PP# 4407 8-30-95

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

AUG 30 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 4F04407. Sulfentrazone in/on Soybeans. **Request for Petition Method Validation.** MRID#s 436510-14 and -15. Barcode D218619. Chemical No 129081. CBTS# 16069.

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

THRU: M.S. Metzger, 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. We requested a validation of the proposed enforcement method for soybeans on 2/16/95. The present memorandum requests validation of a method to be used on rotational crops.

For residues in rotational crops, the petitioner has proposed the following tolerances of 0.10 ppm (expressed as parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone [N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide]): Wheat Forage, Wheat Straw, Wheat Grain, Corn Fodder, Corn Silage, and Corn Grain.

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For enforcement of the proposed rotational crop tolerances on wheat, the registrant has submitted a copy of method P-2982M and an Independent Laboratory Validation (ILV) in the following two volumes which are appended to this memorandum as Attachments 2 & 3:

Analytical Methodology for the Determination of Sulfentrazone and Its Metabolites in/on Winter Wheat. 3/7/95. By I. Kim. FMC Co. MRID# 436510-14

Independent Method Validation of FMC Analytical Method Report P-2982M for Determining Sulfentrazone and Its Metabolite 3-Desmethyl Sulfentrazone in/on Winter Wheat. 4/28/95. By P. Noon. North Coast Laboratories, Arcata, CA MRID# 436510-15

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 16 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.

We note that the metabolite 3-hydroxymethyl sulfentrazone was not included in the ILV. CBTS does not feel that an ILV for this metabolite should be required as the section of the method which is specific for 3-hydroxymethyl sulfentrazone is similar to the proposed enforcement method for soybeans (MRID# 429321-09). This latter method was successfully validated by an independent lab and was forwarded to ACL for a PMV (Memo, G. Kramer 2/16/95).

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, <u>as written</u>, 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 registrant during this PMV. 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: F.B. Suhre, Acting Section Head, Tolerance Petition Section I, Chemistry Branch I, Tolerance Support, Health Effects Division (7509C)

Attachment 1- Experimental Design for PMV

Attachment 2- Proposed Enforcement Method, MRID# 436510-14

Attachment 3- ILV, MRID# 436510-15

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)/D. Morgan
RDI: F.B. Suhre (8/28/95), R.A. Loranger (8/28/95)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C

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ATTACHMENT 1

METHOD: Analytical Methodology for the Determination of Sulfentrazone and Its Metabolites in/on Winter Wheat. 3/7/95. By I. Kim. FMC Co. MRID# 436510-14

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	Chemicals Added	ppm Added	ppm Found	Percent Recovery
Wheat Grain	Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
	3-Desmethyl Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
	3-Hydroxymethyl Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
Wheat Straw	Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
	3-Desmethyl Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
	3-Hydroxymethyl Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
Wheat Forage	Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
	3-Desmethyl Sulfentrazone	0.00		
		0.025		
		0.050		
		0.100		
	3-Hydroxymethyl Sulfentrazone	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: