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MEMORANDUM

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SUBJECT: Pyroxsulam Section 3: Environmental Fate and Ecological Risk Assessment

TO: Joanne Miller, Risk Manager
James Stone, Reviewer
Registration Division (7505P)

FROM: Christopher Salice, Biologist
Greg Orrick, Environmental Scientist
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507P)

EBehl for C. Salice 1/9/08
Greg Orrick 1-9-08

THROUGH: Elizabeth Behl, Branch Chief
Marietta Echeverria, Environmental Scientist
Anita Pease, Senior Biologist
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507P)

EBehl 1/9/08
M. Echeverria 1/9/08
APease 1/9/08

Environmental Fate and Effects Division (EFED) has completed its ecological risk assessment for the new herbicide pyroxsulam and its end-use products GF-1674[®] (oil dispersion: 2.87% a.i.) and GF-1274[®] (water dispersible granule: 7.5% a.i.). The herbicide is initially proposed for use on winter and spring wheat.

The results of this screening-level assessment indicate a potential for direct adverse acute effects to non-target terrestrial and semi-aquatic plants. Although this screening-level analysis showed that there is limited potential for direct adverse effects to animal species associated with the use of pyroxsulam on wheat, indirect effects may result as a consequence of potential effects on plants.

Clarification is recommended for the proposed labels. Application rates are limited per growing season in the "Crop Specific Use Restrictions" sections. While winter and spring wheat only have one growing season per year, other crops may be planted during the same year. In order to clarify the labeling, we recommend modifying the maximum application rate statement to limit application rates per calendar year.

Based on the environmental fate and transport characteristics of pyroxsulam, the following surface water label advisory is recommended.

"This product may contaminate surface water due to runoff of rain water. This is especially true for poorly draining soils and soils with shallow ground water.

This product is classified as having high potential for runoff for several days after application. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from runoff of rain water. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."

Tables 1 and 2 list all of the available environmental fate and ecological effect studies, respectively, that were submitted to fulfill data requirements under 40 CFR Pt. 158 for a terrestrial food use. The environmental fate and toxicology data requirements are not adequately fulfilled for a terrestrial food use. The submitted anaerobic aquatic metabolism, aerobic aquatic metabolism, and terrestrial field dissipation studies were supplemental and no anaerobic soil metabolism study was submitted. However, further submission of data may upgrade the submitted terrestrial field dissipation study. New anaerobic soil metabolism, anaerobic aquatic metabolism, and aerobic aquatic metabolism studies are not requested at this time because they are not expected to significantly alter risk conclusions.

Studies on the effects of the parent compound on the non-vascular plants species, blue-green algae and freshwater diatoms are classified as invalid. Studies on other species of non-vascular plants were used to assess the potential for adverse effects to species in this taxa. Toxicity data for blue-green algae and freshwater diatoms would allow a more thorough characterization of potential risks, although risk conclusions are not likely to change significantly. Additionally, no toxicity data were submitted for estuarine/marine animal species. The toxicity profile based on freshwater species and the physical properties of the chemical indicate that risks to estuarine/marine species are unlikely and that the toxicity data are not a requirement. However, without appropriate toxicity data, some uncertainty exists regarding the potential risks to estuarine/marine animal species associated with the proposed use of pyroxsulam on wheat.

Table 1. Status of environmental fate data adequacy for terrestrial food uses of pyroxsulam.

