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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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MEMORANDUM

May 24, 2011

SUBJECT: **Oryzalin:** Transmittal of Data Evaluation Records for Environmental Fate Studies.

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This memo is to inform you that seven (7) DERs for studies identified in the oryzalin registration review problem formulation as “under review” have been finalized. The MRIDs and classifications are listed in **Table 1** below. Please note that the terrestrial field dissipation study (MRID 42138001), formerly classified as supplemental in the problem formulation has been downgraded to not acceptable and presents a new data gap. Further explanations of “not acceptable” study classifications are provided after **Table 1**. As a result of these classifications, an update to the data call-in (DCI) requirements is needed. Justifications for additional DCI requirements, not previously identified in the problem formulation, are provided in Attachment 1.

Table 1. DERs and Classifications for Oryzalin Studies.

MRID	Study Type (OPPTS Guideline)	DER Electronic File Name(s)	Study Classification
41378401	Hydrolysis (835.2120)	104201 41378401 835.2120.pdf	Acceptable
41050001	Photodegradation in soil (835.2410)	104201 41050001 835.2410.pdf	Supplemental
41322801	Aerobic soil metabolism (835.4100)	104201 41322801 835.4100.pdf	Supplemental

MRID	Study Type (OPPTS Guideline)	DER Electronic File Name(s)	Study Classification
41322802	Anaerobic soil metabolism (835.4200)	104201 41322802 835.4200.pdf	Not acceptable
41479802	Adsorption/desorption (835.1230)	104201 41479802 835.1230.pdf	Acceptable
41479801	Leaching (835.1240)	104201 41479801 835.1240.pdf	Not acceptable
42138001	Terrestrial field dissipation (835.6100)	104201 42138001 835.6100.pdf	Not acceptable

Aerobic Soil Metabolism (MRID 41322801) - This study is classified as supplemental. The extraction procedure (shaking with methanol) appears to have been inadequate at removing identifiable [14C]residues from the soil, since 63% of the applied radioactivity was nonextracted at study termination.

Anaerobic Soil Metabolism (MRID 41322802) - This study is classified as not acceptable. Sampling intervals were too infrequent to adequately assess the rate of dissipation. The water and soil were not analyzed separately. The extraction procedure was not adequate to remove identifiable [14C]residues from the soil. Redox potentials and dissolved oxygen levels were not measured, so it was uncertain if an anaerobic environment was actually achieved.

Leaching (MRID 41479801) - This study is classified as not acceptable. Pesticide residues were aged in a different type of soil (sandy loam) than was used in the leaching columns (sand and loam). OCSPP Guidelines (835.1240) require that the soil used for leaching studies with “aged residues” have a sand content > 70%; the sandy loam soil had a sand content of 66%. Guidelines also specify that the aging period of one half-life is recommended, but should not exceed 120 days. The half-life estimated in the aerobic soil metabolism study (MRID 41322801) was between 1.5 and 2.1 months, slightly longer than the aging period of 30 days used in the study. The lighting conditions used in the leaching phase of the study were not reported. The inner diameter and length of the soil columns used during the leaching phase were not in accordance with OCSPP guidelines.

Terrestrial Field Dissipation (MRID 42138001) - This study is classified not acceptable. The method of extraction may not have been sufficient based on the results observed in aerobic soil studies of oryzalin using the same extraction method, where relatively high levels of bound residues occurred as early as two weeks posttreatment. The transformation products of oryzalin were not determined; the soils were not adequately characterized; meteorological data were incomplete; an independent laboratory method validation was not conducted; application rates were not verified; and field spikes were not used.

Table 2 identifies studies by MRID that offer data for each guideline requirement. Also listed are study classifications, whether or not the studies are collectively sufficient for the data requirement, and whether or not additional data are needed.

Table 2. Environmental Fate Data Submitted for Oryzalin.

Guideline	Description	MRID	Classification	Data Gap?	Additional MRIDs
835.2120 161-1	Hydrolysis	41378401	Acceptable	No	66193, 106697, 131990
835.2240 161-2	Photodegradation in Water	41278701	Acceptable	No	155491
835.2410 161-3	Photodegradation in Soil	41050001	Supplemental	No	38892, 41576, 106695, 106697, 106698, 45716303
835.4100 162-1	Aerobic Soil Metabolism	41322801	Supplemental	Yes	--
835.4200 162-2	Anaerobic Soil Metabolism	41322802	Not acceptable	Yes	--
835.4300 162-3	Aerobic Aquatic Metabolism	--	--	Yes¹	--
835.4400 162-4	Anaerobic Aquatic Metabolism	--	--	Yes¹	--
835.1230 835.1240 163-1	Leaching Adsorption/Desorption	41479801 41479802	Not acceptable Acceptable	No	2803, 2804, 38888, 38889, 106699, 106700, 106732, 160842, 5001264, 43433201, 43433202
835.6100 164-1	Terrestrial Field Dissipation	42138001	Not acceptable	Yes	41859701 (supplemental)
835.6200 164-2	Aquatic Field Dissipation	--	--	Yes²	--
850.1730 165-4	Bioaccumulation in Fish (BCF)	40787501	Acceptable	No	--

1. Identified as a data gap in the problem formulation.
2. Data Call-In only for analytical method and independent laboratory validation for water.

