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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Review of two (2) aquatic field dissipation study protocols (static pond, and flow-through systems) for aminopyralid (MRIDs 47971401 & 47971402)

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The Environmental Fate and Effects Division (EFED) has completed a review of two protocols pursuant to the guideline for aquatic field dissipation studies (OPPTS 835.6200) for aminopyralid (4-aimino-3,6-dichloropyridine-2-carboxylic acid; PC code 005100; CAS number 150114-71-9). These include a flow-through water system protocol titled, *Dissipation of Aminopyralid in Flowing Water Systems Under Operational Conditions* (MRID 47971402), and a static pond system protocol which includes residue determination in fish, shellfish, and crustaceans (OPPTS 860.1400) titled, *Dissipation and Aquatic Organism Residue Monitoring of Aminopyralid in Small Ponds* (MRID 47971401). The sponsor has indicated that the studies will be used to support a section 3 new use registration of aminopyralid as an aquatic use herbicide to control emerged shoreline invasive species (e.g., purple loosestrife (*Lythrum salicaria*), Japanese knotweed (*Polygonum cuspidatum*), or invasive thistle species). A proposed product label was not provided with the protocols. According to OPPTS guidelines (OPPTS 835.6200) "The

Both studies classifies as upgradeable

purpose of aquatic field dissipation studies for pesticides with aquatic and aquatic impact uses is to determine the extent of dissipation and mobility of pesticide residues under actual use conditions. Pesticide dissipation may proceed at a different rate in the aquatic environment than in laboratory aquatic studies. These dissipation studies will generate on-site data for evaluating potential hazards of a pesticide under actual use conditions (e.g., mobility, formation of metabolites, and disappearance of parent compound), and provide information with respect to mechanisms of dissipation in various aquatic environments."

Current labels permit the application of aminopyralid to the edge of water bodies but prohibit the direct application to water. The proposed protocol for static ponds (MRID 47971401) will sample two geographically distinct locations; one in the Southern US (Lewisville, TX), and one in the Midwestern/Northern US (Seymour, IN). The ponds will be constructed water bodies, roughly rectangular, with depths ranging from 3 to 6 feet. There will be two treated ponds and one control at each geographic location. Two species of caged fish (one bottom feeder, and one predator), mollusks, and crustaceans will be held in at least one of the treated ponds at each site, and in the control. Aminopyralid is proposed to be applied directly to the pond water (subsurface injection is preferred) at a target concentration of 40 ug a.e./L.

The proposed flowing water protocol (operational conditions; MRID 47971402) will sample at two geographically distinct sites (not identified) under flowing (operational) conditions. The treated area will consist of a few hundred feet of shoreline at each site (approximately 0.15 acres in size). Water sampling will occur at the treatment site and at incremental locations downstream; the extent will be defined by preliminary testing with inert tracing dye prior to application of aminopyralid.

The proposed protocols contain insufficient detail and justification to fully evaluate its acceptability for fulfilling data requirements and in some cases deviates from the OPPTS Guideline (835.6200). These deviations are outlined below with our recommendations.

Conceptual Model

For field studies, a conceptual model can be developed for an individual pesticide using assumptions derived from laboratory data in combination with the formulation type and field conditions under which the study will be conducted. The conceptual model includes only those fate and transport processes that are "significant" to the pesticide in question. Through the use of the conceptual model approach, study sponsors should be able to provide data that are useful in the assessment and characterization of exposure and risk, fully support claims of dissipation in the final analysis and reduce the number of rejected studies. Before initiating a field study, the study sponsor should develop a working hypothesis of the pesticide-specific conceptual model. The working hypothesis forms the basis for determining how well the study design captures the fate of the pesticide in the field under actual use conditions. The submitted protocols for aminopyralid do not include a conceptual model. Without a hypothesis of the chemical-specific conceptual model it is difficult to evaluate the adequacy of the study design for testing the hypothesis. Aminopyralid is moderately persistent to persistent and is highly mobile in the environment. Aminopyralid is stable to hydrolysis and anaerobic aquatic metabolism, and only slowly degraded by aerobic metabolism in soils and water. Therefore, the temporal and spatial sampling scheme should be revised to adequately to capture the decline and formation of

aminopyralid, and the conceptual model addresses whether all relevant environmental parameters will be measured (e.g., sediment sampling may not be significant transport pathway as aminopyralid is not expected to partition to sediment and remain bound). Further, to adequately characterize the dissipation of aminopyralid the spatial extent of the flowing water sampling must be more accurately described. For more information on the development of pesticide-specific conceptual models see EPA Guidance for Conducting Terrestrial Field Dissipation Studies, http://www.epa.gov/oppts/pubs/frs/publications/Test_Guidelines/series835.htm (OPPTS 835.6100).

Proposed Use Pattern

A proposed product label has not been submitted with the protocol. It is unclear from the protocol itself what comprises the proposed use pattern. The protocol states that starting water concentrations of 40 ug a.e./L is desired, but reaching the exact concentration "is not important to the conduct of the study." OPPTS 835.6200 guideline states that "The test substance should be applied using the method of application stated in the directions for use specified on the product label and at the highest rate recommended on the product label." The extent to which the protocol represents typical use conditions cannot be ascertained at this time.

Test Duration

The sampling design for each protocol may not be sufficient to accurately characterize the dissipation of aminopyralid and its degradation products in aquatic environments. Data show that aminopyralid may persist in aerobic aquatic environments, and anerobic systems; it is stable to hydrolysis and anaerobic aquatic metabolism, and only slowly degraded by aerobic metabolism in soils and water; aerobic aquatic metabolism half-life is > 500 days. The test duration should be longer than 90 days based on these key lines of evidence. OPPTS 835.6200 guideline states, "residue data should be collected until patterns of decline of the test substance and patterns of formation and decline of degradation products are established in the media samples."

Aquatic Animals Sampling

The non-flowing water protocol lacks information regarding the sampling design for residues in caged fish. There is no mention of how many individuals will be collected at each sampling event.

References:

USEPA. 2008. Fate, Transport and Transformation Test Guidelines OPPTS 835.6100 Terrestrial Field Dissipation. USEPA/OPPTS, EPA 712-C-08-020. http://www.epa.gov/oppts/pubs/frs/publications/Test_Guidelines/series835.htm.

USEPA. 2008. Fate, Transport and Transformation Test Guidelines OPPTS 835.6200 Aquatic (Sediment) Field Dissipation. USEPA/OPPTS, EPA 712-C-08-021. http://www.epa.gov/oppts/pubs/frs/publications/Test_Guidelines/series835.htm.

Submitted Protocols for EPA Review:

MRID 47971401 (2010) Dissipation and Aquatic Organism Residue Monitoring of Aminopyralid in Small Ponds: Protocol. Project Number: 101046. Unpublished study prepared by Dow AgroSciences, LLC. 12 p.

MRID 47971402 (2010) Dissipation of Aminopyralid in Flowing Water Systems Under Operational Conditions: Protocol. Project Number: NA10L1B029. Unpublished study prepared by Dow AgroSciences, LLC. 9 p.