Guideline	Study Title	MRID	Issues	Study Classification
161-1	Hydrolysis	46908326	None	Acceptable
161-2	Aqueous photolysis	47260501 (modifies 46908327)	None	Acceptable
161-3	Soil photolysis	46908328	None	Acceptable
161-4	Air photolysis	No study	Study not required.	--
162-1	Aerobic soil metabolism	47202701	None	Acceptable
		46908329 46908335 46908330	Multiple solvent systems were not employed in a reasonable extraction attempt; non-extractable [¹⁴ C]residues were as high as 94% or unmeasured.	Supplemental Unacceptable Supplemental
162-2	Anaerobic soil metabolism	No study	Study not submitted (apparent data gap).	--
162-3	Anaerobic aquatic metabolism	46908331	Anaerobic conditions were not assured; multiple solvent systems were not employed in a reasonable extraction attempt. This study does not adequately fulfill the §162-3 data requirement.	Supplemental
162-4	Aerobic aquatic metabolism	46908336	Multiple solvent systems were not employed in a reasonable extraction attempt; non-extractable [¹⁴ C]residues were as high as 73%. This study does not adequately fulfill the §162-4 data requirement.	Supplemental
163-1	Batch equilibrium/aged leaching	47159601 (modifies 46908332)	None	Acceptable
		46908333	Conducted with six transformation products of pyroxsulam at only one concentration.	Supplemental
163-2	Lab volatility	No study	Study not required.	--
164-1	Terrestrial field dissipation	46908334	Samples were stored as long as 588 days. An ongoing storage stability study of XDE-742 and its transformation products has only confirmed stability for XDE-742, 5-OH-XDE-742, and 6-Cl-7-OH-XDE-742 in frozen soil samples for six months (MRID 46908317). 7-OH-XDE-742 displayed reduced recovery over six months in a loam soil. This study may be upgraded to fulfill the §164-1 data requirement.	Supplemental
164-2	Aquatic field dissipation	No study	Study not required.	--
165-4	Fish bioaccumulation	No study	Study not required due to low K _{ow} .	--

Table 2. Status of ecological effects data adequacy for pyroxsulam.

Guideline	MRID	Study Title	Issues	Study Classification
71-1	469084-16	XDE-742 / BAS 770 H – Avian Single-Dose Oral LD ₅₀ on the Bobwhite Quail (<i>Colinus virginianus</i>)	None	Acceptable
71-1	469084-17	XDE-742 / BAS 770 H – Avian Single-Dose Oral LD ₅₀ on the Mallard Duck (<i>Anas platyrhynchos</i>).	None	Acceptable
850.2200 (71-2b)	469084-18	XDE-742 – Dietary Toxicity Test with the Mallard Duck (<i>Anas platyrhynchos</i>)	None	Acceptable
850.2200 (71-2a)	469084-19	XDE-742 – Dietary Toxicity Test with the Northern Bobwhite Quail (<i>Colinus virginianus</i>).	None	Acceptable
850.2300 (71-4b)	469084-20	XDE-742: Reproductive Toxicity Test with the Mallard Duck (<i>Anas platyrhynchos</i>).	None	Acceptable
850.2300 (71-4a)	469084-21	XDE-742: Reproductive Toxicity Test with the Northern Bobwhite Quail (<i>Colinus virginianus</i>)	None	Acceptable
72-1	469084-22	XDE-742/BAS 770 H: Acute Toxicity Study On The Fathead Minnow (<i>Pimephales promelas</i>) In A Static System Over 96 Hours	None	Acceptable
72-1	469084-23	XDE-742/BAS 770 H: Acute Toxicity Study On The Rainbow Trout (<i>Oncorhynchus mykiss</i>) In A Static System Over 96 Hours	None	Acceptable
72-1	469084-24	7-OH Metabolite of XDE-742- Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) Under Static Conditions	None	Acceptable
72-1	469084-25	ATSA Metabolite of XDE-742: An Acute Toxicity Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i>	None	Acceptable
72-2	469084-26	7-OH Metabolite of XDE-742- Acute Toxicity to Water Fleas, <i>Daphnia magna</i> , Under Static Conditions	None	Acceptable
72-2	469084-27	ATSA Metabolite of XDE-742: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i>	None	Acceptable
72-2	469084-28	XDE-742: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i>	None	Acceptable
72-4a	469084-30; 469086-26 (registrant-prepared DER)	XDE-742: Toxicity to the Early-Life Stages of the Fathead Minnow, <i>Pimephales promelas</i> .	None	Acceptable
72-4b	469084-29	XDE-742: A 21-Day Chronic Toxicity Study with the Daphnid (<i>Daphnia magna</i>)	None	Acceptable

