Docket Number EPA-HQ-OPP-2015-0857
www.regulations.gov

Siduron Preliminary Work Plan

Registration Review: Initial Docket Case Number 3130

June 2016

Approved by:

Yu-Ting Guilaran, P.E.
Director
Pesticide Re-evaluation Division

Date: 6/17/16

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References:

This Preliminary Work Plan summarizes the Environmental Protection Agency's current position based on the following documents:

1. *Problem Formulation for the Registration Review of Siduron.* N. E. Federoff and Edmund Wong. May 11, 2016.

2. *Siduron: Human Health Assessment Scoping Document in Support of Registration Review*. Evisabel Craig, Sumitra Biswas, and Monica Hawkins. May 31, 2016.

3. *Siduron: Tier I (Scoping) Review of Human Incidents and Epidemiology*. Elizabeth Evans and Shanna Recore. February 2, 2016.

4. *BEAD Chemical Profile for Registration Review: Siduron.* Sunil Ratnayake, Jihad Alsadek, and Andrew Lee. December 14, 2015.

These and other supporting documents for the siduron registration review case may be found in the docket EPA-HQ-OPP-2015-0857 at http://www.regulations.gov.

OVERVIEW

The docket for siduron is now open, initiating the first public comment period for this registration review (docket number EPA-HQ-OPP-2015-0857). Siduron is a selective, systemic, preemergence herbicide registered for use on annual grassy weeds in newly seeded or established plantings of cool season grasses. It is of the class of pesticides known as phenylureas. Siduron is not registered for use on food crops. Siduron is applied on sites such as ornamental grasses, golf courses, lawns, and grass seed and sod production fields. This Preliminary Work Plan (PWP) document explains what EPA's Office of Pesticide Programs knows about siduron, highlighting anticipated data and assessment needs, identifying the types of information that would be especially useful to the Agency in conducting the review, and providing an anticipated timeline for completing the registration review for siduron.

The registration review process was designed to include a public participation component to solicit input from interested stakeholders. The Agency intends, by sharing this information in the docket, to inform the public of what it knows about siduron and what types of new data or other information would be helpful for the Agency to receive as it moves toward a decision on siduron. The Agency encourages all interested stakeholders to review the PWP and Appendix and to provide comments and additional information that will help the Agency's decision-making process for this chemical. In addition to general areas on which persons may wish to comment, there are some areas identified in the PWP and Appendix about which the Agency specifically seeks comments and information. Interested stakeholders could include: environmental non-profit or interest groups; pesticide manufacturers; agricultural labor or commodity groups; commercial, institutional, residential, and other users of pesticides; or the public at large.

The Preliminary Work Plan begins by listing the anticipated data needs for siduron. Next, it discusses the statutory and regulatory authority for Registration Review. Then the document provides chemical facts, use and usage information, recent actions, the anticipated risk assessments, and a projected registration review timeline for siduron. Finally, the Appendix to this document includes identification and discussion of some areas that are considered generally in Registration Review along with some additional chemical case-specific information.

ANTICIPATED DATA NEEDS

Table 1 below summarizes anticipated data needs for siduron. For additional discussion of the anticipated data needs, see the *Problem Formulation for the Registration Review of Siduron* and *Siduron: Human Health Assessment Scoping Document in Support of Registration Review*.

