PP# 4407 2-16-95

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

FEB 16 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 4F04407. Sulfentrazone in/on soybeans. Request for Petition Method Validation. MRID#s 429321-09 and 432782-01. Barcode D212077. Chemical No 129081. CBTS# 15105.

FROM: G.F. Kramer Ph.D., Chemist
Tolerance Petition Section III
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 (7503C)

FMC has submitted an application for permanent tolerances for the combined residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and the major metabolite hydroxymethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl] methanesulfonamide). The petitioner has proposed the following tolerances (expressed as parent plus the metabolite hydroxymethyl sulfentrazone): Soybean Seed -- 0.05 ppm, Aspirated Grain Fractions -- 0.05 ppm.

The registrant has submitted a copy of method P-2811M and an Independent Laboratory Validation (ILV) in the following two volumes which are appended to this memorandum as Attachments 2 & 3:

Residue Analytical Method for the Determination of FMC 97285 and FMC 106091 in/on Soybeans Treated with F6285. 6/29/93. By A. Chen. FMC Co. MRID# 429321-09

Independent Method Validation of FMC 97285 and FMC 106091 in/on Soybeans Using FMC Method Report P-2811M. 5/6/94. By R. Perez and

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T. Schreier. Aspen Laboratories, Jacksonville, FL MRID# 432782-01

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 7 of the ILV report.

CBTS requests that BEAD 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 BEAD 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 methods, 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 do not discuss this PMV with the registrant. Any problems encountered should be documented and included in your report. The registrant will be informed of any deficiencies in the method and asked to resolve them.

Please address your written reports to: R.B. Perfetti, Acting Section Head, Tolerance Petition Section III, Chemistry Branch I, Tolerance Support, Health Effects Division (7509C)

Attachment 1- Experimental Design for PMV

Attachment 2- Proposed Enforcement Method, MRID# 429321-09

Attachment 3- ILV, MRID# 432782-01

cc (with Attachment 1 and 2): M. Clower (FDA, HFS-335)
cc (with Attachment 1 only): PP#4F04407, S.F., Kramer, circ., R.F., H. Hundley (ACB/BEAD), J. Miller (PM23/RD)/J. Mayes, R. Thompson (RTP-NC)
RDI: R.B. Perfetti (2/15/95), R.A. Loranger (2/15/95)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C

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METHOD: Residue Analytical Method for the Determination of FMC 97285 and FMC 106091 in/on Soybeans Treated with F6285. 6/29/93. By A. Chen. FMC Co. MRID# 429321-09

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
Soybeans	Sulfentrazone (FMC 97285)	0.00		
		0.025		
		0.050		
		0.100		
Soybeans	Hydroxymethyl Sulfentrazone (FMC 106091)	0.00		
		0.025		
		0.050		
		0.100		

Modifications made to method (major or minor):

Special precautions to be taken:

Source of analytical reference standards:

If derivatized standards used, give source:

Instrumentation for confirmation:

If instrumentation parameters differ from the method as written, list parameters actually used:

Commercial source for any special chemicals or apparatus:

Comments:

Chromatograms: