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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Bayer 309 (Pyrasulfotole) Environmental Fate and Effects New
Chemical Screen

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The Environmental Fate and Effects Division (EFED) has reviewed environmental fate and effects studies submitted by Bayer CropScience in support of a new registration for the herbicide active ingredient Bayer 309 (pyrasulfotole). Several of the studies have issues associated with the design or conduct that may result in deficiencies, but do not prevent EFED from proceeding with an ecological risk assessment. The identified issues are tabulated below [Table 1 (fate studies) and Table 2 (effects studies)].

The Registration Division requested a new chemical screen for the herbicide Bayer 309 (pyrasulfotole). EFED screens submitted fate, transport, and toxicity studies listed under CFR 40.158 for critical flaws in the experimental design and conduct of the study. Additional studies provided by the registrant for our review and use in risk assessment

were screened for scientific soundness based on guidelines provided under OPPTS and the OECD recommendations.

The conclusions of this review are tabulated below. Final determination of the relevance of the issues on the overall acceptability of the study will not be definitively known until completion of the primary and secondary review. However, none of the studies were identified as having critical flaws that would prevent a risk assessment from being conducted.

TABLE 1. New Chemical Environmental Fate Screening Summary.

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
161-1	46801705	[Pyrazole-3- ¹⁴ C] AE0317309: hydrolytic degradation	None	Yes
161-2	46801706	[¹⁴ C-UL-Phenyl] and [¹⁴ C-3-pyrazole] AE0317309: phototransformation in water	The study was terminated after only 212 hours (<i>ca.</i> 9 days) of continuous irradiation, at which time >99% of the applied pyrasulfotole remained undegraded. Subdivision N guidelines specify that a photodegradation study be conducted for the equivalent of 30 days or until the half-life of the parent and the formation and decline of the transformation products is clearly established.	Yes
161-3	46801707	[Pyrazole-3- ¹⁴ C] AE0317309: phototransformation on soil	The study was terminated after only 9 days of continuous irradiation, at which time <i>ca.</i> 87% of the applied pyrasulfotole remained undegraded in the irradiated soil. Subdivision N guidelines specify that a photodegradation study be conducted for the equivalent of 30 days or until the half-life of the parent and the formation and decline of the transformation products is clearly established.	Yes
162-1	46801709	[Phenyl-U- ¹⁴ C]- and [pyrazole-3- ¹⁴ C]-AE 0317309: aerobic soil metabolism in a loamy sand soil of US origin under laboratory conditions at 25°C	None	Yes
162-1	46801710	[Phenyl-U- ¹⁴ C]- and	None	Yes

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
		[pyrazole-3- ¹⁴ C]-AE 0317309: aerobic soil metabolism in a silt loam soil of US origin under laboratory conditions at 25°C		
162-1	46801711	[Phenyl-UL- ¹⁴ C] and [pyrazole-3- ¹⁴ C]AE 0317309: aerobic soil metabolism in a European soil	It was not established that the German soil used in this study is comparable to soils that would be found in typical use areas for pyrasulfotole in the United States.	Yes
162-2	46801712	[Phenyl-UL- ¹⁴ C] and [pyrazole-3- ¹⁴ C]AE 0317309: anaerobic soil metabolism	None	Yes
162-3	46801714	[Phenyl-UL- ¹⁴ C]AE 0317309: anaerobic aquatic metabolism	None	Yes
162-3	46801715	[Pyrazole-3- ¹⁴ C]AE 0317309: anaerobic aquatic metabolism	None	Yes
162-4	46801713	[Pyrazol-3- ¹⁴ C]AE 0317309 and [phenyl-UL- ¹⁴ C]AE 0317309: aerobic aquatic metabolism	None	Yes
163-1	46801703	Adsorption/desorption of AE 0317309 on five soils and one sediment	It could not be determined if the foreign soils used in the study were typical of the pesticide use area in the U.S. Material balances were determined for high-dose soils only.	Yes
163-1	46801704	[14C]-RPA 203328: Adsorption/desorption in five soils	It could not be determined if the foreign soils used in the study were typical of the pesticide use area in the U.S.	Yes
164-1	46801716	Terrestrial field dissipation of AE 0317309 in Kansas soil, 2004	None	Yes
164-1	46801717	Terrestrial field dissipation of AE 0317309 in North Dakota soil, 2004	None	Yes
164-1	46801718	Terrestrial field dissipation of AE 0317309 in Washington soil, 2004	None	Yes

TABLE 2. New Chemical Ecotox Screening Summary.

