



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

(9-1-94)

~~9/1/94~~

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 3F04251. Metolachlor in or on grasses grown for seed.
Evaluation of residue data and analytical methods.
MRID#s 428857-01 to -07. Barcode D194844. CBTS# 12494.

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

THRU: R.A. Loranger, Acting Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

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

104801
Ciba Geigy has submitted a proposal for the following tolerances for metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide] in/on grasses grown for seed:

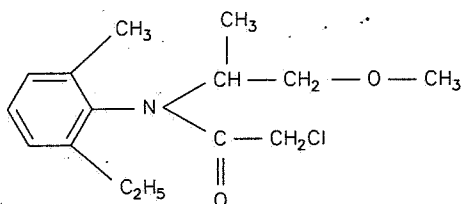
Grass Seed Screenings -- 0.1 ppm

Grass Straw -- 0.2 ppm

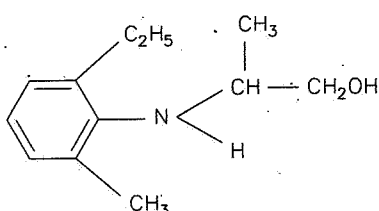
Grass Forage -- 30 ppm

Metolachlor is a List A chemical. The metolachlor RED was completed on 6/28/93. Tolerances for residues of metolachlor in or on numerous RACs (raw agricultural commodities) are currently expressed in terms of the combined residues (free and bound) of metolachlor and its metabolites, determined as the derivatives, CGA-37913 (2-[(2-ethyl-6-methylphenyl)amino]-1-propanol) and CGA-49751 (4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone), each expressed as metolachlor [40 CFR §180.368(a), (b), and (c)]. The structure of metolachlor and its hydrolysates measured by the enforcement method are shown in Figure 1. Metolachlor is the active ingredient in Dual 8E Herbicide, Dual Herbicide, Medal Herbicide and Dual II Herbicide. Applications to amend the uses of these products to allow use on grasses grown for seed were submitted simultaneously with this petition.

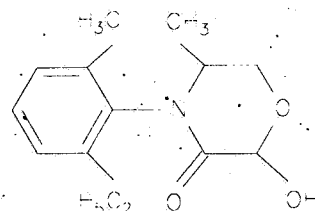
Figure 1: Structure of Metolachlor and its derivatives



Metolachlor



CGA-37913



CGA-49751

CONCLUSIONS

1. Data gaps in the product chemistry of metolachlor (GLN § 62-3) are being addressed through reregistration. For the purposes of this petition, the product chemistry is considered to be adequate.
2. Metolachlor may be applied once per season with a maximum application rate of 2.0 lbs. ai/A. The proposed use is adequate for this petition with the following exception: the label specifies not to graze for 60 days in areas west of the Cascades, but in areas east of the cascades, not to graze until regrowth occurs in the spring. The registrant should revise this grazing restriction to provide a discrete postapplication interval (i.e., 4/5 months) for areas east of the Cascades. Also, a PHI for hay cutting should be provided. **A revised Section B is required.**
3. The qualitative nature of the residue in plants and animals is considered to be adequately understood. The residues of concern are metolachlor and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound.
4. Adequate methodology exists to enforce the proposed tolerances.

In the analytical enforcement method (AG-338), metolachlor and its free and bound metabolites are converted to CGA-37913 and CGA-49751. The LOQ for CGA-37913 is 0.03 ppm; and, for CGA-49751 is 0.05 ppm.

5. Residues of CGA-37913 and CGA-49751 have been shown to be stable in corn forage, corn grain, peanut nutmeat and potato tubers for up to 2 years. Grass samples in the magnitude of the residue studies were stored for a maximum of 15 months prior to analysis. CBTS is willing to translate this data to grass RACs and conclude that the available storage stability data is adequate for this petition.

6a. Six field trials were conducted in three different states, which together accounted for 37.4% of the U.S. seed grass acreage in 1987. The maximum residues observed were 27 ppm in forage (60 day PHI), 0.11 ppm in straw and 0.04 in seed screenings.

