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

SEP 1 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 3G04272. ID# 00279-EUP-RGR. New Chemical-Sulfentrazone in or on soybeans. Amendments of 5/12/94 and 6/22/94 (Volumes 2 and 4). MRID#s 432334-01 & -02 and 432782-01 & -02. Barcodes D205746, D205985 & D205738. Case 044615. CBTS#s 14070, 14071 & 14156.

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

THRU: P.V. Errico, Section Head
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: JoAnne Miller, Product Manager
Jesse Mayes, Team 23 Reviewer
Registration Division (7505C)

FMC is proposing temporary tolerances for 3-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 major metabolite of sulfentrazone (N-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]phenyl]methanesulfonamide). The registrant has proposed the following tolerance for 3-hydroxymethyl sulfentrazone:

Soybeans -- 0.025 ppm

The current amendment partially addresses deficiencies identified in CBTS' previous review (Memo G. Kramer 4/25/94).

In the Detailed Considerations section of this Memo, the outstanding deficiencies, listed as presented in the Memo of G. Kramer 4/25/94, are followed by the petitioner's response and our conclusions.

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RECOMMENDATIONS

CBTS continues to recommend against the proposed temporary tolerances for hydroxymethyl-sulfentrazone on soybeans for reasons detailed in conclusions 2b (revised Section B), and 8c (revised Section F) from the Memo of G. Kramer, 4/25/94.

CONCLUSIONS

1. An ILV of the proposed analytical enforcement method has been submitted. Satisfactory recoveries were obtained by the independent lab. CBTS can now send method P-2811M to ACL for Agency validation.

2a. A new soybean processing study has been performed in which the samples were analyzed using the proposed analytical enforcement method. Residues of sulfentrazone and 3-hydroxymethyl sulfentrazone were below the LOQ (0.025 ppm) in the RAC and all processed fractions. CBTS will thus not require Food/Feed Additive Tolerances for this petition.

2b. This processing study may be adequate for the permanent tolerance petition provided that storage stability of 3-hydroxymethyl sulfentrazone is demonstrated. If, however, metabolites other than 3-hydroxymethyl sulfentrazone are determined to be of regulatory significance, then residue data for soybean processed fractions will be required for all such metabolites.

3. The registrant has proposed to change the sulfentrazone formulation employed for the EUP program. Previously, sulfentrazone was formulated as F6285 4F Herbicide, containing 39.6% a.i. by weight and 4 lbs. a.i./gal. The registrant is now proposing to use F6285 75DF Herbicide, a dry-flowable formulation containing 75% a.i. by weight. The directions for use of the 75DF formulation are the same as for the 4F formulation except that the maximum use rate is 0.375 lbs. ai/A instead of 0.50 lbs. ai/A. CBTS has no objection to this change in formulation. The petitioner should also be made aware of our comments below under "other considerations."

Note to PM: The registrant has also submitted product chemistry data for the end use product, F6285 75DF Herbicide (MRID#s 432334-01 & -02). These data requirements are under purview of RD and are thus not reviewed herein.

DETAILED CONSIDERATIONS

Deficiency - Conclusion 6b (from Memo, G. Kramer 4/25/94)

6b. This method is not adequate for the purposes of this EUP. **CBTS will not recommend in favor of this EUP until we receive an ILV of the proposed enforcement method.** Once we receive the ILV report, the method will be sent to ACL for the Agency's petition method validation (PMV).

Petitioner's Response: Submission of:

> Independent Method Validation of FMC 97285 and FMC 106091 in/on Soybeans Using FMC Method Report P-2811M. MRID# 432782-01

CBTS' Conclusion: Satisfactory recoveries were obtained by the independent lab. CBTS can now send method P-2811M to ACL for Agency validation. This deficiency is now resolved.

Deficiency - Conclusion 9b (from Memo, G. Kramer 4/25/94)

9b. This processing study is not adequate to support this EUP application. The need for feed/food additive tolerances can not be determined because the samples were not analyzed for the sulfentrazone metabolite included in the tolerance expression (hydroxymethyl-sulfentrazone). As this metabolite is organosoluble and was detected in seed samples from the field trials, it is likely that significant residues would be present in the oil fractions. **For this EUP, the registrant should repeat this processing study and analyze the samples with Method P-2811M which measures both sulfentrazone and hydroxymethyl-sulfentrazone.** Alternatively, the samples from this study could be reanalyzed using this method provided some evidence of storage stability could be provided. If residues are found to concentrate, then the appropriate temporary feed/food additive tolerances should be proposed.

