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

OCT 21 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 4F04407. Sulfentrazone (Authority Herbicide) for Use on Soybeans. **Request for Petition Method Validation.** MRID#s 441188-01 & -02. Barcode D230579. Chemical No 129081. Case 285935.

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)

FMC has submitted a petition for tolerances for the combined residues of the herbicide sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl]methanesulfonamide) and its major metabolite 3-hydroxymethyl sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-hydroxymethyl-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl] methanesulfonamide) on soybeans and rotational crops. For residues on the primary crop, the petitioner has proposed the following tolerance (expressed as the combined residues parent plus the metabolite 3-hydroxymethyl sulfentrazone):

Soybean Seed	--	0.05 ppm

For residues in rotational crops (inadvertent residues), the petitioner has proposed the following tolerances (expressed as the combined residues of parent plus the metabolites 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone [N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-5-oxo-1*H*-1,2,4-triazol-1-yl]phenyl] methanesulfonamide]):

Cereal Grains (excluding sweet corn), Forage	--	0.2 ppm
Cereal Grains (excluding sweet corn), Straw	--	0.6 ppm
Cereal Grains (excluding sweet corn), Hay	--	0.2 ppm
Cereal Grains (excluding sweet corn), Grain	--	0.1 ppm
Cereal Grains (excluding sweet corn), Stover	--	0.1 ppm
Cereal Grains (excluding sweet corn), Bran	--	0.1 ppm
Cereal Grains (excluding sweet corn), Hulls	--	0.2 ppm

The petitioner has submitted a copy of method P-3173 and an Independent Laboratory Validation (ILV) in the following volumes which are appended to this memorandum as Attachments 2 & 3:

Analytical Methodology for the Determination of Sulfentrazone, 3-Desmethyl Sulfentrazone, and 3-Hydroxymethyl Sulfentrazone in/on Various Matrices. P-3173. Appendix B of MRID# 441188-01.

Independent Laboratory Validation of Analytical Methodology for the Determination of Sulfentrazone, 3- Desmethyl Sulfentrazone, and 3-Hydroxymethyl Sulfentrazone in/on Wheat Forage. Centre Analytical Labs. MRID# 441188-02.

Note that ACL has previously performed PMVs of separate methods for soybeans and rotational crops. The new method differs from the previous ones in that a single method is utilized for all commodities.

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 pages 19-22 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 sulfentrazone and its metabolites are not available from the

Repository, then please contact the Registration Specialist at FMC (Callista Chukwunenye, 215-299-6592) 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 sulfentrazone and its metabolites.

The review is not in expedite status. The Registration Division Product Manager for sulfentrazone 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, Appendix B of MRID# 441188-01.

Attachment 3- ILV, MRID# 441188-02.

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-7503W), F. Griffith (PAM-II File), J. Miller/D. Morgan (RD, 7505C), S. Robbins (RCAB-7509C)
RDI: E.T. Haeberer (10/21/96). R.A. Loranger (10/18/96)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

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ATTACHMENT 1

METHOD: Analytical Methodology for the Determination of Sulfentrazone, 3- Desmethyl Sulfentrazone, and 3-Hydroxymethyl Sulfentrazone in/on Various Matrices. P-3173. Appendix B of MRID# 441188-01.

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	Sulfentrazone		3-Hydroxymethyl Sulfentrazone		3-Desmethyl Sulfentrazone	
			ppm Found	Percent Recovery	ppm Found	Percent Recovery	ppm Found	Percent Recovery
Soybean Seed	Sulfentrazone, & 3-Hydroxymethyl Sulfentrazone	0.000						
		0.025						
		0.050						
Wheat Forage	Sulfentrazone, 3-Hydroxymethyl Sulfentrazone, & 3-Desmethyl Sulfentrazone	0.000						
		0.025						
		0.100						
		0.200						
Wheat Straw	Sulfentrazone, 3-Hydroxymethyl Sulfentrazone, & 3-Desmethyl Sulfentrazone	0.000						
		0.050						
		0.300						
		0.600						
Wheat Grain	Sulfentrazone, 3-Hydroxymethyl Sulfentrazone, & 3-Desmethyl Sulfentrazone	0.000						
		0.025						
		0.050						
		0.100						

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