Guideline	MRID	Study Title	Issues	Study Classification
123-2	469084-31	XDE-742-Growth Inhibition Test with Freshwater Blue-Green Alga (<i>Anabaena flos-aquae</i>)	Test material was detected at a concentration above the LOQ in the negative control at test termination; however, this was believed to be an error during analytical sampling.	Invalid
123-2	469084-32	XDE-742-Growth Inhibition Test with Freshwater Diatom (<i>Navicula pelliculosa</i>)	None	Invalid
850.4400 (123-2)	469084-33	7-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	None	Acceptable
850.4400 (123-2)	469084-34	ADTP Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	None	Acceptable
850.4400 (123-2)	469084-35	5,7-Di-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	None	Acceptable
850.4400 (123-2)	469084-36	5-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	None	Acceptable
850.4400 (123-2)	469084-37	6-Cl-7-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	None	Acceptable
850.4400 (123-2)	469084-38	XDE-742 Sulfinic Acid Metabolite- Toxicity to Duckweed, <i>Lemna gibba</i>	None	Acceptable
850.4225 (123-1b)	469084-39	Effects of GF-1674 on Seedling Emergence and Seedling Growth on Non-Target Terrestrial Plants (Tier II)-2005	None	Acceptable
850.4250 (123-1a)	469084-40	Effects of GF-1674 on the Vegetative Vigor on Non-Target Terrestrial Plants (Tier II)- 2005	None	Acceptable
123-2	469084-41	XDE-742: Growth Inhibition Test with the Saltwater Diatom <i>Skeletonema costatum</i>	None	Acceptable
850.4400 (123-2)	469084-42	XDE-742: Growth Inhibition Test with the Aquatic Plant, <i>Lemna gibba</i>	None	Acceptable
123-2	469084-43	XDE-742 Sulfinic Acid Metabolite- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Acceptable
850.4400 (123-2)	469084-44	Inhibition of Growth of the Aquatic Plant Duckweed, <i>Lemna gibba</i> , Following One and Three Day Exposures to XDE-742	None	Supplemental
123-2	469084-45	XDE-742: Growth Inhibition Test with the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Acceptable
123-2	469084-46	ADTP Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Acceptable

Guideline	MRID	Study Title	Issues	Study Classification
123-2	469084-47	5-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Supplemental
123-2	469084-48	6-Cl-7-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Supplemental
123-2	469084-49	5,7-Di-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Supplemental
123-2	469084-50	7-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Supplemental
123-2	469084-51	ATSA Metabolite of XDE-742: Growth Inhibition Test with the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	None	Acceptable
850.4400 (123-2)	469084-52	ATSA Metabolite of XDE-742: Growth Inhibition Test with the Aquatic Plant Duckweed, <i>Lemna gibba</i>	None	Acceptable
OECD 207	469085-04	5-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	None	Supplemental
OECD 207	469085-05	XR-742: 14 Day Soil Exposure Acute Toxicity to the Earthworm, <i>Eisenia foetida</i>	None	Supplemental
OECD 207	469085-06	6-Cl-7-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	None	Supplemental
OECD 207	469085-07	7-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	None	Supplemental
OECD 213 & 214	469085-08	Effects of XDE-742/ BAS770H (<i>Acute Contact and Oral</i>) on Honey Bees <i>Apis mellifera</i> L. In the Laboratory	None	Acceptable
OECD 219 (Non-G)	469085-09	7-OH Metabolite of XDE-742 – Chironomid Toxicity Test with Midge (<i>Chironomus riparius</i>) Under Static Conditions using Spiked Water.	None	Acceptable
OECD 219 (Non-G)	469085-10	XDE-742: 28-Day Chronic Toxicity Study with the Midge, <i>Chironomus riparius</i> , Using Spiked Water in a Sediment-Water Exposure System.	Midge larvae were added to each vessel on the same day the vessels were spiked, and aeration was stopped for approx. 3 hours during and thereafter.	Acceptable
OECD 222 (Non-G)	469085-11	6-Cl-7-OH Metabolite of XDE-742: A Reproduction Study with the Earthworm in an Artificial Soil Substrate	None	Supplemental

Guideline	MRID	Study Title	Issues	Study Classification
None	469085-12	Herbicidal Activity of XDE-742 Soil Metabolites on Weeds and Crops in a Discovery Weed Management Level 3 Postemergence Screen	No quantitative data were provided on survival, plant height or dry weight. Therefore, this study cannot be considered for a traditional review as it only provides qualitative data on the injury to the plants from exposure to the test material and associated metabolites.	Supplemental