6b. This petition is for a group tolerance; i.e., the grass forage, fodder and hay group. The product label restricts use to seed crops. The label also restricts use to the Pacific Northwest. CBTS concludes that the submitted residue data are deficient in that: i) The three representative commodities of the grass forage, fodder and hay group (Bermuda grass, bluegrass and brome grass or fescue) were not represented; ii) Inadequate geographic representation of residue data have been submitted for grass grown for seed. According to criteria set forth in the Federal Register Notice (Vol. 51 No. 63, 4/2/86) grass grown for seed is not qualified as a crop for which regional registration is possible; iii) The number of field trials is not sufficient; iv) The minimum spray volume specified on the label (10 gal/A) was not represented in any of the trials; and v) No data on grass hay was reported

6c. CBTS requests that the registrant perform at least six more field trials including three in MO (fescue), and one each in MN (bluegrass), SD (bluegrass) and CA (Bermuda grass). The addition of these trials to those already submitted will cover the representative commodities of the grass forage, fodder and hay group and increase the geographic representation to 73.8% of the U.S. seed grass acreage. Additionally at least three of these trials should employ a spray volume of 10 gal/A or the registrant should revise the label to specify a minimum spray volume of 13 gal/A and one trial should include residue decline data. If residue decline studies have been performed on similar crops, then this data can be translated to grass as specified in the *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, page 15. Field residue data on grass hay should also be submitted. As grass grown for seed would not normally be cut for hay between the time of metolachlor application (late summer through November 15) and seed

harvest, hay samples may be obtained from the regrowth after harvest. All field trials initiated in 1995 or later should conform to the new field trial guidance document (*EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, 6/2/94).

6d. The proposed tolerances in Section F are also not acceptable. Tolerances must be proposed for all grass RACs and be worded to reflect a group tolerance. The appropriate tolerances for this petition are thus: "Forage of the grass forage, fodder and hay group; Hay of the grass forage, fodder and hay group; and Seed Screenings of the grass forage, fodder and hay group." **A revised Section F is required.**

6e. CBTS notes that Bermuda grass is a very minor seed crop and that the Dual and Medal labels have no directions for use on Bermuda grass. If the registrant does not wish to perform a Bermuda grass trial, then a bluegrass or fescue trial in KS may be substituted. If the registrant chooses not to perform a Bermuda grass trial, then the proposed tolerances should be expressed as: "Seed Screenings of the grass forage, fodder and hay group (excluding Bermuda grass); Forage of..." Also, the Express label should be revised to specifically restrict use on Bermuda grass.

6f. CBTS would consider a tolerance request for metolachlor in/on grass RACs, accompanied by an application for regional registration (OR, WA and ID only) of Dual and Metal Herbicides, based on geographically limited field trial data, if one of the following criteria is met:

- (i) The Biological and Economic Analysis Division (BEAD) concludes that "...there is little likelihood of use of the pesticide outside the geographically limited area" (FR 51:63, 4/2/86), based on the known range of the problem or the lack of economic importance of the problem outside the geographically limited area;

OR,

- (ii) BEAD concludes that the geographically limited use will meet the economic criteria for tolerance fee waivers, also described in FR 51:63, 4/2/86 (see Anne Lindsay memo of 7/7/93 on Policy for Regional Registration).

6g. If BEAD determines that a regional registration is appropriate for this petition, then the field trial data requirements will be determined in accordance with Attachment 11 of *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, 6/2/94. The states of OR, WA and

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ID together account for 37.4% of the U.S. seed grass acreage and 12 field trials are required for a national registration. Thus, a total of five acceptable trials (12×0.37), including multiple year data and a residue decline study, would be required for regional registration. Since the submitted trials were not fully acceptable (no hay data, single year, no residue decline study), CBTS would require an additional five trials to be conducted in OR (3), WA (1) and ID (1). The representative crops of the grass forage, fodder and hay group should be represented as described above. Each trial should include data for forage (60 day), seed screenings and hay and a residue decline study should be performed in forage. If residue decline studies have been performed on similar crops, then this data can be translated to grass as specified in the *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, page 15. It should be noted that whereas five residue trials requested in this conclusion will be adequate for a tolerance to support a regional registration, only six trials at the locations listed in conclusion 6c would provide adequate information to recommend for a tolerance which would support a national registration.