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
71-1	468017-29	Technical AE0317309: An Acute Oral LD ₅₀ with Northern Bobwhite.	None	Yes
71-2	468017-30	Technical AE0317309: A Subacute Dietary LC ₅₀ with Northern Bobwhite	None	Yes
71-2	468017-31	Technical AE0317309: A Subacute Dietary LC ₅₀ with Mallards	None	Yes
71-4	468017-32	Effect of Technical AE 0317309 on Northern Bobwhite Reproduction	Cage size was significantly smaller than recommended. OPPTS recommends at least 5000 cm ² per bird. In this study, the floor space was only 784 cm ² per bird. The duration of both the pre-egg-laying and egg-laying phases were not clearly reported.	Yes
71-4	468017-33	Effect of Technical AE 0317309 on Mallard Reproduction.	Cage size was significantly smaller than recommended. OPPTS recommends at least 10,000 cm ² per bird. In this study, the floor space was only 2410 cm ² per bird. The duration of both the pre-egg-laying and egg-laying phases were not clearly reported.	Yes
72-1	468017-24	The 96 Hour Acute Toxicity to the Rainbow Trout, <i>Oncorhynchus mykiss</i> , in a Static System; AE 0317309 Technical 97.4% w/w (Amended Report).	This study was conducted as a limit test with a single nominal concentration of 100 mg/L; however, the mean-measured concentration corrected for the purity of the active ingredient (97.4%) was 93.5 mg a.i./L. The reported hardness of the dilution water (176 mg/L as CaCO ₃) was higher than recommended (40-48 mg/L as CaCO ₃). The pH of the dilution water (8.0-8.4) ranged higher than the recommended values (7.2-7.6).	Yes
72-1	468017-25	The 96 Hour Acute Toxicity to the Bluegill Sunfish, <i>Lepomis macrochirus</i> , in a Static System, AE 0317309 Technical, 98.2% w/w (Amended Report)	This study was conducted as a limit test with a single nominal concentration of 100 mg/L; however, the mean-measured concentration corrected for the purity of the active ingredient (97.4%) was 93.5 mg a.i./L. The reported hardness of the dilution water (160 mg/L as CaCO ₃) was higher than recommended (40-48 mg/L as CaCO ₃). The reported pH	Yes

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
			values in the dilution water (8.1-8.6) were higher than recommended (7.2-7.6).	
72-2	468017-21	The 48-Hour Acute Toxicity to the Water Flea, <i>Daphnia magna</i> , in a Static System AE 0317309 Technical 97.4% w/w	This study was conducted as a limit test with a single nominal concentration of 100 mg/L; however, the mean-measured concentration corrected for the purity of the active ingredient (97.4%) was 93.5 mg a.i./L. The reported hardness of the dilution water (164 mg/L as CaCO ₃) was higher than recommended (40-48 mg/L as CaCO ₃). The reported range of pH values of the dilution water (7.3-8.3) exceeded the recommended values (7.2-7.6).	Yes
72-3	468017-22	AE 0317309-Acute Toxicity to Eastern Oysters (<i>Crassostrea virginica</i>) Under Flow-Through Conditions	Filtered sea water was used instead of the recommended unfiltered sea water. The TOC of the dilution water was not reported.	Yes
72-3	468017-23	AE 0317309- Acute Toxicity to Mysids (<i>Americamysis bahia</i>) Under Static Conditions	The reported temperature during the definitive test (24-26°C) exceeded the recommended values (22±1°C). The size and fill volume of the test vessels (1 L and 900 mL, respectively) were smaller than recommended (3.9 and 2-3 L, respectively).	Yes
72-3	468017-26	Acute Toxicity of AE 0317309 Technical to the Sheepshead Minnow (<i>Cyprinodon variegates</i>) Under Static Conditions.	The reported hardness of the dilution water (40-60 mg/L as CaCO ₃) exceeded the recommended values (40-48 mg/L as CaCO ₃). The reported pH values of the dilution water (7.6-8.1) were exceeded the recommended ranges for estuarine fishes (7.7-8.0).	Yes
72-4	468017-27	Chronic Toxicity of AE 0317309 Technical to the <i>Daphnia magna</i> Under Static Renewal Conditions.	None	Yes
72-4	468017-28	Early Life Stage Toxicity of AE 0317309 Technical to the Fathead Minnow (<i>Primephales promelas</i>) Under Flow-Through	None	Yes

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
		Conditions		
141-1	468017-35	Contact toxicity (LD50) to honey bees (<i>Apis mellifera</i> L.), Substance technical	A solvent (acetone) control was tested without a concurrent negative control. After 72 hours, mortality in the solvent control was 12%, which is greater than the recommended for control mortality during testing (10%).	Yes
850.4400	468017-36	Toxicity of AE 0317309 Technical to Duckweed (<i>Lemna gibba</i> G3) Under Static Conditions.	The reported pH of the test solutions at Day 0 (7.8-7.9) and at Day 7 (8.6-8.7) exceeded the recommended values 7.5 ± 0.1 . Fewer plants per replicate (3) were used than are recommended (5), making the total number of fronds per treatment (13) less than recommended (15).	Yes
850.5400	468017-38	Toxicity of AE 0317309 Technical to the Freshwater Diatom <i>Navicula pelliculosa</i>	The recommended pH for this species is 7.5 ± 0.1 . The reported pH of the test solutions was outside of the recommended range at 0-hours (5.1-7.9) and at 96-hours (5.1-8.7). Only three replicates of <i>Navicula pelliculosa</i> were tested in each treatment level; given the inherently variable response of this species, four replicates are recommended in the study design.	Yes
850.5400	468017-37	Toxicity of AE 0317309 Technical to the Green Alga <i>Pseudokirchneriella subcapitata</i> (a.k.a. <i>Selenastrum capricornutum</i>).	The recommended pH for this species is 8.1 ± 0.1 . The reported pH of the test solutions was below the recommended range at 0-hours (5.3-7.9) and exceeded the range at 96-hours (5.4-10.0).	Yes
850.5400	468017-39	Toxicity of AE 0317309 Technical to the Blue-Green Algae <i>Anabaena flos-aquae</i>	The recommended pH for this species is 7.5 ± 0.1 . The reported pH of the test solutions exceeded the recommended range at 0-hours (7.4-8.1) and at 96-hours (7.9-8.8). The NOAEC, EC_{10} , and EC_{05} values for biomass could not be determined (<2.4 mg a.i./L) because of significant inhibition at all treatment levels, including 20% at the lowest level.	Yes

