



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

J. Miller - PM-22

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

JAN 16 1997

MEMORANDUM

SUBJECT: PP# 6F04664. Isoxaflutole in/on Field Corn and Animal RACs. Request for Petition Method Validation. MRID#s 441690-04 & -05. Barcode D232362. Chemical 123000. Case 287353.

FROM: G.F. Kramer, Ph.D., Chemist
Tolerance Petition Team I
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: E.T. Haeberer, Acting Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economics Analysis Division (7503W)

Rhône-Poulenc Ag Company has proposed permanent tolerances for the combined residues of the herbicide isoxaflutole and its metabolites 1-(2-methylsulfonyl-4-trifluoromethylphenyl-2-cyano-3-cyclopropyl propane-1,3-dione (RPA 202248) and 2-methylsulfonyl-4-trifluoromethyl benzoic acid (RPA 203328), calculated as the parent compound, in/on:

Field Corn, Grain	--	0.20 ppm		Field Corn, Fodder	--	0.50 ppm
Field Corn, Forage	--	1.0 ppm				

Tolerances are also proposed for the combined residues of the herbicide isoxaflutole and its metabolite RPA 202248, calculated as the parent compound, in/on:

Milk	--	0.02 ppm		Liver*	--	2.0 ppm
Poultry Liver	-	2.0 ppm		Kidney*	--	0.40 ppm
Meat Byproducts (except liver and kidney)	--				--	0.20 ppm

*of cattle, goat, hogs, poultry and sheep

The petitioner has submitted a copy of method EC-96-340 and an Independent Laboratory Validation (ILV) in the following two volumes which are appended to this memorandum as Attachments 2 & 3:

"Isoxaflutole- Validation of Method of Analysis for Isoxaflutole and Its Metabolite in Animal Tissues." 11/15/96. RPA. MRID# 441690-04.

"Independent Method Validation of RPA 201772 and RPA 202248 in/on Bovine Kidney/Liver Tissue." 11/08/96. Mckenzie Labs. MRID# 441690-05.

CBTS has conducted a preliminary review of the ILV. Acceptable recoveries were obtained by the laboratory. A summary of the laboratory's findings may be found on page 18 of the ILV report. CBTS requests that ACL conduct a Petition Method Validation (PMV) on the submitted analytical method.

Samples should be run in duplicate per the experimental design specified in Attachment 1. Please complete and return this attachment as part of your report. Also, please include with your report, copies of the standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Any deficiencies in the method, as written, should also be noted and reported. Please comment on the length of time necessary to complete a set of samples.

One of the purposes of conducting a PMV is to determine whether all necessary instructions are included in the submitted method. For this reason, we are requesting that laboratory staff scientists have minimal contact with the petitioner during this PMV. Any problems encountered should be documented and included in your report. The petitioner will be informed of any deficiencies in the method and asked to resolve them.

Please obtain the necessary analytical reference standards from the EPA Repository. If the analytical reference standards of isoxaflutole and its metabolite RPA 202248 are not available from the Repository, then please contact the Registration Specialist at RPA (Karen Shearer, 919-549-2365) directly requesting several hundred milligrams of each standard not available along with the required MSDS be provided directly to ACL to start the PMV. In your final report please note that all standards are or are not available from the Repository as of (date). Also confirm the Repository ordering codes for isoxaflutole and its metabolite RPA 202248.

The review is not in expedite status. The Registration Division Product Manager for isoxaflutole is JoAnne Miller. She should be contacted directly concerning the priority for completion of the PMV.

Please address your written reports to: E.T. Haeberer, Acting Chief, Chemistry Branch I, Tolerance Support, Health Effects Division (7509C)

Attachment 1- Experimental Design for PMV

Attachment 2- Proposed Enforcement Method, MRID# 441690-04.

Attachment 3- ILV, MRID# 441690-05.

cc (with Attachment 1 only): PP#6F04664, S.F., Kramer, Circ., R.F., H. Hundley (ACB/BEAD), F. Griffith (PAM-II File), J. Miller (PM22/RD)/D. Kenny, C. Eiden (RCAB-7509C)

RDI: TPT1 (1/9/97), E.T. Haeberer (1/15/97), R.A. Loranger (1/14/97)

G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

ATTACHMENT 1

METHOD: Isoxaflutole- Validation of Method of Analysis for Isoxaflutole and Its Metabolite in Animal Tissues. MRID# 441690-04.

Please: (i) Indicate the limit of detection and quantitation;
(ii) Do not use control values for recovery calculations; and (iii) Do not report control values as zero; if less than the limit of detection, report as such.

Commodity	Chemical Added	ppm Added	ppm Found	Percent Recovery
Milk	Isoxaflutole	0.00		
		0.01		
		0.02		
	RPA 202248	0.00		
		0.01		
		0.02		
Cattle Kidney	Isoxaflutole	0.00		
		0.20		
		0.40		
	RPA 202248	0.00		
		0.20		
		0.40		