7. The proposed tolerance on grass forage results in a potential dietary burden of 84 ppm in dairy cattle. Based on the residues observed in feeding studies, a dietary burden of 84 ppm could result in over-tolerance residues in liver and kidney and possibly also in milk, meat and fat. The registrant must therefore propose to raise meat and milk tolerances. **A revised Section F is required.**

8. There is no Codex proposal, nor Canadian or Mexican limits for residues of metolachlor in grass. Therefore, a compatibility issue is not relevant to the proposed tolerance. A copy of the IRLS is attached to the memorandum.

RECOMMENDATIONS

CBTS recommends against the proposed tolerance metolachlor on grasses grown for seed for reasons detailed in conclusions 2, 6b, 6c or 6g, 6d and 7.

DETAILED CONSIDERATIONS

Product Chemistry

No new studies were submitted with this petition.

Data gaps in the product chemistry of metolachlor (GLN § 62-3) are being addressed through reregistration. For the purposes of this petition, the product chemistry is considered to be adequate.

Metolachlor is formulated as the following emulsifiable concentrates containing 8 lbs. ai/gal: Dual 8E Herbicide, Dual Herbicide, Medal Herbicide and Dual II Herbicide.

Proposed Use

The proposed use is for grasses grown for seed in the Pacific Northwest. To control weeds and volunteer grasses in established grass grown for seed, apply metolachlor to established stands of tall fescue, orchardgrass, perennial ryegrass, fine fescue, bentgrass and Kentucky bluegrass just before, during, or immediately following the first fall rains or irrigation, but before target grasses emerge. Do not apply after November 15. The seed crop must have had at least one seed harvest or been established at least one year.

Apply by ground equipment in a minimum of 10 gal./A. The maximum use rate is 2 pt./A (2.0 lbs. ai/A). Metolachlor may be applied only once per season.

Do not graze for 60 days in areas west of the Cascades. In areas east of the cascades where growth of desirable grasses is dormant, do not graze until regrowth occurs in the spring. The registrant should revise this grazing restriction to provide a discrete postapplication interval (i.e., 4 or 5 months) for areas east of the Cascades. Also, a PHI for hay cutting should be provided. **A revised Section B is required.**

Nature of Residue- Plants

No new studies were submitted with this petition.

The qualitative nature of the residue in plants is considered to be adequately understood. The residues of concern are metolachlor and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound.

Nature of Residue- Animals

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No new studies were submitted with this petition.

The qualitative nature of the residue in animals is considered to be adequately understood. The residues of concern are metolachlor and its metabolites determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound.

Analytical Methodology- Plants

Adequate methodology exists to enforce the proposed tolerances. In the analytical enforcement method (AG-338), metolachlor and its free and bound metabolites are converted to CGA-37913 and CGA-49751 by refluxing with HCl. One aliquot of the hydrolysate is cleaned-up and analyzed for CGA-37913 using GC with N/P detection in the N mode. Another aliquot of the hydrolysate is cleaned-up and analyzed for CGA-49751 also using GC with N/P detection. The LOQ for CGA-37913 is 0.03 ppm; and, for CGA-49751 is 0.05 ppm.

Storage Stability Studies

No storage stability data were submitted with this petition.

Residues of CGA-37913 and CGA-49751 have been shown to be stable in corn forage, corn grain, peanut nutmeat and potato tubers for up to 2 years. Samples in the magnitude of the residue studies were stored for a maximum of 15 months prior to analysis. CBTS is willing to translate this data to grass RACs and conclude that the available storage stability data is adequate for this petition.

Magnitude of Residue- Plants

Submitted with this petition:

Metolachlor - Magnitude of residues in or on grasses grown for seed following application of Dual 8E. MRID# 428857-01

Six test sites were established in OR (3), WA (2) and ID (1), which together accounted for 37.4% of the U.S. seed grass acreage in 1987 (1987 Census of Agriculture, Volume 1, Part 51). Two varieties of ryegrass were utilized (OR), two varieties of fescue were used (OR, WA) and one variety each of brome grass (WA) and bluegrass (ID) were also used. Metolachlor, formulated as Dual 8E Herbicide, was applied in the fall prior to weed emergence at a rate of 1X (2.0 lbs. ai/A) except for the ryegrass trials which used 1.5 lbs. ai/A (0.75X) due to problems with phytotoxicity. The trials of tall