Table 1: Anticipated Data Needs for the Siduron Registration Review

Guideline Number[1]	Study Title[1]	Test Material	Estimated Timeframe (Months from receipt of DCI)
835.4300	Aerobic aquatic metabolism	TGAI	24
850.6100	Environmental chemistry method and independent laboratory validation for soil	TGAI	12
850.6100	Environmental chemistry method and independent laboratory validation for water	TGAI	12
850.1400	Fish early-life stage test with both a freshwater and estuarine species	TGAI	12
850.1300/1350	Life cycle invertebrate toxicity test with both a freshwater and estuarine species	TGAI	12
NONGDLN	Chronic sediment studies[2]	TGAI	
850.4400	Aquatic plant growth (aquatic vascular plant toxicity) with *Lemna spp.*	TEP	12
850.4500	Diatom toxicity test with two species[3]	TEP	
850.4550	Cyanobacteria toxicity test	TEP	12
850.4100	Seedling Emergence	TEP	12
850.4150	Vegetative Vigor	TEP	12
OECD TG 213	Honeybee adult acute oral exposure (Tier I)	TGAI	12
OECD TG 213	Honeybee adult chronic oral exposure (Tier I)	TGAI	12
OECD TG 237	Honeybee larval acute oral exposure (Tier I)	TGAI	12
OECD TG 237	Honeybee larval chronic oral exposure (Tier I)	TGAI	12
NONGDLN	Residue in pollen and nectar (Tier II)[4]	TEP	24

[1] On June 27, 2012, EPA announced certain revisions in harmonized guideline series 850 – Ecological Effects Tests – including renumbering and other designations or changes for some guideline studies. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0154-0028

[2] Three species should be tested: *Leptocheirus*, an amphipod (*Hyalella azteca*) and a midge (*Chironomus dilutus*)

[3] The green algae test has already been submitted (MRID 42111002)

[4] The need for Tier II and III testing for pollinators will be determined based upon lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.

Table 1: Anticipated Data Needs for the Siduron Registration Review			
Guideline Number[1]	**Study Title[1]**	**Test Material**	**Estimated Timeframe (Months from receipt of DCI)**
NONGDLN	Semi-field testing for pollinators (tunnel and feeding studies) (Tier II)[4]	TEP	24
OECD TG 75 and 850.3040	Full-field testing for pollinators (Tier III)[4]	TEP	24
870.6200	Acute Neurotoxicity	TGAI	12
870.3800	Reproduction and Fertility Effects Study	TGAI	36
870.4200	Carcinogenicity Study (in rats and mice)	TGAI	36

TGAI = technical grade active ingredient; TEP = typical end-use product;

STATUTORY AND REGULATORY AUTHORITY

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States (U.S.) generally must be registered by the Environmental Protection Agency (EPA or the Agency), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided on EPA's website.[5]

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 CFR 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop a Final Work Plan (FWP) and anticipated schedule for the registration review of siduron.

CHEMICAL FACTS

Table 2 provides a summary of the chemical facts for siduron

Table 2: Chemical Facts for Siduron	
PC code	035509
Case Number	3130
CAS Number	1982-49-6
Year first registered	1964
Pesticide Type	Herbicide
Chemical class	Phenylurea
Reregistration Eligibility Decision (RED)	May 2008
Tolerance Reassessment Eligibility Decision (TRED)	Not applicable. No tolerances exist for siduron as it is not registered for use on food or feed crops.
Cumulative group	Phenylurea

[5] http://www2.epa.gov/pesticide-reevaluation

Table 2: Chemical Facts for Siduron	
40 CFR Citation	There are no established tolerances for siduron.
Dual-use	Siduron is registered for conventional pesticidal uses only and has no registered antimicrobial or biopesticidal uses.
Non-pesticidal uses	There are no identified non-pesticidal uses of siduron.
Pesticide Re-evaluation Division, Chemical Review Manager	Leigh Rimmer, rimmer.leigh@epa.gov, (703) 347-0553
Registration Division, Product Manager	Heather Garvie, garvie.heather@epa.gov, (703) 308-0034

USE AND USAGE INFORMATION

Table 3 summarizes the use and usage information for siduron. Please see the *BEAD Chemical Profile for Registration Review: Siduron* in the registration review docket for more details.