Attachment 1. Additional DCI Justification Tables

<p>Guideline Number: 835.4100 Study Title: Aerobic Soil Metabolism</p>
<p style="text-align: center;">Rationale for Requiring the Data</p>
<p>Acceptable data on the aerobic soil metabolism of oryzalin are required under 40 CFR Part 158, Subpart N (revised July 1, 2009) for labeling of terrestrial outdoor uses. The Agency has a limited understanding of how oryzalin behaves in soil once applied. Depending on how quickly, to what extent, and to which transformation products the compound degrades, oryzalin may or may not pose potential exposure concern. Because the submitted aerobic soil metabolism study (MRID 41322801) was supplemental, this degradation route is not well understood. Therefore, the Agency is requiring an aerobic soil metabolism study conducted on an additional three relevant soils of different organic carbon content, pH, clay content, and microbial biomass.</p>
<p style="text-align: center;">Practical Utility of the Data</p>
<p>How will the data be used? Additional aerobic soil metabolism data will facilitate a better understanding of the fate of oryzalin residues in soil. If data indicate that degradation in aerobic soil occurs rapidly and produces nontoxic transformation products, then the Agency could determine that oryzalin residues of concern do not persist in soil under aerobic conditions. If data indicate that degradation is not appreciable in soil or that the transformation products are of similar or higher toxicity than the parent compound, then the Agency could conclude that oryzalin residues of concern persist in soil under some aerobic conditions.</p> <p>How could the data change the Agency’s decision, or impact the Agency’s future decision-making? In the absence of the required data, oryzalin will be considered stable in aerobic soil. If the required data indicate that oryzalin in aerobic soils is rapidly biodegraded to nontoxic transformation products, then risk assessment conclusions and associated labeled use precautions and/or restrictions could be made less restrictive.</p>

<p>Guideline Number: 835.4200 Study Title: Anaerobic Soil Metabolism</p>
<p style="text-align: center;">Rationale for Requiring the Data</p>
<p>Acceptable data on the anaerobic soil metabolism of oryzalin are required under 40 CFR Part 158, Subpart N (revised July 1, 2009) for labeling of terrestrial outdoor uses. The Agency has a limited understanding of how oryzalin behaves in soil under anaerobic conditions once applied. Depending on how quickly, to what extent, and to which transformation products the compound degrades, oryzalin may or may not pose potential exposure concern. Because the submitted anaerobic soil metabolism study (MRID 41322801) was unacceptable, this degradation route is not well understood. Therefore, the Agency is requiring an anaerobic soil metabolism study conducted on four relevant soils of different organic carbon content, pH, clay content, and microbial biomass.</p>
<p style="text-align: center;">Practical Utility of the Data</p>

How will the data be used?

Anaerobic soil metabolism data will facilitate a better understanding of the fate of oryzalin residues in soil. If data indicate that degradation in anaerobic soil occurs rapidly and produces nontoxic transformation products, then the Agency could determine that oryzalin residues of concern do not persist in soil under anaerobic conditions. If data indicate that degradation is not appreciable in soil or that the transformation products are of similar or higher toxicity than the parent compound, then the Agency could conclude that oryzalin residues of concern persist in soil under some anaerobic conditions.

How could the data change the Agency’s decision, or impact the Agency’s future decision-making?

In the absence of the required data, oryzalin will be considered stable in anaerobic soil. If the required data indicate that oryzalin in anaerobic soils is rapidly biodegraded to nontoxic transformation products, then risk assessment conclusions and associated labeled use precautions and/or restrictions could be made less restrictive.

Guideline Number: 835.6100

Study Title: Terrestrial Field Dissipation

Rationale for Requiring the Data

Because oryzalin’s dissipation from terrestrial use sites is not well understood, EPA is requiring these data.

Since the RED was signed in 1994, the Agency has finalized the data requirements in 40 CFR part 158. These updated data requirements were promulgated on October 26, 2007. For terrestrial uses, a terrestrial field dissipation study is now required.

While the laboratory studies are designed to address one dissipation process at a time, terrestrial field dissipation studies address pesticide loss as a combined result of chemical and biological processes (e.g., hydrolysis, photolysis, microbial transformation) and physical migration (e.g., volatilization, leaching, plant uptake). Pesticide dissipation may proceed at different rates under field conditions and may result in formation of degradates at levels different from those observed in laboratory studies. Data from these studies can reduce potential overestimation of exposure and risk and can confirm assumptions of low levels of toxic degradates. Results can be used to propose scenario-specific effective risk mitigation.

Practical Utility of the Data

How will the data be used?

Terrestrial field dissipation data will facilitate a better understanding of oryzalin under actual conditions of use. The laboratory studies address one environmental fate process at a time. The terrestrial field dissipation study examines pesticide loss or movement in treated fields over several months, as it combines results of the processes measured in the laboratory. The study verifies the integrated routes and rates of pesticide degradation and movement demonstrated in the laboratory.

Under field conditions degradation/dissipation processes can proceed differently than they occurred under laboratory conditions. Data from this study can reduce the potential overestimation to both exposure and risk that can result from having only laboratory generated data.

How could the data change the Agency's decision, or impact the Agency's future decision-making?

If data indicate that oryzalin degrades slowly in terrestrial environments, then ecological risks of concern, additional use precautions and/or restrictions may be necessary.