fescue in OR and bromegrass in WA also included plots that were treated at 4.0 lbs. ai/A (2X). Forage samples were harvested 60 and 75 days after metolachlor application and seed and straw samples were harvested 240-306 days after application. After collection, samples were shipped frozen to the analytical lab and stored at $<-15^{\circ}\text{C}$ until analysis. Samples were analyzed with a slightly modified version of method AG-338. The method was validated by spiking control grass RACs with either CGA-37913 or CGA-49751 over a range of LOQ-20 ppm. The average recoveries for CGA-37913 were $98 \pm 16\%$ ($n=36$); and, for CGA-49751 were $118 \pm 27\%$ ($n=36$). The results of the analysis of treated samples are shown in Table 1. The maximum residues observed were 27 ppm in forage (60 day PHI), 0.11 ppm in straw, <0.08 ppm in seed and 0.04 in seed screenings at the 1X rate. At the 2X rate, maximum residues observed were 1.7 ppm in forage (75 day PHI), 0.13 ppm in straw, <0.08 ppm in seed and 0.09 in seed screenings.

Table 1- Field residue data for metolachlor in grass RACs. The total metolachlor residue is the sum of the derivatives, CGA-37913 and CGA-49751, which are measured independently.

Location	Grass Type	Application Rate (lbs. ai/A)	Application Volume (gal/A)	PHI (Days)	RAC	Maximum Metolachlor Residue (ppm)
OR	Ryegrass	1.5	13.0	60	Forage	1.4
				75	Forage	1.5
				247	Seed	<0.08
				247	Straw	<0.08
				247	Screenings	<0.08
OR	Ryegrass	1.5	13.0	60	Forage	0.66
				75	Forage	1.0
				244	Seed	<0.08
				244	Straw	<0.08
				244	Screenings	0.04
OR	Fescue	2.0	13.0	60	Forage	0.58
				75	Forage	0.60
				240	Seed	<0.08
				240	Straw	0.11
				240	Screenings	<0.08
WA	Fescue	2.0	32.0	60	Forage	27.0
				75	Forage	8.4
				279	Seed	<0.08
				279	Straw	<0.08
				279	Screenings	<0.08
WA	Brome grass	2.0	33.0	206	Forage	0.04
				306	Seed	<0.08
				306	Straw	0.04
				306	Screenings	0.04
ID	Bluegrass	2.0	33.0	60	Forage	13.0
				75	Forage	3.5

				270	Seed	<0.08
				270	Straw	<0.08
				270	Screenings	<0.08

This petition is for a group tolerance; i.e., the grass forage, fodder and hay group. The product label restricts use to seed crops. The label also restricts use to the Pacific Northwest. CBTS concludes that the submitted residue data are deficient in that: 1) The three representative commodities of the grass forage, fodder and hay group (Bermuda grass, bluegrass and bromegrass or fescue) were not represented; 2) Inadequate geographic representation of residue data have been submitted for grass grown for seed. According to criteria set forth in the Federal Register Notice (Vol. 51 No. 63, 4/2/86) grass grown for seed is not qualified as a crop for which regional registration is possible; 3) The number of field trials is not sufficient; 4) The minimum spray volume specified on the label (10 gal/A) was not represented in any of the trials; and 5) No data on grass hay was reported

CBTS requests that the registrant perform at least six more field trials including three in MO (fescue), and one each in MN (bluegrass), SD (bluegrass) and CA (Bermuda grass). The addition of these trials to those already submitted will cover the representative commodities of the grass forage, fodder and hay group and increase the geographic representation to 73.8% of the U.S. seed grass acreage. Additionally at least three of these trials should employ a spray volume of 10 gal/A or the registrant should revise the label to specify a minimum spray volume of 13 gal/A and one trial should include residue decline data. If residue decline studies have been performed on similar crops, then this data can be translated to grass as specified in the *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, page 15. Field residue data on grass hay should also be submitted. As grass grown for seed would not normally be cut for hay between the time of metolachlor application and seed harvest, hay samples may be obtained from the regrowth after harvest. All field trials initiated in 1995 or later should conform to the new field trial guidance document (*EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, 6/2/94).

The proposed tolerances in Section F are also not acceptable. Tolerances must be proposed for all grass RACs and be worded to reflect a group tolerance. The appropriate tolerances for this petition are thus: "Forage of the grass forage, fodder and hay group; Hay of the grass forage, fodder and hay group; and Seed Screenings of the grass forage, fodder and hay group." A revised

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Section F is required.

