, Inc. 106 p.

42153401 Baer, K. (1991) Chronic Toxicity of DPX-Z326-198 (Linuron) to Daphnia magna: Lab Project Number: MR-9118-001: 558-91. Unpublished study prepared by E. I. du Pont de Nemours and Co. 429 p.

42159601 Atkins, R.; Kesterson, A. (1991) Aerobic Metabolism of Carbon 14-Siduron in Silt Loam Soil: Lab Project Number: AMR-1791-90: 1621-90-100-03-28D-4: 1397. Unpublished study prepared by E.I. du Pont de Nemours and Co. 62 p.

42270301 Cohle, P.; Muckerman, M. (1992) Early Life-Stage Toxicity of Thidiazuron to Fathead Minnows (Pimephales promelas) in a Flow-through System: Lab Project Number: 39113: 506/AW. Unpublished study prepared by ABC Laboratories, Inc. 86 p.

42312901 Ward, T.; Boeri, R. (1992) Early Life Stage Toxicity of DPX-14740-166 (Diuron) to the Sheepshead Minnow, Cyprinodon variegatus: Lab Project Number: 866-91. Unpublished study prepared by Resource Analysts, Inc. 513 p.

42498006 Machado, M. (1992) Fluometuron: Acute Toxicity to Mysid Shrimp (Mysidopsis bahia) Under Flow-Through Conditions: Lab Project Number: 92-6-4301: 1781.0292.6297.515. Unpublished study prepared by Springborn Laboratories Inc. 63 p.

42500600 Du Pont (1992) Submission of toxicity data to support DPX-14740-166 registration. Transmittal of 1 study.

42535801 Silvoy, J. (1992) Terrestrial Field Dissipation of LX1100-03 (Siduron) Applied to Cool-Season Turf and Bare Ground in California and Wisconsin: Lab Project Number: 1792-90: 270W: 1641-89-100-03-24A-0. Unpublished study prepared by PTRL-WEST and Research for Hire. 169 p.

42568501 Lintott, D. (1992) Fluometuron: Acute Toxicity to the Mysid, Mysidopsis bahia, under Flow-through Test Conditions: Lab Project Number: J9201001C. Unpublished study prepared by Toxikon Environmental Sciences. 24 p.

42627001 Frame, S. (1993) Repeated Dose Dermal Toxicity: 21-day Study with IN Z1318-70 (Siduron) in Male Rabbits: Lab Project Number: 8816-001: 108-91 SUPP 1. Unpublished study prepared by Dupont's Haskell Laboratory for Toxicology and Industrial Medicine. 28 p.

43075201 Schupner, J. (1994) Thidiazuron: Chronic Toxicity of Thidiazuron to Daphnia magna Under Flow-through Test Conditions: W-81 Addendum #1: Lab Project Number: 39114: 507-AW. Unpublished study prepared by Nor-Am Chemical Co. 33 p.

43324501 Davis, J.; Kernaghan, N. (1994) Siduron Technical: Acute Toxicity to Rainbow Trout, Oncorhynchus mykiss, Under Static Test Conditions: Lab Project Number: J9403003E. Unpublished study prepared by Toxikon Environmental Sciences. 55 p.

43324502 Kernaghan, N.; Davis, J. (1994) Siduron Technical: Acute Toxicity to the Water Flea, Daphnia magna, Under Static Test Conditions: Lab Project Number: J9403003F. Unpublished study prepared by Toxikon Environmental Sciences. 54 p.

43327902 Davis, J.; Kernaghan, N. (1994) Siduron Technical: Acute Toxicity to the Sheepshead Minnow, Cyprinodon variegatus, under Static Test Conditions: Lab Project Number: J9403003G. Unpublished study prepared by Toxikon Environmental Sciences. 49 p.

43351501 Glaza, S. (1994) Dermal Sensitization Study of Siduron Technical in Guinea Pigs: Closed Patch Technique: Final Report: Lab Project Number: 40501303: HWI/40501303. Unpublished study prepared by Hazleton Wisconsin, Inc. 31 p.

43385401 Davis, J.; Kernaghan, N. (1994) Siduron Technical: Acute Toxicity to Embryos and Larvae of the Eastern Oyster, Crassostrea virginica, Under Static Test Conditions: Lab Project Number: J9403003I. Unpublished study prepared by Toxikon Environmental Sciences. 55 p.

43385402 Schwab, D. (1994) Evaluating the Effects of Siduron on the Germination, Emergence, and Vegetative Vigor of Non-target Terrestrial Plants: Lab Project Number: 41542. Unpublished study prepared by ABC Labs, Inc. 123 p.

43587001 Clark, A. (1995) Product Chemistry for Siduron, Series 63: Physical and Chemical Characteristics: Lab Project Number: 3660-03. Unpublished study prepared by Midwest Research Institute. 40 p.

43846701 Atkins, R. (1995) Aerobic Soil Metabolism of Methylcyclohexyl- (carbon 14)-Siduron in Sandy Loam: Lab Project Number: 840: 1851. Unpublished study prepared by PTRL Esat, Inc. 105 p.

43883301 Rodgers, M. (1995) Siduron: Bobwhite Quail Dietary Reproduction and Tolerance Studies: Lab Project Number: GWN 1: GWN 1/951478. Unpublished study prepared by Huntingdon Life Sciences Ltd. 252 p.

43996501 Brown, M. (1996) Static, Acute, 48-Hour EC50 of DPX-Z326-198 (Linuron) to Daphnia magna: Lab Project Number: 10496: HLR 141-96: HA-95-019. Unpublished study prepared by DuPont's Haskell Lab for Toxicology and Industrial Medicine. 39 p.

43996502 Boeri, R.; Magazu, J.; Ward, T. (1996) Early Life Stage Toxicity of DPX-Z326-198 (Linuron) To the Sheepshead Minnow, Cyprinodon variegatus: Lab Project Number: 113-96: 10373: 815-DU. Unpublished study prepared by T.R. Wilbury Lab, Inc. 1032 p.

43996503 Boeri, R.; Magazu, J.; Ward, T. (1996) Chronic Toxicity of DPX-Z326-198 (Linuron) To The Mysid, Mysidopsis bahia: Lab Project Number: 114-96: 10373: 814-DU. Unpublished study prepared by T.R. Wilbury Labs, Inc. 821 p.

45868301 Mahabir, S.; Glover, S. (2003) Siduron Technical: Acute Toxicity to the Mysid Shrimp, Mysidopsis bahia, Under Static Test Conditions: Lab Project Number: 02J0050B: 0104. Unpublished study prepared by Toxikon Corporation. 38 p. {OPPTS 850.1035}

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.

47081601 Baris, R.; Cohen, S. (2007) A Summary of Water Quality Monitoring Studies; Detections of Siduron in Ground Water and Surface Water. Project Number: 06/40, 474047, EHL/RF/261/00. Unpublished study prepared by Environmental & Turf Services, Inc. 25 p.

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

Pesticide Registration Forms are available via the Agency's website at *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 hard copy 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@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 (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-35	Data Matrix (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*

Pesticide Registration Kit

http://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
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 §156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR §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' website.

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 22161-0002

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 website.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website at *http://www.ncis.orst.edu*.

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.