Table 3: Siduron Use and Usage Information	
Summary of Use	Siduron is a selective herbicide used to control certain annual grass weed species in newly seeded or established cool season grasses.
Use Sites	Siduron is registered to use on non-agricultural use sites such as commercial/industrial lawns, golf course turf, grasses grown for seed, nonagricultural rights-of-way/fencerows/hedgerows, ornamental lawn and turf, ornamental sod farm (turf), and lawn in recreation areas.
Summary of Usage	Based on private market usage data no agricultural or non-agricultural usage data are reported for this herbicide. However, according to a report published in California, in 2006, 24,882 lbs of a.i. of siduron have been sold in California (California Environmental Protection Agency, 2007).
Formulation Type(s)	Siduron is formulated as granular and wettable powder.
Application Method(s)	Application methods for siduron include banded, broadcast, spot treatment, and chemigation.
Technical Registrant(s)	Gowan Company
No. of Registrations	11 Section 3 products[6]
Restricted Use	No

Guidance for Commenters: Additional areas of *use and usage related information* requested for this registration review, and of particular interest to EPA, are described below.

- Confirmation of the following label information: sites of application; formulations; application methods and equipment; maximum application rates; frequency of

[6] Section 3 product labels can be obtained from the Pesticide Product Label System (PPLS) website (http://oaspub.epa.gov/pestlabl/ppls.home).

application, application intervals, and maximum number of applications per season; and geographic limitations on use.
- Use distribution (*e.g.*, acreage and geographical distribution of relevant use sites).
- Median and 90th percentile reported use rates (lbs ai/A) from usage data – national, state, and county.
- Typical application timing (date of first application and application intervals) – national, state, and county.
- Usage/use information for non-agricultural uses.
- Typical application interval (days).
- State or local use restrictions.
- Foreign technical registrants not listed above who supply technical siduron to the US market.

RECENT ACTIONS

There are no recent actions for siduron.

ANTICIPATED RISK ASSESSMENTS FOR REGISTRATION REVIEW

The most recent comprehensive human health risk assessment for siduron was completed in August 2008 in preparation for the Reregistration Eligibility Decision. The most recent ecological and environmental fate risk assessment was completed May 15, 2008 for the same purpose. Findings and conclusions from these risk assessments are summarized in the *Problem Formulation for the Registration Review of Siduron* and *Siduron: Human Health Assessment Scoping Document in Support of Registration Review*.

During registration review, the Agency anticipates the need to conduct a comprehensive ecological risk assessment, including an endangered species assessment, for all uses of siduron. For human health, EPA anticipates the need to conduct revised dietary, residential, and occupational risk assessments during registration review. If toxicological endpoints or points of departure are revised based on the data that are anticipated to be required for registration review, they will be considered in the new assessments, as well as any changes to the standard operating procedures or default exposure assumptions.

Table 4 below summarizes the anticipated registration review risk assessments based on the EFED Problem Formulation and HED Scoping Document.

Table 4: Anticipated Risk Assessments for the Siduron Registration Review		
Type of Risk Assessment	**Conduct?**	**Notes**
Ecological and Environmental Fate		
Comprehensive ecological (species to be assessed include terrestrial and aquatic organisms), including endangered species	Y	
Incidents	Will check for updates	From 2010-2015, there have been no incidents involving siduron.
Human Health		
Dietary		
Food	Y	An updated dietary exposure assessment is likely to be needed during the registration review because EFED anticipates that there will be updates to the drinking water estimates and because of potential changes to the toxicological PoDs or UF/SFs.
Drinking water	Y	The Environmental Fate and Effects Division (EFED) has determined that an updated drinking water risk assessment will be required for siduron.
Occupational		
Handlers (mixers, loaders, applicators)	Y	The occupational exposure database is adequate to support the Registration Review process for siduron. During registration review, an updated occupational handler assessment will be conducted to reflect current ORE policies and/or updated toxicological PODs.
Post-application	N	Occupational post-application dermal exposure will not be assessed during Registration Review because there is no identified systemic dermal hazard for siduron.
Residential		
Handlers	Y	The residential exposure database is adequate to support Registration Review. An updated residential handler inhalation exposure assessment will be required under Registration Review based upon revisions to HED's Residential Standard Operating Procedures (SOPs).