Petitioner's Response: Submission of:

> Magnitude of the Residue of Sulfentrazone and its 3-hydroxymethyl Metabolite in/on Soybeans and the Processed Parts of Soybeans Treated with F6285 75DF at 1.5 lbs. ai/A. MRID# 432782-02

Procedure: Soybeans were treated preemergent with F6285 75DF at a rate of 1.5 lbs. ai/A. (4X). Mature soybeans were harvested at maturity and frozen. Samples were shipped to TX A & M for processing. The processed fractions were shipped frozen to the FMC residue labs (NJ) for analysis. Samples of soybean (RAC), meal, hulls and grain dust were analyzed by method P-2811M which measures both sulfentrazone and 3-hydroxymethyl sulfentrazone. This method was modified in order to analyze the oil and soapstock fractions. A hexane partitioning step was substituted for the initial acid reflux step. The LOQ for each analyte was 0.025 ppm. The LOD was

0.005 ppm. The method was validated in each commodity at 0.025 ppm. The average recovery for sulfentrazone was 89 ± 14% (n=30); and for 3-hydroxymethyl sulfentrazone, was 81 ± 14 (n=29).

Results: No residues of sulfentrazone or 3-hydroxymethyl sulfentrazone in excess of the LOQ (0.025 ppm) were observed in soybeans or any processed fraction (Table 1). Detectable residues (>0.005 ppm) of sulfentrazone and 3-hydroxymethyl sulfentrazone were observed in soybeans (maximum of 0.008 ppm, total of sulfentrazone and 3-hydroxymethyl sulfentrazone), hulls (0.020 ppm) and meal (0.011 ppm). Quantifiable residues of sulfentrazone and 3-hydroxymethyl sulfentrazone were observed in grain dust (>2450 μm, 0.144 ppm) and grain dust (<425 μm, 0.079 ppm).

Table 1- Residues of sulfentrazone and 3-hydroxymethyl sulfentrazone in soybeans and processed fractions

Matrix	Maximum Residue (ppm)			Concentration Factor
	Sulfentrazone	3-HM Sulfentrazone	Total	
Soybeans	ND	0.008	0.008	-
Hulls	0.005	0.015	0.020	2.5
Meal	ND	0.011	0.011	1.4
Crude Oil	ND	ND	ND	-
Refined Oil	ND	ND	ND	-
Soapstock	ND	ND	ND	-
Dust (>2450 μM)	0.016	0.128	0.144	18.0
Dust (<425 μM)	0.069	0.010	0.079	9.9

3-HM = 3-hydroxymethyl
ND = Not Detected (<0.005 ppm)

Storage Stability: The RAC samples were stored for a maximum of 5 months; and the processed fractions, 24 days. Sulfentrazone *per se* has been shown to be stable in soybeans for 6 months of storage (Memo, G. Kramer 4/25/94). The registrant reports that a storage stability study for 3-hydroxymethyl sulfentrazone is in progress.

CBTS' Conclusion: Residues of sulfentrazone and 3-hydroxymethyl sulfentrazone appear to concentrate in hulls and meal. However, as the residue levels are below the LOQ of the proposed analytical enforcement method, CBTS will not require Food/Feed Additive

Tolerances for this petition. All residues in the soybeans from the field residue trials were also less than the LOQ.

The residues in grain dust appear to exceeded the proposed tolerance for soybeans. This result is quite unexpected as sulfentrazone is applied preemergence. However, the >2540 μm fraction does not meet the Agecny's definition of grain dust (Aspirated Grain Fractions (Grain Dust): A Tolerance Perspective, 6/7/94) as it exceeds 2500 μm in size and is described by the registrant as "plant debris." Also, the <425 μm fraction appears to be comprised primarily of soil particles as the residue is comprised mainly of sulfentrazone *per se* rather than the plant metabolite, 3-hydroxymethyl sulfentrazone. This material thus appears to be field trash. CBTS thus concludes that tolerances for aspirated grain fractions will not be required.

This processing study may be adequate for the permanent tolerance petition provided that storage stability of 3-hydroxymethyl sulfentrazone is demonstrated. If, however, metabolites other than 3-hydroxymethyl sulfentrazone are determined to be of regulatory significance, then residue data for soybean processed fractions will be required for all such metabolites.

Other Considerations

The registrant has proposed to change the sulfentrazone formulation employed for the EUP program. Previously, sulfentrazone was formulated as F6285 4F Herbicide, containing 39.6% a.i. by weight and 4 lbs. a.i./gal. The registrant is now proposing to use F6285 75DF Herbicide, a dry-flowable formulation containing 75% a.i. by weight. The directions for use of the 75DF formulation are the same as for the 4F formulation except that the maximum use rate is 0.375 lbs. ai/A instead of 0.50 lbs. ai/A. CBTS has no objection to this change in formulation. For the permanent tolerance petition, residue data using each formulation will be required if registration of both is desired. Also, field residue data representing both preplant incorporated and preemergence applications will be required as specified in "EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances, 6/2/94".

cc: PP#3G4272, Kramer, circ., R.F.
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