

U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: June 07, 2007

Chemical: Mefluidide, Mefluidide -DEA and Mefluidide-K

PC Code: 114001,114002, 114003

DP Barcode: D340048

MEMORANDUM

SUBJECT: Error Corrections First Phase for Reregistration of
Mefluidide acid, Mefluidide -DEA and Mefluidide-K

Mefluidide acid (CAS Reg. No.53780-34-0)

Mefluidide-DEA (CAS Reg. No.53780-36-2)

Mefluidide-K (CAS Reg. No. 83601-83-6)

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Attached please find the Environmental Fate and Effects Division's (EFED) revised environmental risk assessment, which is for the phase of error corrections only.

In this Phase I of the public process, only comments considered as errors were corrected. Mefluidide-DEA application rates and modeled scenarios were also corrected from 1.2 to 1.0 lb ae/A. The registrant offered other comments on the draft risk assessment which dealt with substantive questions on interpretation. Such comments will not be addressed in this phase, but will be addressed in Phase III, the response to public comment.

All errors comments were responded as identified by the task force in the error correction document.

#1 Registrant comments:

Page 4, Disclaimer: “Based on the maximum application rate of 1.2 lb ae/A” is an incorrect statement. The 1.2 lb ae/A rate is taken from the 2217-788 label which is an RTU label and the product treats less than 1000 ft². As HED concluded this label rate should not be used as the maximum use rate. The maximum use rate is 1 lb ae/A for both Mefluidide-K and Mefluidide-DEA as a liquid. The maximum use rate for a granular product is 0.5 lb ae/A from registration 538-181.

Page 15, paragraph 2 (continued): “The maximum application rates for mefluidide applied as ground sprays are 0.89 lb ae/A for mefluidide-K and 1.5 lb ae/A for mefluidide-DEA. The maximum application rates for mefluidide, as a granular formulation, is 0.05 lb ae/A.” These rates are incorrect, they should be 1.0 lbs ae/A for both mefluidide-K and mefluidide-DEA liquid. The mefluidide granular rate should be 0.5 lb ae/A. Similar language should also be corrected on page 23.

Page 25, Section 3.2.2.1, Aquatic Exposure Modeling: “Table 3.4 contains a summary of the various labeled application rates which suggests that the maximum rate is that of mefluidide-DEA.” This statement is incorrect, both mefluidide-K and Mefluidide-DEA have equivalent maximum rates of 1 lb ae/A.

Page 26, Table 3.1: Application rate input values are all three incorrect and should be changed to acid - 0.56 kg ae/ha, DEA salt – 1.12 kg ae/ha, K Salt – 1.12 kg ae/ha.

#1 EFED response:

The application rate and modeled scenarios for mefluidide-DEA were changed from 1.2 lb ae/A to 1 lb ae/A in the risk assessment to address comments for pages 4, 15, 25 and 26. Application rate input values for mefluidide-DEA salt was changed to 1.12 kg ae/ha. Only DEA was changed with new application rate of 1.0 lb ae/A.

#2 Registrant comment:

Page 5, Executive Summary: “1.1 Nature of Stressor”

The word stressor should be replaced by compound here and globally in the document.

#2 EFED response:

The word “Stressor” in the executive summary will remain the same.

#3 Registrant comment:

“No mortality occurred at the single dose treatment level (1500 mg ae/L)”, should this be “1500 mg ae/A”

#3EFED response:

1500 mg ae/L was changed to 1500 mg/kg-bw for acute bird single dose treatment, 1500 mg ae/A is incorrect.

#4 Registrant comment:

Page 5, paragraph 1: “*Although the registrant did not submit dissociation data for the Mefluidide-K and Mefluidide-DEA*” This is an incorrect statement. PBI-Gordon submitted dissociation studies for both forms. MRID 42282001-2 mefluidide-K dissociation, MRID 42283301-2 mefluidide-DEA dissociation. Mefluidide-K completely dissociated in 7 min. Mefluidide-DEA completely dissociated in 3 min.

#4 EFED response:

Page 5, paragraph 1 and throughout the assessment: the above statement was replaced with the following: “Based on the ionic nature of mefluidide-K and mefluidide-DEA and two unreviewed dissociation studies, mefluidide-K and mefluidide-DEA will dissociate rapidly and completely to form mefluidide acid. The two unreviewed dissociation studies (MRIDs 422833-01 and 42282001) indicated mefluidide-K completely dissociated in 7 minutes and mefluidide-DEA completely dissociated in 3 minutes”.

#5 Registrant comment:

Page 15, Use Characterization, paragraph 2: “*Annual use of mefluidide in the United States is generally less than 10,000 lbs ae.*” This sentence should be removed. PBI-Gordon currently has the only sales of either mefluidide-K or Mefluidide-DEA products and this would reveal market intelligence to potential competitors. Similar sentences should be removed if present in other locations (e.g. page 23).

#5 EFED response:

EFED removed the following sentence from the assessment: “*Annual use of mefluidide in the United States is generally less than 10,000 lbs ae.*”

#6 Registrant comment:

Pages 40, 41, 42 and in Table E6, Appendix E: *Studies 41602101, 41602102, 41602103, 41601901, 41601902, and 41601903 are listed as supplemental.* However in Appendix A all are listed acceptable.

#6 EFED response:

Appendix A studies with MRIDs 41602101, 41602102 and 41602103 were changed from acceptable to Supplemental.

#7 Registrant comment:

Page 62, paragraph 4: *Acute RQs were calculated for birds based on the non-definitive LD50 value of >1500 mg ae/A.* PBI-Gordon considers this an error since data from the following MRID No.s were not used: 00073632, 00073633, and 00073634. MRID No. 00073632 was a mefluidide acid acute LD₅₀ oral study that concluded a purity corrected LD₅₀ > 4315 mg ae/kg. Coupling this LD₅₀ value with the correct 1.0 lb ae/A maximum rate should correct any RQ exceedances for birds.

#7 EFED response:

The above comment will be addressed in Phase 2 comment period. However, the following statements were inserted in Appendix E:

Appendix table E-5: Avian acute oral studies were submitted for 114001-Mefluidide and are in review MRIDs 7362 with LD₅₀ 4640 mg/kg bw.

Appendix table E-6: Avian acute dietary studies were submitted for 114001-Mefluidide and are in review MRIDs, 7633 and 7634 with LC₅₀s of >10,000 mg/kg diet.

#8 Registrant comment:

Appendix E, Table 1 : *No freshwater fish studies were submitted for 114001-Mefluidide and 114003-Mefluidide potassium salt.* This statement is incorrect, MRID No.s 41602101, 41602102, & 41602103 were conducted with Mefluidide acid.

#8 EFED response:

Appendix table E-1: The following sentences replaced the above sentence: Freshwater fish studies were submitted for 114001-Mefluidide and are in review MRIDs 73635, 80027, 80028 , 87475, 41893801 and 41893802 with LC₅₀s ranging from > 96.4 mg/L to 1720 mg/L
No freshwater fish studies were submitted for 114003 -Mefluidide potassium salt

#9 Registrant comment:

Appendix E, Table 2: *No freshwater invertebrate studies were submitted for 114001-Mefluidide and 114003-Mefluidide potassium salt.* This statement is incorrect, MRID No. 41893803 was conducted with Mefluidide acid.

#9 EFED response:

Appendix table E-2 The following sentences replaced the above sentence:

Freshwater invertebrate study was submitted for 114001-Mefluidide and is in review, MRID 41893803 with an EC₅₀ of >111.

No freshwater invertebrate studies were submitted for 114003 -Mefluidide potassium salt