

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PC - 108702

MEMORANDUM

DATE: October 24, 2006

SUBJECT: Preliminary Data Screen (DP Barcodes D333304, D333305 and D333306)
of the Environmental Fate and Ecological Effects of XDE-742 (PC Code
108702)

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THRU: Elizabeth Behl, Branch Chief *EBE 10/24/06*
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TO: James Stone, Risk Manager Reviewer
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In a follow-up to the emails forwarded to the Registration Division on October 5, 2006, the Environmental Fate and Effects Division (EFED) has completed the preliminary screens of the environmental fate and ecological effect data submitted in support of the registration of XDE-742 (Pyroxsulam). Except for what appear to be a few minor discrepancies identified in **Attachment 1**, none of the ecological effect studies contain significant problems that would prevent their further review. Similarly, all of the environmental fate studies are deemed as reviewable; comments regarding each of the submitted studies are contained in **Attachment 2**. The ecological effect and environmental fate studies have been retrieved from the contractor, and EFED is awaiting the primary reviews from APVMA/Australia and PMRA/Canada, respectively.



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Attachment 1. Ecological Effect Data Screen

XDE-742

Guideline	MRID	Study Title	Problems
71-1	469084-16	XDE-742 / BAS 770 H – Avian Single-Dose Oral LD ₅₀ on the Bobwhite Quail (<i>Colinus virginianus</i>).	NP
71-1	469084-17	XDE-742 / BAS 770 H – Avian Single-Dose Oral LD ₅₀ on the Mallard Duck (<i>Anas platyrhynchos</i>).	NP
850.2200 (71-2b)	469084-18	XDE-742 – Dietary Toxicity Test with the Mallard Duck (<i>Anas platyrhynchos</i>).	NP
850.2200 (71-2a)	469084-19	XDE-742 – Dietary Toxicity Test with the Northern Bobwhite Quail (<i>Colinus virginianus</i>).	NP
850.2300 (71-4b)	469084-20	XDE-742: Reproductive Toxicity Test with the Mallard Duck (<i>Anas platyrhynchos</i>).	NP
850.2300 (71-4a)	469084-21	XDE-742: Reproductive Toxicity Test with the Northern Bobwhite Quail (<i>Colinus virginianus</i>).	NP
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	NP
72-1	469084-23	XDE-742/BAS 770 H: Acute Toxicity Study On The Fathead Minnow (<i>Oncorhynchus mykiss</i>) In A Static System Over 96 Hours	NP
72-1	469084-24	7-OH Metabolite of XDE-742- Acute Toxicity to Rainbow Trout (<i>Oncorhynchus mykiss</i>) Under Static Conditions	NP
72-1	469084-25	ASTA Metabolite of XDE-742: An Acute Toxicity Study with the Rainbow Trout, <i>Oncorhynchus mykiss</i>	NP
72-2	469084-26	7-OH Metabolite of XDE-742- Acute Toxicity to Water Fleas, <i>Daphnia magna</i> , Under Static Conditions	NP
72-2	469084-27	ASTA Metabolite of XDE-742: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i>	NP
72-2	469084-28	XDE-742: An Acute Toxicity Study with the Daphnid, <i>Daphnia magna</i>	NP
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> .	NP
72-4b	469084-29	XDE-742: A 21-Day Chronic Toxicity Study with the Daphnid (<i>Daphnia magna</i>)	NP

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.
123-2	469084-32	XDE-742-Growth Inhibition Test with Freshwater Diatom (<i>Navicula pelliculosa</i>)	NP
850.4400 (123-2)	469084-33	7-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	NP
850.4400 (123-2)	469084-34	ADTP Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	NP
850.4400 (123-2)	469084-35	5,7-Di-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	NP
850.4400 (123-2)	469084-36	5-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	NP
850.4400 (123-2)	469084-37	6-Cl-7-OH Metabolite of XDE-742- Toxicity to Duckweed, <i>Lemna gibba</i>	NP
850.4400 (123-2)	469084-38	XDE-742 Sulfinic Acid Metabolite- Toxicity to Duckweed, <i>Lemna gibba</i>	NP
850.4225 (123-1b)	469084-39	Effects of GF-1674 on Seedling Emergence and Seedling Growth on Non-Target Terrestrial Plants (Tier II)-2005	NP
850.4250 (123-1a)	469084-40	Effects of GF-1674 on the Vegetative Vigor on Non-Target Terrestrial Plants (Tier II)-2005	NP
123-2	469084-41	XDE-742: Growth Inhibition Test with the Saltwater Diatom <i>Skeletonema costatum</i>	NP
850.4400 (123-2)	469084-42	XDE-742: Growth Inhibition Test with the Aquatic Plant, <i>Lemna gibba</i>	NP
123-2	469084-43	XDE-742 Sulfinic Acid Metabolite- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
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	NP
123-2	469084-45	XDE-742: Growth Inhibition Test with the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
123-2	469084-46	ADTP Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
123-2	469084-47	5-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
123-2	469084-48	6-Cl-7-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
123-2	469084-49	5,7-Di-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
123-2	469084-50	7-OH Metabolite of XDE-742- Acute Toxicity to the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP

