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

FEB 14 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

**MEMORANDUM**

SUBJECT: PP#5G04484 & PP#6F04664. Proposed Temporary Tolerance Request For Isoxaflutole in/on Field Corn Grain. **Request for Petition Method Validation.** MRID# 435732-51. Barcode D222828. Chemical No 123000. CBTS# 16831.

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

THRU: E. Zager, 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)

Rhone-Poulenc Ag Company has proposed a temporary tolerance for the preemergent herbicide 5-cyclopropyl-4-isoxazolyl [2-(methylsulfonyl)-4-trifluoromethyl) phenyl] methanone (isoxaflutole, RPA 201772) and its metabolites, 1-(2-methylsulphonyl-4-trifluoromethylphenyl-2-cyano-3-cyclopropyl propane-1,3-dione (RPA 202248) and 2-methylsulphonyl-4-trifluoromethyl benzoic acid (RPA 203328) in/on the raw agricultural commodity: field corn, grain at 0.1 ppm. In conjunction with the Section 3 registration, the following permanent tolerances for isoxaflutole and its metabolites RPA 202248 and RPA 203328 are proposed: field corn, grain --- 0.2 ppm; field corn, fodder --- 0.4 ppm; and field corn, forage --- 0.4 ppm.

The petitioner has submitted a copy of method US93702R and an Independent Laboratory Validation (ILV) in the following two volumes which are appended to this memorandum as Attachments 2 & 3:

EXP 30953B/Field Corn Magnitude of the Residue (US93702R):

"Analytical Method for the Determination of Residues of RPA 201772, RPA 202248, and RPA 203328 in Corn Grain and Fodder." 12/30/94. By U. Nandihalli. Performing lab: Hazelton. Appendix B of MRID# 435732-51

"PR Notice 88-5 Enforcement Method Confirmation for RPA 201772 and Its Metabolites RPA 202248 and RPA 203328 in Corn Grain." 2/23/95. By L. Schuster. Performing lab: ABC Laboratories, Madera, CA MRID# 435732-51

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 25-27 of the ILV report.

CBTS requests that ACL review the method for acceptability as a tolerance enforcement method. The ILV should also be reviewed to determine if the method has been adequately validated. If the method and the ILV are satisfactory, 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 metabolites RPA 202248 and RPA 203328 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 metabolites RPA 202248 and RPA 203328.

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. Zager, Acting Chief, Chemistry Branch I, Tolerance Support, Health Effects Division (7509C)

Attachment 1- Experimental Design for PMV

Attachment 2- Proposed Enforcement Method, Appendix B of MRID# 435732-51

Attachment 3- ILV, MRID# 435732-51

cc (with Attachment 1 and 2): M. Clower (FDA, HFS-335)
cc (with Attachment 1 only): PP#5G04484 & PP#6F04664, S.F., Kramer, Circ., R.F., F. Griffith (PAM-II File), H. Hundley (ACB/BEAD), J. Miller (PM23/RD)/D. Kenny
RDI: TPT1 (2/13/96), E. Zager (2/14/96). R.A. Loranger (2/13/96)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

ATTACHMENT 1

METHOD: EXP 30953B/Field Corn Magnitude of the Residue (US93702R): Analytical Method for the Determination of Residues of RPA 201772, RPA 202248, and RPA 203328 in Corn Grain and Fodder. Appendix B of MRID# 435732-51

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 |
|---|---|---|---|---|
| Grain | Isoxaflutole | 0.00 | | |
| | | 0.01 | | |
| | | 0.10 | | |
| | | 0.20 | | |
| | RPA 202248 | 0.00 | | |
| | | 0.01 | | |
| | | 0.10 | | |
| | | 0.20 | | |
| | RPA 203328 | 0.00 | | |
| | | 0.01 | | |
| | | 0.10 | | |
| | | 0.20 | | |
| Corn Fodder | Isoxaflutole | 0.00 | | |
| | | 0.01 | | |
| | | 0.20 | | |
| | | 0.40 | | |
| Corn Forage | Isoxaflutole | 0.00 | | |
| | | 0.01 | | |
| | | 0.20 | | |
| | | 0.40 | | |