10-12-94

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

October 12, 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Metolachlor (108801) Addendum to RED, Reregistration Case No. 0001
Confined Rotational Crop Data (GLN 165-1)
[MRID No. 41470601; CB No. 14435; DPBarcode D207842]

FROM: Susan V. Hummel, Chemist
Special Review Section II
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THRU: Francis B. Suhre, Section Head
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TO: Jane Mitchell/W. Waldrop, PM#71
Reregistration Branch
Special Review and Reregistration Division (7508W)

SRRD has requested an updated review of the Metolachlor Confined Rotational Crop study (MRID 41470601; 1990) originally reviewed by EFGWB (J. Tompkins). When review of Rotational Crop data was transferred to HED, additional guidance for the registrants was issued by HED. Soil analysis and identification of soil metabolites is no longer required.

Metolachlor is on List A. A Registration Standard was completed 9/80, and the FRSTR 1/87 (Residue Chemistry Chapter 6/13/86). A Registration Standard Followup (Update) was completed 6/14/89. The Residue and Product Chemistry Chapters for the RED were completed 6/30/93, with an addendum for anticipated residues on 11/16/93 (S. Knizner, CB 12521, DP Barcode D194942), and addendum for Craven replacement data on field corn, cottonseed (1 application), and soybean (S. Hummel, CB 13482, D201438, 6/23/94, an addendum for legumes (D. Miller, CB 14160, D206103, 9/13/94), an addendum for partial replacement of Craven data on peanuts (S. Hummel, CB 12875, D204467, 9/29/94), and an addendum for replacement of Craven data on rotational alfalfa and clover (non-grass animal feeds) (S. Hummel, CB 14431, D207867, 10/04/94).

We have re-examined the original Confined Rotational Crop Study (MRID 41470601; 1990) and the EFGWB DER (J. Tompkins). Our conclusions follow.

Conclusions

1. The Confined Rotational Crop study is inadequate to satisfy GLN 165-1, but potentially upgradeable.

1a. Radioactive residues in crops were not adequately characterized. The quantitative data on water-soluble residues were not correlated to specific metolachlor metabolites (in Figures 10, 13, and 17), and a large percentage of the radioactivity applied to the TLC plates for lettuce and wheat was unaccounted for. Additionally, the radioactive residues appear as a smear on a one-dimensional TLC plate, whereas the soil metabolites appear as discrete spots on two-dimensional TLC plates. The quantitative data must be correlated to specific metolachlor plant metabolites or to classes of metolachlor metabolites, i.e., *metabolites convertable to the metolaclor derivatives* included in the tolerance expression, CGA-37913, CGA-49751; and the identity of those plant metabolites must be confirmed by a second analytical technique.

1b. Information on the percentage of the residue measured by the current enforcement method is required. This can be done by providing recovery data for the identified metabolites, or by radiovalidating the analytical method using samples from the confined rotational crop studies.

1c. Storage stability data were not provided and are required. The length and conditions of sample storage were not provided and are required.

2. Soil analyses are no longer required. Characterization of soil radioactivity is not required to satisfy GLN 165-1.

3. Radioactive residues were found at the only planting interval tested (115 days). If radioactivity reflects residues of toxicological concern, then, field rotational crop data are required, along with appropriate tolerance proposals. Alternatively, the metolachlor label could prohibit planting of any crop other than those specified on the label.

Recommendation

The registrant should be informed that soil analyses are no longer required to support Confined Rotational Crop studies. However, additional characterization and identification of residues in plants is required, as specified in conclusions 1, 1a, 1b, and 1c. The metolachlor label should prohibit planting of any crop not specified on the label, unless all appropriate rotational crop tolerances are established.

Attachment: EFGWB (J. Tompkins) Review (DER) of Confined Rotational Crop data
Selected pages from MRID 41470601

cc w/ attachment: addressee, R.F., circu, S.F., S. Hummel, Metolachlor RSF
RDI:FBS:10/07/94:MM:10/12/94:EZ:10/12/94
7509C:CBII:SVH:svh:RM:804:CM#2:10/12/94

DATA EVALUATION RECORD

CHEM 108801 Metolachlor §165-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 41470601
Thede, B. 1990. Uptake of ^{14}C-metolachlor in rotational crops grown in soil which has been previously used for growing potatoes. Laboratory/Study No. ABR-90037. Unpublished study performed and submitted by Ciba-Geigy Corporation, Greensboro, NC.

