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OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM: Drinking Water Assessment for Isoxaflutole

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General Conclusions

Parent isoxaflutole is not expected to persist in surface water or to reach ground water. However, the metabolites RPA 202248 (also an active ingredient) and RPA 203328 (terminal residue) are expected to reach both ground and surface water, where they are expected to persist and accumulate.

This assessment contains a review of modeling for both surface and ground water for parent isoxaflutole and its metabolites RPA 202248 and RPA 203328. Since there are no registered uses for isoxaflutole in the U.S., there are no monitoring data to compare against the modeling. Table 1 presents the EEC's for **surface water** using Tier 2 modeling. Table 2 presents the acute and chronic **ground water** concentrations using the SCI-GROW model. For surface water, the maximum concentrations should be used for acute risk calculations. The 90-day values and annual means are available for chronic risk calculations. For cancer, the long-term means should be used. For ground water, the SCI-GROW numbers for each compound should be used for acute, chronic, and cancer risk assessment.

If residues of isoxaflutole reach water resources, they will be primarily associated with the aqueous phase with minimal adsorption to sediment because of their low adsorption coefficients. Standard coagulation-flocculation and sedimentation processes used in water treatment are not expected to be effective in removing isoxaflutole residues, based on their adsorption coefficients. The use of GAC (Granular Activated Carbon) is also not expected to be effective in removing isoxaflutole residues because of low binding affinity to organic carbon.

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 (µg ·L⁻¹)	4 Day (µg ·L⁻¹)	21 Day (µg ·L⁻¹)	60 Day (µg ·L⁻¹)	90 Day (µg ·L⁻¹)	Annual Mean* (µg ·L⁻¹)	Long-Term Mean* (µg ·L⁻¹)
Parent Isoxaflutole[1]	0.4	0.3	0.2	0.07	0.05	0.01	0.005
RPA 202248[2] (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
* 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 (µg ·L⁻¹)	Chronic (µg ·L⁻¹)	Cancer (µg ·L⁻¹)
Parent Isoxaflutole[1]	0.0008	0.0008	0.0008
RPA 202248[2] (Phytotoxic metabolite)	0.23	0.23	0.23
RPA 203328[3]	6.1	6.1	6.1

[1]The calculated value for parent isoxaflutole using SCI-GROW was 0.00025 ug/L. However, EFED is extrapolating beyond the range of data used to construct the model. For parent isoxaflutole, the application rate of 0.14 lbs ai/A and the short half-life (2.4 days in aerobic soil) increase the uncertainty of the calculated value of 0.00025 ug/L. Therefore, for dietary risk assessment, EFED recommends multiplying 0.006 (SCI-GROW estimate for 1 lb ai/A rate of a non-persistent chemical) by 0.14 lb ai/A to obtain a value of 0.0008 ug/L, since this number reflects the increased uncertainty caused by the extrapolation.

<u>Surface Water</u>

Tier II estimated environmental concentrations (EECs) for parent isoxaflutole and its primary metabolites applied to corn in Pottawattamie County, Iowa were calculated to generate aquatic exposure estimates for use in the aquatic risk and human health risk assessments as part of the registration process. The PRZM 2-3 and EXAMS 2.94 progams were dated 4/30/97 and 1/26/92, respectively. The Tier II upper tenth percentile EECs are listed in Table 1.

Environmental Fate Parameters used for PRZM-EXAMS Modeling

For parent isoxaflutole, EFED used the maximum rate on the latest label (0.14 lbs ai/A) applied using ground equipment. For soil K_{oc}, the mean value of 122 ml/g was used (MRID 43588009). For soil metabolism in the field, an aerobic soil metabolism value of 3.5 days was used. This value was the upper 90th percentile bound of the 1.3 and 2.4 day half-lives in MRID 43588006. For degradation in the pond (EXAMS), EFED used an anaerobic aquatic metabolism half-life of six hours, calculated by multiplying the 2-hour half-life (MRID 43588007) times three to account for the uncertainty of having only one half-life for this guideline. EFED has not formally reviewed the aerobic aquatic metabolism study submitted by Rhone Poulenc. Therefore, EFED multiplied the 3.5-day aerobic soil half-life used in the model by an uncertainty factor of 2 to account for a change in media. Hydrolysis was not included as a model input since both the aerobic and anaerobic aquatic metabolism inputs include the contribution to degradation from hydrolysis. An aqueous photolysis half-life of 6.7 days was used as an input into EXAMS (MRID 43588004). The water solubility of parent isoxaflutole was reported to be 3.5 mg/l (MRID 42275501)