Post-application	Y	Residential post-application dermal exposure will not be assessed during Registration Review because there is no identified systemic dermal hazard for siduron. A post-application incidental oral exposure assessments will be required under Registration Review based upon revisions to HED's Residential Standard Operating Procedures (SOPs). The need for a volatilization risk assessment for siduron will be examined during Registration Review.
Other		
Aggregate	Y	An aggregate risk assessment will be required due to updates to HED policies which consider potential aggregate risks from residential and drinking water exposures.
Cumulative	N	The Food Quality Protection Act (FQPA) requires the Agency to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to siduron and any other substances, and siduron does not appear to produce a toxic metabolite produced by other substances. Therefore, the cumulative risk assessment has not been performed.
Tolerances	N	Currently, there are no registered food or feed uses for siduron in the U.S. that require the establishment of tolerances.
Incidents	Will check for updates	From 2010 to 2015 there were no incidents reported involving siduron.

TIMELINE

EPA has created the following estimated timeline for the completion of the siduron registration review in Table 5 below.

Table 5: Projected Siduron Registration Review Timeline

Activities	Estimated Date
Opening the Docket	
Open Docket and 60-day Public Comment Period	June 2016
Close Public Comment	September 2016
Case Development	
Final Work Plan	November 2016
Issue DCI	January-March 2017

Table 5: Projected Siduron Registration Review Timeline	
Activities	**Estimated Date**
Data Submission	January-March 2020
60-day Public Comment Period for Draft Risk Assessments[7]	June-August 2021
Registration Review Decision	
60-day Public Comment Period for Proposed Registration Review Decision	March-June 2022
Registration Review Decision and Begin Post-Decision Follow-up	2022
Total (years)	6

NEXT STEPS

After the 60-day public comment period closes, the Agency will review and respond to any comments received in a timely manner and then issue a Final Work Plan for the registration review of siduron.

[7] The regulations governing Registration Review generally require the Agency to provide a public comment period of at least 30 calendar days for draft risk assessments; see 40 CFR Part 155.53(c). For conventional pesticides, the Agency plans to provide a 60 calendar day public comment period generally for draft risk assessments.

Appendix – Additional Areas Considered in the Siduron Registration Review

PUBLIC COMMENTS AND FEEDBACK:

Guidance for Commenters: The areas below highlight topics of special interest to the Agency where your comments, data submissions, or reference to sources of additional information could be of particular use.

Water Quality:

Siduron is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.[8] In addition, no Total Maximum Daily Loads (TMDL) have been developed for siduron.[9] More information on impaired water bodies and TMDLs can be found at the Agency's website.[10] **The Agency invites submission of water quality data for this pesticide.** To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process*[11] in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice:

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to siduron compared to the general population. **Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.**

ENDANGERED SPECIES:

A risk assessment that supports a complete endangered species determination has not been conducted for siduron. The ecological risk assessment planned during registration review will allow the Agency to determine whether use of siduron has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.

ENDOCRINE DISRUPTOR SCREENING PROGRAM:

[8] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

[9] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

[10] http://www.epa.gov/owow/tmdl/

[11] http://www2.epa.gov/pesticide-reevaluation/opp-guidance-submission-state-and-tribal-water-quality-monitoring-data

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for siduron, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), siduron is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[12] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[13]

HUMAN STUDIES:

Occupational and Residential

[12] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

[13] http://www2.epa.gov/endocrine-disruption

Past siduron risk assessments rely in part on data from studies in which adult human subjects were intentionally exposed to a pesticide to determine their dermal and inhalation exposure. Many such studies, involving exposure to many different pesticides, comprise generic pesticide exposure databases such as the Pesticide Handlers Exposure Database (PHED), the Agricultural Reentry Task Force (ARTF) Database, and the Outdoor Residential Exposure Task Force (ORETF) Database. EPA has reviewed all the studies supporting these multi-pesticide generic exposure databases, and has found no clear and convincing evidence that the conduct of any of them was either fundamentally unethical or significantly deficient relative to the ethical standards prevailing at the time the research was conducted. All applicable requirements of EPA's Rule for the Protection of Human Subjects of Research (40 CFR Part 26) have been satisfied, and there is no regulatory barrier to continued reliance on these studies.