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
850.5400	468017-40	Toxicity of AE 0317309 Technical to the Saltwater Diatom <i>Skeletonema costatum</i> .	The recommended pH for this species is 8.1±0.1. The reported pH of the test solutions was lower than recommended at 0-hours (7.4-8.1) and exceeded the recommended range at 96-hours (7.9-8.8). The photoperiod during the definitive test (16L:8D) provided longer light exposure than recommended (14L:10D).	Yes
123-1a	468019-26	Non-target terrestrial plants: Seedling emergence and growth test (Tier 2) Suspo-emulsion: 50+12.5 g/L (Code: AE 0317309 02 SE06 A102)	The LOQ and LOD were not reported. The geographic location, depth of collection, CEC and moisture at 1/3 atm were not reported. All species were tested under the same environmental conditions instead of testing cold-preferring species separately from warm-preferring species. While test containers were bottom-watered for the duration of the study, pots were initially top watered to establish the water column in the soil and to facilitate germination. It is unclear if loss of test material occurred at this initial watering and what impact this may have had on seed exposure to the test material.	Yes
123-1a	468019-36	Non-target terrestrial plants: Seedling emergence and seedling growth test (Tier 2); AE 0.317309+Mefenpyr di-ethyl+Bromoxynil (Code: AE 0317309 03 EC23 A8)	The LOQ and LOD were not reported. The geographic location, depth of collection, CEC and moisture at 1/3 atm were not reported. All species were tested under the same environmental conditions instead of testing cold-preferring species separately from warm-preferring species. While test containers were bottom-watered for the duration of the study, pots were initially top watered to establish the water column in the soil and to facilitate germination. It is unclear if loss of test material occurred at this initial watering and what impact this may have had on seed exposure to the test	Yes

GUIDE-LINE	MRID	STUDY TITLE	REMARKS	REVIEWABLE?
			material.	
123-1b	468019-27	Non-target terrestrial plants: Vegetative vigor test (Tier 2) AE 0317309 + Mefenpyr di-ethyl (AE F107892); Suspo-emulsion: 50+12.5 g/L (Code: AE 0317309 02 SE06 A102)	The LOQ and LOD were not reported. The geographic location, CEC and moisture content at 1/3 atmospheres were not reported. All species were tested under the same environmental conditions instead of testing cold-preferring species separately from warm-preferring species.	Yes
123-1b	468019-37	Non-target terrestrial plants: Vegetative Vigor test (Tier 2), AE 0317309+Mefenpyr di-ethyl+Bromoxynil (Code: AE 0317309 03 EC23 A8)	The LOQ and LOD were not reported. The geographic location, CEC and moisture content at 1/3 atmospheres were not reported. All species were tested under the same environmental conditions instead of testing cold-preferring species separately from warm-preferring species. Neither a NOAEC nor an EC ₀₅ could be identified for cucumber dry weight, the most sensitive endpoint, due to significant inhibition (18%) at the lowest treatment level.	Yes
850.6200	468017-41	AE 0317309, substance, technical (Code: AE 0317309 00 1C96 0001): Acute Toxicity to Earthworms (<i>Eisenia fetida</i>) tested in Artificial Soil	The study duration was 14 days instead of the recommended 28 days. The light intensity range of 400-800 lux ranged higher than recommended (400 lux). The acclimation period of 1 day was less than recommended (7 days).	Yes
850.6200	468017-42	RPA 203328, Acute Toxicity (14-Day) to Earthworms (<i>Eisenia foetida</i>)	The study duration was 14 days instead of the recommended 28 days. The light intensity of 586-640 lux was greater than recommended (400 lux). The acclimation period of 24 hours was less than recommended (7 days).	Yes
Non-Guideline	468017-43	Isoxaflutole-RPA 203328 (AE B197555): Reproduction toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil	None	Yes
Non-Guideline	468017-34	Oral toxicity (LD50) to honey bees (<i>Apis mellifera</i> L.), Substance technical	None	Yes