

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

DEC 1 1988

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3671: Alachlor (Lasso®) In Or On Sorghum Forage. Evaluation of Analytical Methods and Residue Data. (No Acc. and MRID numbers, Record #229364; DEB #4299)

FROM: W. T. Chin, Ph. D., Chemist
Tolerance Petition Section III
Dietary Exposure Branch
Health Effects Division (TS-769)

W. T. Chin

THRU: Charles L. Trichilo, Ph. D., Chief
Dietary Exposure Branch
Health Effects Division (TS-769)

TO: Robert J. Taylor, PM #25
Herbicide-Fungicide Branch
Registration Division (TS-767)

and

Toxicology Branch
Health Effects Division (TS-769)

Dr. R. P. Schneider of Monsanto Company submitted a cover letter dated 7/25/88 and a document (Record #229364) entitled "Administrative Materials in Support of Registration of the Lasso® Micro-Tech® Herbicide on Grain Sorghum (Milo), R.D.#841, 1/4/88" to Robert J. Taylor of EPA requesting an increased tolerance for the combined residues of alachlor, 2-chloro-2',6'-diethyl-N-(methoxymethyl) acetanilide, and its metabolites containing the 2,6-diethylaniline (DEA) and 2-(hydroxyethyl)-6-ethylaniline (HEEA) moieties in or on the raw agricultural commodity sorghum forage at 2 ppm.

Various tolerances of alachlor ranging from 0.02 to 3 ppm have been established under 40 CFR 180.249, including sorghum forage at 1.0 ppm and sorghum grain at 0.1 ppm in connection with PP#0F2338. The Alachlor Registration Standard was issued on 11/20/84. Alachlor was placed into special review in Dec., 1984. The Alachlor PD2/3 was issued in Sept., 1986 and Alachlor PD4 is in preparation.

In response to data deficiencies specified in the Alachlor Registration Standard, the petitioner has continuously submitted documents to the Agency for review. The petitioner's current request to establish an increased tolerance for alachlor and its metabolites in or on sorghum forage at 2 ppm is a response to the deficiencies "2c" (p.29) and "8a" (p.44-47) specified in Susan V. Hummel's 11/3/87 memo.

CONCLUSIONS

- 1a. The metabolism of alachlor in plants has been adequately delineated for the proposed use. The residues of concern are alachlor and its metabolites containing the 2,6-diethylaniline (DEA) and 2,6-dihydroxyethylethylaniline (HEEA) moieties.
- 1b. The nature of residue of alachlor in animals has not been completely understood, but will be addressed in connection with the Alachlor Registration Standard.
2. Adequate analytical methods are available in PAM II for enforcing the proposed tolerance.
- 3a. 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).
- 3b. The 0.02 ppm tolerance established under 40 CFR 180.249 for animal commodities is adequate to cover this increased tolerance request.
4. 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.
5. 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.
6. There are no Codex or foreign tolerances established for alachlor in or on the agricultural commodity sorghum forage. Therefore, no compatibility questions exist with this commodity.

RECOMMENDATIONS

At this time, DEB recommends against the petitioner's request to establish an increased tolerance for the combined residues of alachlor and its metabolites containing the DEA and HEEA moieties in or on the raw agricultural commodity sorghum forage at 2 ppm because of the deficiencies specified in Conclusions 3a, 4 and 5.

NOTE TO PM

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).

DETAILED CONSIDERATIONS

Manufacturing Process

The manufacturing process of alachlor was reviewed in detail in connection with PP#9F0776 and PP#3F1406. Impurities in alachlor technical [redacted] are not expected to cause residue problems. No formation of nitrosamines during the manufacturing process is expected.

Formulations

The proposed formulations are Lasso® (EPA Reg. #524-314), Lasso® II (EPA Reg. No. 524-296) (both are emulsifiable concentrates) and the newly registered Lasso® Micro-Tech® Herbicide (EPA Reg. #524-344) which is a micro-encapsulated formulation containing 43% active ingredient (4 lb a.i./ gal). These formulations are also proposed to be used with tank mixtures of Atrazine® or Propazine®.

INFORMATION WHICH MAY REVEAL A QUALITY CONTROL PROCEDURE IS NOT INCLUDED

Two Confidential Statements of Formula of Lasso® Micro-Tech® Herbicide dated 1/12/86 and 3/14/86 are submitted on EPA Form 8570-4 (Rev. 10-81). Through a telephone call on 10/20/88, the petitioner was asked to submit an updated Confidential Statement Formula for Lasso® Micro-Tech® Herbicide using EPA Form 8570-4 (Rev. 2-85). This up-dated CSF was received on 10/25/88.

In connection with PP#2F2681, an exemption from the requirement of a tolerance for the encapsulating polymer was granted when used on drybeans, lima beans, peas, potatoes and soybeans before edible portions of the crops form (see M. F. Kovacs's 12/5/85 memo). However, sorghum was not included in the above list. Therefore, an exemption is needed for the encapsulating polymer for use on sorghum.