CBTS notes that Bermuda grass is a very minor seed crop and that the Dual and Medal labels have no directions for use on Bermuda grass. If the registrant does not wish to perform a Bermuda grass trial, then a bluegrass or fescue trial in KS may be substituted. Replacement the CA trial with a MN trial would increase the geographic representation to 75.3%. If the registrant chooses not to perform a Bermuda grass trial, then the proposed tolerances should be expressed as: "Seed Screenings of the grass forage, fodder and hay group (excluding Bermuda grass); Forage of..." Also, the Express label should be revised to specifically restrict use on Bermuda grass.

CBTS would consider a tolerance request for metolachlor in/on grass RACs, accompanied by an application for regional registration (OR, WA and ID only) of Dual and Metal Herbicides, based on geographically limited field trial data, if one of the following criteria is met:

- (1) The Biological and Economic Analysis Division (BEAD) concludes that "...there is little likelihood of use of the pesticide outside the geographically limited area" (FR 51:63, 4/2/86), based on the known range of the problem or the lack of economic importance of the problem outside the geographically limited area;

OR,

- (2) BEAD concludes that the geographically limited use will meet the economic criteria for tolerance fee waivers, also described in FR 51:63, 4/2/86 (see Anne Lindsay memo of 7/7/93 on Policy for Regional Registration).

If BEAD determines that a regional registration is appropriate for this petition, then the field trial data requirements will be determined in accordance with Attachment 11 of *EPA Guidance on Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*, 6/2/94. The states of OR, WA and ID together account for 37.4% of the U.S. seed grass acreage and 12 field trials are required for a national registration. Thus, a total of five acceptable trials (12 X 0.37), including multiple year data and a residue decline study, would be required for regional registration. Since the submitted trials were not fully acceptable (no hay data, single year, no residue decline study), CBTS would require an additional five trials to be conducted in OR (3), WA (1) and ID (1). The representative crops of the grass forage, fodder and hay group should be represented as described above. Each trial should include data for forage (60 day), seed screenings and hay and a residue decline study should be performed.

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Magnitude of the Residue- Ruminants

No new studies were submitted with this petition.

The primary new dietary source of metolachlor associated with this petition is grass forage, which can compromise up to 70% of dairy cattle diets. The potential dietary burden is:

$$(70\% \text{ diet} / 25\% \text{ DM}) \times 30 \text{ ppm} = 84 \text{ ppm}$$

The maximum dietary burden utilized in cow feeding studies was 60 ppm. Extrapolating the metolachlor residue levels at this feeding level to 84 ppm demonstrates that the expected residues in liver and kidney would exceed the current tolerances (Table 2). Over tolerance residues in muscle, fat and milk are also possible.

Table 2- Anticipated metolachlor residues in dairy cattle RACs with resulting from a dietary burden of 84 ppm.

Tissue	Maximum Residue at 60 ppm	Anticipated Residue at 84 ppm	Current Tolerance (ppm)
Milk	<0.02	<0.03	0.02
Muscle	<0.04	<0.06	0.02
Fat	<0.04	<0.06	0.02
Liver	0.13	0.18	0.05
Kidney	0.42	0.59	0.2

The registrant argues that this situation is unlikely to occur since the 60 day postapplication grazing restriction applies only to areas west of the Cascades. In areas east of the Cascades, grazing is not permitted until the following spring (5-6 months). The field residue data show that the maximum forage residues in the three trials conducted west of the Cascades (OR trials) were 1.4 ppm. The registrant has provided calculations demonstrating that if 2 ppm is used instead of 30 ppm, the dietary burden from forage would not result in over-tolerance residues in meat and milk. However, CBTS must use the proposed tolerance to assess the potential dietary burden and residues in animal RACs. Otherwise, a situation, like the present case, could result in which legal residues in a feed item could result in illegal residues in meat and/or milk. The registrant must therefore propose to raise meat and milk tolerances. **A revised Section F is required.**

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Magnitude of the Residue- Poultry

There are no poultry feed items associated with grass.

cc: PP#3F04251, Kramer, circ., R.F., Metolachlor List A File
RDI: P.V. Errico (8/31/94), M.T. Flood (9/1/94)
G.F. Kramer:804T:CM#2:(703)305-5079:7509C