DIRECT REVIEW TIME = 8

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CONCLUSIONS:

Confined Accumulation - Rotational Crops

1. This study cannot be used to fulfill data requirements at this time.

2. These data are considered to be of uncertain value and should not be used to predict the environmental behavior of metolachlor.

3. This study is unacceptable at this time for the following reason:

   data from analysis of day 0 soil samples were not provided; therefore, the application rate could not be confirmed.

4. It can be concluded from the data submitted that metolachlor residues accumulated in lettuce, beets, and wheat planted 115 days after [^{14}C]-metolachlor was applied at approximately 3.0 lb ai/A to a loamy sand soil. At mature harvest, total [^{14}C]residues were 0.32 ppm in lettuce; 0.66 and 0.86 ppm in beet tops and roots; and 2.86, 0.14, and 1.17 ppm in wheat stalks, grain, and hulls, respectively. Metolachlor, CGA-13656, CGA-40172, CGA-41638, CGA-42444, CGA-37913, and CGA-118243 were detected in all crops.

5. The application rate must be confirmed with immediate posttreatment soil data in order to be reevaluated.

METHODOLOGY:

Ring-labeled [^{14}C]metolachlor (radiochemical purity 99.1%, specific activity 22.3 uCi/mg, Ciba-Geigy), dissolved in ethanol, was added to 30 kg of loamy sand soil (83.2% sand, 12.0% silt, 4.8% clay, 2.1% organic matter, pH 5.4, CEC 5.34 meq/100 g) at 21.6 mg ai/kg.

Untreated loamy sand soil was placed in thirty-eight 14-quart plastic (aluminum-lined) pails (amount of soil per pail not specified) and planted with potato quarters/sets. A portion (1 kg) of the treated soil was layered over the potatoes in thirty of the pails; the final calculated treatment rate was 3.0 lb ai/A. For controls, untreated soil was layered over the potatoes in the remaining eight pails. The potatoes were harvested at 110 days posttreatment, and the top 3 inches of the soil were tilled and sampled. Leaf lettuce, sugar beets, and winter wheat were planted in the pails at 115 days posttreatment (ten pails each for the treated soil; three pails each for wheat and beets, two pails for lettuce of the control soil). The crops were maintained in separate cubicles of a greenhouse at 60-84^{0} F, with a relative humidity of 23 to 100% and a 13- to 14-hour photoperiod. Crops were harvested when immature and at maturity [42 days postplanting for lettuce (157 days posttreatment), 168 days for beets (283 days posttreatment), and 182 days for wheat (297 days posttreatment)]. Soil samples (1- x 8-inch cores) were taken immediately posttreatment, at time of planting of the rotational crops (115 days posttreatment), and at 84 and 182 days postplanting (199 and 297 days posttreatment). Soil cores were separated into 0- to 3-, 3- to 6-, and 6- to 8-inch increments; crop and soil samples were stored frozen (temperature not specified) until analysis.

The plants were homogenized using a blender, and portions of each sample were analyzed for total radioactivity by LSC following combustion. Plant tissue containing [^{14}C]residues at >0.05 ppm was extracted with methanol:chloroform:water (ratio unspecified). Aliquots of the organic and aqueous phases were analyzed by one-dimensional TLC on silica gel plates using methylene chloride:methanol (192:8, v:v) or chloroform:methanol:formic acid:water (140:50:8:4, v:v:v:v) and by two-dimensional TLC using chloroform:methanol:formic acid:water in both directions or methylene chloride:methanol in the first dimension followed by n-butanol:glacial acetic acid:water (133:33:33, v:v:v) in the second dimension. Unlabeled reference standards were cochromatographed with the samples and detected using UV light (254 nm). Radioactive areas were detected with a Berta spark chamber and/or a radioanalytical imaging system and identified by comparison to the reference standards; [^{14}C]residues were quantified using the radioanalytical imaging system.

The soil was homogenized using a Wiley mill, and portions of each sample were analyzed for total radioactivity by LSC following combustion. Samples containing [^{14}C]residues at >0.05 ppm were extracted with methanol:water (90:10, v:v), then the extract was partitioned with chloroform. The organic phase analyzed by two-dimensional TLC using hexane:toluene:methanol:ethyl acetate (136:25:25:14, v:v:v:v) in the first dimension and methylene chloride:methanol (192:8, v:v) in the second dimension. Unlabeled reference standards were cochromatographed with the samples and detected using UV light. Radioactive areas were detected by autoradiography and identified by comparison to reference standards; radioactivity was quantified by scraping the gel from the plates and analyzing for total radioactivity by LSC.