Registered Use

The EC formulations mentioned above are recommended for use on sorghum in water or sprayable fluid fertilizer solution for control of various weeds listed in the "Weeds Controlled" section of the submitted label. Applications can be conducted by preplant incorporation and preemergence surface. The approved application systems include center pivot irrigation and ground application only. The maximum registered rate is 4 lbs a.i./A. More detailed rates are given on the label depending on soil textures. Precautions and restrictions specified in the special review of Alachlor PD2/3 issued in Sept. 1986 have been added to the proposed label.

According to the data deficiency "1b" specified in Susan V. Hummel's 11/3/87 memo, the petitioner is requested to add the following restriction to the label: "Do not apply more than once per season." In addition, a PHI should also be added to the label. The residue data submitted support a 70-day PHI.

The Micro-Tech® product currently is not registered for use on sorghum.

Proposed Use

Monsanto proposes to add use directions for sorghum to the Lasso® Micro-Tech® Herbicide label. In addition to the use directions above, Monsanto proposes an early postemergence application (before the sorghum is 5" high) and aerial application and dry bulk fertilizer impregnation.

Nature of the Residue

The nature of the residue of alachlor in plants is adequately understood. The residues of concern are alachlor and its metabolites containing the DEA and HEAA moieties. The nature of the residue in animals is not adequately understood, but will be addressed in connection with the Alachlor Registration Standard (see S. V. Hummel's 11/3/87 memo).

Analytical Methodology

A successful MTO has been conducted for the methodology entitled "Analytical Method for the Determination of 2,6-Diethylaniline (DEA) and 2-(1-Methoxyethyl)-6-ethylaniline (MEEA) Yielding Alachlor Metabolites in Peanut Hay, Vines, Hulls and Nutmeats" (Acc. #263022) (see S. V. Hummel's 4/1/88 memo). This method is considered adequate for enforcement purposes and has been recommended to be included in PAM II as Method III.

For generating residue data of sorghum commodities submitted in MRID #402718-1 and #402718-2, a method entitled "Analytical Method for the Determination of 2,6-Diethylaniline (DEA) and 2-(1-Methoxyethyl)-6-ethylaniline (MEEA) Yielding Alachlor Metabolites in Milo Forage, Milo Stover and Milo Grain (Acc. #262999) was used. This method was reviewed by S. V. Hummel and considered essentially the same as the above enforcement method. DEB, therefore, concludes that this method is adequate for residue analysis.

Storage Stability

In response to the deficiency "8a" specified in Susan V. Hummel's 11/3/87 memo, the petitioner indicates: "In lieu of storage stability data for six years and validation data for the previously submitted residue data, Monsanto has submitted new residue data for sorghum which includes validation data." DEB has concluded that this deficiency has been resolved (see S. V. Hummel's 11/3/87 memo).

Residue Data

The residue data of sorghum commodities generated in the 1980 field trials were submitted in Acc. #263002 and reviewed (see S. V. Hummel's 1/30/87 memo). These trials included preemergence treatments with Lasso® and Lasso® Micro-Tech® Herbicide at 3 and 6 lbs a.i./A in six states (KS, NE, OK, CA, TX and IL). Samples of sorghum grain, forage and fodder were analyzed. Results of maximum residues of alachlor and its DEA and HEEA metabolites expressed as alachlor equivalents are reported in S. V. Hummel's 1/30/87 memo and cited in Table 1 below:

Table 1. Maximum Residues of Alachlor in Sorghum Commodities (1980)
(one application)

rac sample	Formulation	Alachlor Equivalent (ppm)	
		Dose: 3 lb	6 lb a.i./A
Sorghum Grain	Lasso®	0.02	0.06
	Lasso® Micro-Tech®	0.03	0.04
Sorghum Forage	Lasso®	1.10	1.90
	Lasso® Micro-Tech®	0.90	1.40
Sorghum Fodder	Lasso®	0.47	1.00
	Lasso® Micro-Tech®	0.21	0.61

DEB has commented: "... The 1 ppm tolerance in/on sorghum forage needs to be raised. A tolerance of 2 ppm may be appropriate if the label is amended to prohibit sequential treatments." (see page 25 of S. V. Hummel's 1/30/87 memo).

Between 1985 and 1986, new field trials for sorghum were conducted in seven representative states (NE, KS, OK, TX, MO, AR and LA). Three formulations, Lasso® (EC), Lasso® Micro-Tech® (MT) and Lasso® II (II), were used for treatments preemergently at 4 to 6 lbs a.i./A. Samples of sorghum grain, forage and fodder were analyzed in duplicate. Residue data were submitted in MRID #402718-1 and #402718-2 and were also reviewed by S. V. Hummel. In these reports, adequate examples of calculation and chromatograms were provided. Results of alachlor and its DEA and HEEA metabolites reported in S. V. Hummel's 11/3/87 memo are cited in Table 2.

