PP 8F3671/9F5576
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 19 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3671/#9H5576: Alachlor In/On Sorghum Forage. Amendment of 2/10/89. (PP#9H5576 and MRID #40511201) (DEB #5251 and #5252).

FROM: W. T. Chin, Chemist, Ph.D.
Tolerance Petition Section III
Dietary Exposure Branch
Health Effect Division (H7509C)

W. T. Chin

THRU: Philip V. Errico, Section Head
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Health Effect Division (H7509C)

Philip V. Errico

TO: Robert Taylor PM #25
Registration Division (H7505C)

and

Toxicology Branch
Health Effect Division (H7509C)

BACKGROUND

The data deficiencies specified in the Alachlor Registration Standard (11/20/84) have been previously answered by the petitioner, Monsanto Co., and reviewed by DEB (see Susan V. Hummel's 11/3/87 memo). DEB also reviewed the successive responses to the deficiencies "2c" and "8b" specified in S. V. Hummel's 11/3/87 memo pertaining to sorghum commodities (see W. T. Chin's 12/1/88 memo). The current submissions, PP#9H5576 and MRID #40511201, are responses to the data deficiencies identified as Conclusions "3a", 4 and 5 of W. T. Chin's 12/1/88 memo. The subject deficiences and responses are restated below, followed by DEB's comments/conclusions.

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED

The petitioner is requested to submit a revised Section F proposing the following tolerances:

A permanent tolerance:	Sorghum, forage	2.0 ppm
A feed additive tolerance:	Sorghum milling fractions	0.5 ppm
A food additive tolerance:	Sorghum milling fractions	0.5 ppm

RECOMMENDATION

The petitioner is requested to submit a revised Section F proposing a permanent tolerance on sorghum, forage at 2.0 ppm, a feed and a food additive tolerances on sorghum milling fractions both at 0.5 ppm. After these tolerances are established, all the data deficiencies pertaining to sorghum commodities specified in the Deficiencies "2c" and "8b" of S. V. Hummel's 11/3/87 memo and Conclusions "3a", 4 and 5 of W. T. Chins's 12/1/89 memo will be resolved

DETAILED CONSIDERATIONS

The Deficiency Identified as Conclusion "3a" of W. T. Chin's 12/1/89 Memo

"The requested tolerance in/on sorghum forage at 2 ppm is supported by the residue data, provided Section B is revised to allow only preemergence ground applications (see Conclusion 4 below)."

The Deficiency Identified as Conclusion 4 of W. T. Chin's 12/1/89 Memo

"The petitioner is requested to revise Section B by adding a PHI (the residue data support a PHI of 70 days) for sorghum forage, adding the restriction: "Do not apply more than once per season," and deleting the postemergence and aerial applications. Alternatively, residue data representing postemergent and aerial uses can be submitted for our review."

The Petitioner's Responses

1. The petitioner has revised Section B adding the following restriction: "Do not graze/harvest grain sorghum (milo) forage for 70 days following application...."

2. The petitioner requests to waive the restriction "Allow only preemergence ground applications" based on the reason that ".... this product is applied to the soil surface prior to planting the crop, the method of delivery of the product to the soil surface has no impact on the subsequent residue in the crop."

3. The petitioner requests to modify the restriction "Do not apply more than once per season" to "Do not apply more than 4 quarts of this product per acre per growing season as an early preplant surface and/or preplant incorporated or preemergence surface treatment." The petitioner argues that the split applications made pre-plant and pre-emergence will reduce the potential crop residues because the PHI for the preplant applications has actually increased to 70 days.

DEB's Comment/Conclusion

DEB considers that the petitioner's explanation for including aerial application on the label and other modifications are reasonable and acceptable. Therefore, DEB concludes that deficiencies identified in Conclusions "3a" and 4 of W. T. Chin's 12/1/88 memo have been resolved.

The Deficiency Identified as Conclusion 5 of W. T. Chin's 12/1/89 Memo

"An exemption from the requirement of a tolerance is needed for the encapsulating polymer used in the Lasso® Micro-Tech® formulation and proposed for use on sorghum."

The petitioner's Response

The petitioner submitted PP#9F3738 requesting to add corn and grain sorghum (milo) to the list of crops under the current exemption, 40 CFR 180.1082.

DEB's Comment/Conclusion

DEB has concurred with the exemption request in connection with PP#9F3738. Therefore, deficiency 5 has been resolved (see W. T. Chin's 6/12/89 memo of PP#9F3738).

OTHER CONSIDERATIONS

I. The NOTE TO PM identified in W. T. Chin's 12/1/88 memo reads: According to the data and discussion shown on pp. 44-48 in S. V. Hummel's 11/3/87 memo, the petitioner should be notified of the following requests:

1. The established 0.1 ppm tolerance for residues of alachlor and its metabolites in sorghum grain should be raised to 1.0 ppm.

2. A 5 ppm feed additive tolerance is needed for sorghum milling fractions.

3. A 5 ppm food additive tolerance is needed for sorghum, germ.

4. A 3 ppm food additive tolerance is needed for sorghum milling fractions (except germ).

The Petitioner's Response to the Above Notice

On page 31 of the current submission PP#9H5576(R.D. No. 913, 2/10/89), the following NOTES TO REVIEWER reads: "The request by the Agency to increase the tolerances in sorghum grain cannot be supported by the residue data submitted to the Agency (R. D. No. 682, Acc. No. 263002 and R. D. No.785, MRID No. 40271801). The highest residue level found in sorghum at 4 lb/A was 0.053 ppm, not 0.53 ppm as has been indicated by the Agency. Therefore, a tolerance of 0.1 ppm is adequate and does not need to be increased. Consequently, the food and feed additive tolerance requests will reflect this difference as well, i.e. 10 fold."

DEB's Comment/Conclusion

1. DEB has re-examined the original residue data presented in Table 1, p.12 of MRID #40271801 and found that the maximum residue data determined in sorghum grain

listed in Table 2, p. 46 of S. V. Hummel's 11/3/87 memo should be "0.053, 0.036 and 0.049" instead of "0.54, 0.36 and 0.49", respectively. Therefore, DEB concludes that the established 0.1 ppm tolerance on sorghum grain is adequate.

2. Based on concentration of up to 4.2X for sorghum germ and the established 0.1 ppm tolerance on sorghum grain, DEB concludes that it would be more appropriate to propose both food and feed additive tolerances on sorghum milling fractions at 0.5 ppm. Therefore, the petitioner is requested to submit a revised Section F proposing food and feed additive tolerances on sorghum milling fractions at 0.5 ppm.

II. Additional Information Regarding Alachlor Residues in Sorghum Commodities

The petitioner submitted the following supporting documents. Since these documents were not considered responses to deficiencies, they are kept in file as reference.

MRID #40511201: Alachlor Residue From Two Metabolite Classes in Milo Forage, Milo Stover, and Milo Grain which contains three Appendixes as follows:

Appendix A: Complete Sample Histories For Alachlor in Milo (Protocol 80-02-4) containing six Tables illustrating detailed histories of the milo samples analyzed.

Appendix B: Storage Conditions for Alachlor in Milo Samples indicating that all samples were stored between -10°F and -30°F from time of receipt until analyzed.

Appendix C: Sample Chromatograms for DEA and MEEA Producing Metabolites of Alachlor in Milo showing examples of chromatograms generated from residue analysis.

cc: Circu., R.F., PP#8F3671/#9F5576, PP#0F2348, PP#9F3738, W.T.Chin, R.D.Schmitt, PMSD-ISB and Alachlor Reg. Std.

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