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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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12/9/1997

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM: Corrections to Isoxaflutole Drinking Water Assessment Memo Dated 11/10/97

TO: Barbara Madden
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

FROM: James Breithaupt
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James Breithaupt 12/8/97

THRU : Elizabeth Leovey, Ph.D., Branch Chief
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12/9/97

Corrections and Clarifications

The maximum, 4-day, 21-day, 60-day, 90-day, and annual means in Table 1 below are <u>one-in-10 year means.</u> The long-term means in Table 1 below are **Student's upper 90 % confidence bound on the 36-year mean with the variance calculated from the annual means. Long-term means are NOT one-in-10 year means.** In the memorandum dated 11/10/97, the long-term means for RPA 202248 and RPA 203328 were incorrectly reported as 2.7 and 5.4 ug/L, respectively. The long-term means should be 1.3 and 5.8 ug/L, respectively. The long-term means changed because the output was read incorrectly.

In Table 2 below, the original reported value of 0.00025 ug/L for parent isoxaflutole changed to 0.0008 due to a change in the method of calculating concentrations. Previously, EFED was extrapolating beyond the range of the data used to construct the model for low application rates and short persistence. EFED now recommends multiplying the application rate by 0.006 to account for the uncertainty associatd with low use rate compounds.

Table 1. Tier II upper tenth percentile EEC's for Parent Isoxaflutole, RPA 202248, and RPA 203328 for simulated corn using PRZM 2.3 and EXAMS 2.94.

Compound	Maximum ($\mu g \cdot L^{-1}$) **(1-in-10 year mean)**	4 Day ($\mu g \cdot L^{-1}$) **(1-in-10 year mean)**	21 Day ($\mu g \cdot L^{-1}$) **(1-in-10 year mean)**	60 Day ($\mu g \cdot L^{-1}$) **(1-in-10 year mean)**	90 Day ($\mu g \cdot L^{-1}$) **(1-in-10 year mean)**	Annual Mean ($\mu g \cdot L^{-1}$) **(1-in-10 year mean)**	Long-Term Mean* ($\mu g \cdot L^{-1}$) **(Not a 1-in-10 year mean). This is an upper 90 % confidence bound on the 36 year mean with the variance calculated from the annual means**
Parent Isoxaflutole	0.4	0.3	0.2	0.07	0.05	0.01	0.005
RPA 202248 (Phytotoxic metabolite)	2.0	2.0	2.0	1.9	1.9	1.7	1.3
RPA 203328[3]	10.0	10.0	10.0	10.0	10.0	9.3	5.8

* Students Upper 90% confidence bound on the 36 year mean with the variance calculated from the annual means.

Table 2. Acute and Chronic Concentrations of Parent Isoxaflutole and Metabolites in Ground Water Using SCI-GROW.

Compound	Acute ($\mu g \cdot L^{-1}$)	Chronic ($\mu g \cdot L^{-1}$)	Cancer ($\mu g \cdot L^{-1}$)
Parent Isoxaflutole	0.0008	0.0008	0.0008
RPA 202248 (Phytotoxic metabolite)	0.23	0.23	0.23
RPA 203328	6.1	6.1	6.1

Also, the input parameters were unclear in the 11/10/97 memorandum, and HED questioned these inputs. PRZM-EXAMS input parameters were not changed.

For RPA 202248, the 11/10/97 memorandum (p.3, 1st paragraph, sentences 8 and 9) stated "For degradation in the pond (EXAMS), EFED used an **anaerobic** aquatic metabolism half-life of 1155 days, which is the upper 90th percentile bound of the extrapolated half-lives of 250 and 700 days in the aerobic aquatic metabolism study, which has not been formally reviewed. The quality of this data is uncertain since the study has not been formally reviewed." The word "**anaerobic**" was included in error and should have been "**aerobic**" in the sentences.

The sentences should read as follows:

"For degradation in the pond, EFED used an **aerobic** aquatic metabolism half-life of 1155 days, which is the upper 90th percentile bound of the extrapolated half-lives of 250 and 700 days in the aerobic aquatic metabolism study, which **has** been formally reviewed. The quality of this data is good, leading to high certainty."

The 11/10/97 memorandum (p.3, 2nd paragraph, sentences 5 and 6), furthermore states "For soil K_{oc}, the mean value of 69 ml/g was used (MRID 44291503). The quality of this data is uncertain, since the study has not been formally reviewed."

The data have since been reviewed, therefore the sentences should read as follows:

For soil K_{oc}, the mean value of 69 ml/g was used (MRID 44291503). The data were formally reviewed, and the quality of this data is good, leading to high certainty in our conclusions."

The 11/10/97 memorandum also should be changed on p.4, 4th paragraph, 1st sentence. It reads "Results from the SCI-GROW screening model predict that the maximum chronic concentration of parent isoxaflutole in shallow ground water is not expected to exceed the 2.5×10^{-4} ug/L for the proposed use on corn at 0.14 lbs ai/A."

Based on the changes in the method of calculation of SCI-GROW numbers above, the sentence should read:

Results from the SCI-GROW screening model predict that the maximum chronic concentration of parent isoxaflutole in shallow ground water is not predicted to exceed 8×10^{-4} ug/L for the proposed use on corn at 0.14 lbs ai/A.

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To: Isoxaflutole files

Re: Data requirements

From: Mike Davy

Today, 7/25/97, I chatted with Dr. Ed Fite (noted avian expert in EFED) regarding the data requirements for birds after our meeting with the registrant on 7/24/97. Ed and I both agree on the points for the acute and chronic testing. Since parent isoxaflutole is not very persistence, there is no need to have chronic studies on it. The acute studies show that the degradates may not be a problem, on an acute basis. However, there is no link of toxicity between the acute and the chronic. Since there are no acute problems with the degradates, we can rule out any sub-lethal affects. We need to have both species, (bobwhite and mallard) tested for the primary degradate, RPA-202248. If no problem is detected then we should look for the terminal degradate, RPA-202328 because we do not know if there is a problem from such a persistence chemical reproductively or estrogenic. If we do detect a problem, then there is no need to test for the terminal degradate since we have indicated for our risk assessment that there is chronic problem with the use of this chemical. Ed is of the opinion that we can request both species be tested with either the terminal degradate or the primary degradate first since we may have more concern with the terminal one. The argument from the registrant that the terminal degradate may not be around long enough to be exposed to the birds because of mobility is moot since the exposure will be via water. If a second test is necessary, then the registrant can choose either the bobwhite or the mallard to be tested since one species can be the bridge with the first species.

Regarding the avian acute studies, Ed and I feel that there really is nothing to gain from any further testing of degradates for acute affects to birds. So, therefore the mallard test for RPA-202248 and both species for the terminal degradate can be waived.

Regarding the aquatic tests, I will standby my requests for additional acute studies of degradates since this was planned out in detail with Dr. Tom Bailey.

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