Table 2. Maximum Residues of Alachlor In Sorghum Commodities (1985)

(One application, Maximum Dosage: 4 lb a.i./A)

rac sample	Formulation	Alachlor Equivalent (ppm)
Sorghum Grain	Lasso®	0.53
	Lasso® Micro-Tech®	0.36
	Lasso® II	0.49
Sorghum Forage	Lasso®	0.66
	Lasso® Micro-Tech®	0.55
	Lasso® II	0.44
Sorghum Fodder	Lasso®	0.60
	Lasso® Micro-Tech®	0.79
	Lasso® II	0.80

DEB's comment on the petitioner's response to deficiency "8a" specified in S. V. Hummel's 11/3/87 memo indicated: "... A 1 ppm tolerance is needed to cover residues of alachlor and its metabolites in sorghum grain and fodder and 2 ppm in sorghum forage" (see page 47 of S. V. Hummel's 11/3/87 memo). This conclusion was based on the registration of ground applications of the EC formulation for preemergence and preplant incorporated use only.

Based on the above comments, the petitioner is currently requesting an increased tolerance for the combined residues of alachlor and its metabolites in or on the

raw agricultural commodity sorghum forage by raising the established 1 ppm tolerance to 2 ppm. DEB concludes that the residue data shown in Tables 1 and 2 do not support the petitioner's request. The petitioner's request would be supported if only preemergence ground applications were proposed for the Micro-Tech® formulation. Residue data for the early post-emergence use and for aerial applications will be needed before we can conclude that the proposed tolerance will be adequate.

In addition, since sorghum milling fractions are used for both feed and food additives, according to the residue data shown in Table 3 and on page 48 of S. V. Hummel's 11/3/ 87 memo, the following tolerances would be needed: (1) a 5 ppm feed additive tolerance for sorghum milling fraction; (2) a 5 ppm food additive tolerance for sorghum, germ and (3) a 3 ppm food additive tolerance for sorghum milling fractions (except germ).

Meat, Milk, Poultry and Eggs

In connection with PP#9F0740, a tolerance of alachlor for animal commodities has been established at 0.02 ppm under 40 CFR 180.249. Feeding studies supporting this tolerance were conducted with diets containing 2 ppm metabolites of alachlor. Residue analysis indicated that less than 0.02 ppm residues were determined in all treated animal tissues, milk and eggs.

Sorghum forage is not considered a feeding item for poultry. However, it is an important feeding item for other livestock. The exposure analysis shown in Table 3 is based on the assumption that a tolerance for alachlor residues in/on sorghum forage is increased to 2 ppm.

Table 3. An Exposure Analysis for Livestocks With Sorghum Forage

Feeding Item	Tolerance (ppm)	% of livestock diet		Exposure to livestock diet	
		Beef	Dairy	Beef	Dairy
Sorghum forage	2.0*	25	25	0.50	0.50 ppm
Peanut hay	3.0**	10	20	0.30	0.60 ppm
Corn grain	0.2**	65	50	0.13	0.10 ppm
Sum		100	100	0.93	1.20

* The increased alachlor tolerance for sorghum forage.

** The established tolerances for alachlor under 40 CFR 180.249.

Data shown in Table 3 indicate that even under a maximum exposure, the alachlor residues in the feeding diets are less than 2 ppm by which the 0.02 ppm tolerance of alachlor have been established in animal tissues, milk and eggs under 40 CFR 189.249. Therefore, DEB concludes that the petitioner's request to establish an increased tolerance for the combined residues of alachlor and its metabolites in or on the raw agricultural commodity sorghum forage at 2 ppm is adequate and that the established 0.02 ppm tolerance in meat and milk is adequate to cover this increased tolerance request.

Other Considerations

An International Tolerance Sheet is attached. There are no Codex or foreign tolerances established for alachlor in or on the agricultural commodity sorghum forage. Therefore, no compatibility questions exist with this commodity.

Attachment: Codex sheet.

cc: R.F., Circu., W.T.Chin, PP#8F3671 and PMSD-ISB, S.F.

RDI: P.V.Errico(11/30/88), R.A.Loranger(11/30/88)
TS-769: RCB: CM#2, RM812,557-4352, W.T.Chin,wc(12/1/88)

INTERNATIONAL RESIDUE LIMIT STATUS

J. Lewis
12/17/85

CHEMICAL Alachlor

CODEX NO. _____

CODEX STATUS:

No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

PROPOSED U.S. TOLERANCES:

Petition No. 8F3671

RCB Reviewer W. T. Chin

Residue: Alachlor + its metabolites DEA + MEEA

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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<u>Sorghum, forage</u>	<u>2.0</u>
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CANADIAN LIMITS:

No Canadian limit

Residue: _____

MEXICAN LIMITS:

No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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NOTES:

* DEA: 2,6-diethylaniline
MEEA: 2-(1-methoxyethyl)-6-ethylaniline