For RPA 202248, a phytotoxic metabolite of isoxaflutole, surface water EEC's were calculated using an application rate of 0.15 lbs ai/A, and corrected by adjusting for the new maximum application rate of parent isoxaflutole (0.14 lbs ai/A). In the aerobic soil metabolism study, RPA 202248 was observed at 80 % of parent isoxaflutole on a mass basis. However, the registrant has not demonstrated that there are additional dissipation pathways for isoxaflutole dissipation in the environment. Therefore, EFED is assuming 100 % conversion from parent isoxaflutole to RPA 202248 in soil and water. For soil K_{oc}, the mean value of 93 ml/g was used (MRID 44065801). For soil metabolism in the field, an aerobic soil metabolism value of 106 days was used. This value was the upper 90th percentile bound of the 17 and 61 day half-lives (EFED-calculated) in MRID 43588006. For degradation in the pond (EXAMS), 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 that has not been formally reviewed. This value was used for both aerobic and anaerobic aquatic metabolism in EXAMS. The quality of this data is uncertain, since the study has not been formally reviewed. The registrant has not shown that RPA 202248 actually degrades at a significant rate in aquatic environments. RPA 202248 was observed to be stable to hydrolysis (MRID 43573254) and to aqueous photolysis (MRID 43588004). Based on ths persistence, EFED expects that continued use of parent isoxaflutole will lead to accumulation of RPA 202248 in water resources. The water solubility of RPA 202248 was reported to be 300 mg/l (Rhone Poulenc Fax).

For RPA 203328, another metabolite of isoxaflutole, surface water EEC's were calculated using an application rate of 0.15 lbs ai/A, and corrected by adjusting for the new maximum application rate of parent isoxaflutole (0.14 lbs ai/A). In the aerobic soil metabolism study, RPA 202248 was observed at 60 % of parent isoxaflutole on a mass basis. The registrant has not demonstrated that there are additional dissipation pathways for isoxaflutole dissipation in the environment. Therefore, EFED is assuming 100 % conversion from RPA 202248 to RPA 203328 in soil and water. 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. For soil metabolism in the field, an aerobic soil metabolism value of 977 days was used. This value was the maximum registrant-calculated half-life in the aerobic soil metabolism study in MRID 43588006. The registrant has not shown that RPA 203328 degrades due to hydrolysis (MRID 43573254), aqueous photolysis (MRID 43588004), or aquatic metabolism. Therefore, no degradation rates were put into EXAMS. Based on ths persistence, EFED expects that continued use of parent isoxaflutole will lead to accumulation of RPA 203328 in water resources. The water solubility of RPA 2003328 was reported to be 8,000 mg/l (Rhone Poulenc Fax).

Limitations of This Analysis

There are certain limitations imposed when Tier II EEC's are used for drinking water exposure estimates. Obviously, a single 10 hectare field with a 1 hectare pond does not accurately reflect the dynamics in a watershed large enough to support a drinking water facility. A basin of this size would certainly not be planted completely to a single crop nor be completely treated with a pesticide. Additionally, treatment with the pesticide would likely occur over several days or weeks, rather than all on a single day. This would reduce the magnitude of the concentration peaks, but also make them broader, reducing the acute exposure but perhaps increasing the chronic exposure. The fact that the simulated pond has no outlet is also a limitation as water bodies in this size range would have at least some flow through (rivers) or turnover (reservoirs). In spite of these limitations, a Tier II EEC can provide a reasonable upper bound on the concentration found in drinking water if not an accurate assessment of the real concentration. The EECs have been calculated so that in any given year, there is a 10% probability that the maximum average concentration of that duration in that year will equal or exceed the EEC at the site. Risk assessment using Tier II values can capably be used as refined screens to demonstrate that the risk is below the level of concern.

A Tier II EEC uses a single site which represents a high exposure scenario for the use of the pesticide on a particular crop or non-crop use site. The weather and agricultural practices are simulated at the site over multiple (in all cases, 36) years so that the probability of an EEC occurring at that site can be estimated.

Ground Water

Method for Estimating Concentrations in Ground Water

The SCI-GROW model (Screening Concentrations in Ground Water) is a model for estimating concentrations of pesticides in ground water under "worst case" conditions. SCI-GROW provides a screening concentration, an estimate of likely ground water concentrations if the pesticide is used at the maximum allowed label rate in areas with ground water exceptionally vulnerable to contamination. In most cases, a majority of the use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate.

The SCI-GROW model is based on scaled ground water concentration from ground water monitoring studies, environmental fate properties (aerobic soil half-lives and organic carbon partitioning coefficients-Koc's) and application rates. The model is based on permeable soils that are vulnerable to leaching and on shallow ground water (10-30 feet).

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 8×10^{-4} ug/L for the proposed use on corn at 0.14 lbs ai/A. The concentrations of the metabolites RPA 202248 and RPA 203328 are estimated to reach 0.23 and 6.1 ug/L, respectively. These concentrations are not expected to persist and accumulate, since there is no apparent means of degradation in the environment for these metabolites. This modeling of the metabolites using the proposed maximum labeled rate of 0.14 lb ai/acre/season assumed 100 % conversion to each of these sequentially-formed metabolites since they are both persistent, mobile, and are expected to persist and accumulate in water. SCI-GROW is a model that provides an "upper bound" of EEC's in shallow ground water.