123-2	469084-51	ASTA Metabolite of XDE-742: Growth Inhibition Test with the Freshwater Green Alga, <i>Pseudokirchneriella subcapitata</i>	NP
850.4400 (123-2)	469084-52	ASTA Metabolite of XDE-742: Growth Inhibition Test with the Aquatic Plant Duckweed, <i>Lemna gibba</i>	NP
OECD 207	469085-04	5-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	NP
OECD 207	469085-05	XR-742: 14 Day Soil Exposure Acute Toxicity to the Earthworm, <i>Eisenia foetida</i>	NP
OECD 207	469085-06	6-Cl-7-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	NP
OECD 207	469085-07	7-OH Metabolite of XDE-742: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	NP
OECD 213 & 214	469085-08	Effects of XDE-742/ BAS770H (<i>Acute Contact and Oral</i>) on Honey Bees <i>Apis mellifera L.</i> In the Laboratory	NP
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.	NP
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.
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	NP
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.

NP= no problem

Appendix 2. Environmental Fate Data Screen

New Chemical Screening Summary Environmental Fate - XDE-742

Guideline	MRID	Study Title	Issues	Reviewable (Yes/No)
161-1	469083-26	Hydrolysis Study	No issues affecting the acceptability of the study were identified.	Yes
161-2	469083-27	Photodegradation in Water	At least one transformation product reacted with the buffer used in the primary experiment. In a supplementary study using a different buffer (TRIS) included in this MRID, the buffer failed to adequately buffer and the pH of the solution decreased from pH 7 to pH 5.4-5.9.	Yes. The supplementary study appears to support the rate of degradation and the identification of transformation products.
161-3	469083-28	Photodegradation on Soil	No issues affecting the acceptability of the studies were identified. The rate of degradation in the dark control was much faster in the dark control than in the irradiated samples.	Yes
161-4	---	Photodegradation in Air	---	---
162-1	469083-29 469083-30 469083-35	Aerobic Soil Metabolism	MRIDs 46908329 and 46908335 are companion studies, with MRID 46908335 intended only to provide additional information on the rate of dissipation of XDE-742. In MRID 46908335, only the concentration of XDE-742 was measured; material balance and transformation products were not addressed. MIRD 46908330 was conducted using a transformation product. It was assumed that all extractable radioactivity was parent compound.	Yes
162-2		Anaerobic Soil Metabolism	---	---
162-3	469083-31	Anaerobic Aquatic Metabolism	This study was defined by the registrant as anaerobic soil metabolism (162-2). However, it is an anaerobic aquatic metabolism study (162-3). The systems were incubated for 30 days under nitrogen prior to treatment.	Yes
162-4	46908-36	Aerobic Aquatic Metabolism	No issues affecting the acceptability of the studies were identified.	Yes
163-1	469083-32 469083-33	Mobility - Adsorption/Desorption	No issues affecting the acceptability of the studies were identified.	Yes

Guideline	MRID	Study Title	Issues	Reviewable (Yes/No)
164-1	469083-34	Terrestrial Field Dissipation	The study was conducted in Canada.	Yes
164-2	---	Aquatic Sediment Dissipation	---	---
164-3	---	Forestry Dissipation	---	---
165-4	---	Fish Accumulation		---
165-5	---	Accumulation in Aquatic Non-target Organisms	---	---
166-1	---	Groundwater	---	---
N/A	469083-16 469083-17	<i>Other Special Studies</i>	Storage stability	MRID 469083-16 was conducted using cloquintocet-mexyl. This compound is the safener used with XDE-742 in the formulated product.

Note: The majority of MRIDs include data for two label positions. Although the radiolabeled positions were studied in separate experiments, the study authors combine the data into the same tables. In several cases, averaged data rather than data for the individual samples/different radiolabels are provided, so it is difficult to confirm the material balance.