DATA SUMMARY:

[^{14}C]Metolachlor residues accumulated in lettuce, beets, and wheat planted 115 days after ring-labeled [^{14}C]metolachlor (radiochemical purity 99.1%) was applied at approximately 3.0 lb ai/A to loamy sand soil subsequently planted to potatoes. At mature harvest, total [^{14}C]residues were 0.32 ppm in lettuce; 0.66 and 0.86 ppm in beet tops and roots; and 2.86, 0.14, and 1.17 ppm in wheat stalks, grain, and hulls, respectively (Table II). In immature and mature crops, organosoluble residues ranged from 4.09 to 19.66% of the recovered radioactivity, water-soluble residues ranged from 55.44 to 92.74%, and unextractable residues ranged from 1.82 to 28.52% (Tables III-V).

Metolachlor

accounted for a major portion of the organosoluble radioactivity in immature and mature lettuce, but was only detected in trace amounts in beets and wheat (Figures 6-9; no quantitative data provided). Organosoluble degradates that were recovered from the crops included

CGA-13656,

CGA-40172,

CGA-41638,

CGA-42444, and

CGA-37913.

In addition, in the water-soluble fraction, CGA-37913 comprised 19.8-20.9% of the total radioactivity in immature and mature lettuce, 4.6-10.3% in mature wheat, and only trace quantities in mature beets (Figures 10, 13, and 17).

CGA-118243

was also detected in all crops and comprised 16.1-25.0% of the total radioactivity in lettuce, but was only detected in trace amounts in beets and wheat. In lettuce, up to 9 unknowns (1.4-8.5% of the total radioactivity) were detected, while up to 15 unknowns were detected in the beets (0.9-22.4%) and wheat (0.7-47.6%).

In the 0- to 3-inch soil depth, total [^{14}C]residues were 2.89 ppm at 115 days posttreatment, 1.92 ppm at 199 days, and 2.54 ppm at 297 days (Table I). Between 115 and 297 days posttreatment, [^{14}C]residues ranged from 0.76 to 1.51 ppm in the 3- to 6-inch depth and from 0.39 to 0.55 ppm in the 6- to 8-inch depth. In the 0- to 3-inch soil depth, metolachlor decreased from 37.7 to 14.3% of the total radioactivity between 115 and 297 days posttreatment. At all depths, the degradates CGA-42444, CGA-37913, CGA-41638, CGA-13656, and CGA-37735 comprised <2.0% of the total radioactivity, and up to eight unknowns (0.1-94.3%) were detected.

COMMENTS:

1. Data from analysis of the day 0 soil samples were not provided; therefore, the application rate could not be confirmed.

2. [^{14}C]Residues in the crops were not adequately characterized. Organo-

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soluble residues were not quantified. For the water-soluble residues, unknowns comprised a significant portion of the total radioactivity; however, these data were difficult to quantitate because the results were poorly presented (see Figures 10, 13, and 17). In addition, following TLC of the water-soluble fractions from lettuce and wheat samples, up to 29.5 and 47.6% of the radioactivity applied to the plates, respectively, was unaccounted for. There was quantitative recovery of radioactivity from the TLC plates with the beet samples.

3. [^{14}C]Residues in the soil were not adequately characterized. Unknowns comprised up to 98.2% of the total radioactivity following TLC of soil extracts.

4. Freezer storage stability data were not provided for the plant substrates or soil; it was also not specified how long samples were stored frozen prior to analysis.

5. Except for two sampling intervals (immature beets sampled at 84 days postplanting and mature wheat sampled at 182 days postplanting), the residues in the soil were not analyzed at the time of harvest of the rotational crops.

6. Prior to planting, the potato quarters were treated with a 1.0 ppm gibberellic acid solution for bud activation, and the fungicide Manzate 200 (maneb, a dithiocarbamate plus zinc and magnesium). It was also reported that nutrients and pesticide treatments were applied to the crops during the study as needed, but the treatments were not described in detail.

7. Lettuce and sugar beets grown in the treated soil exhibited stunting at 16 days postplanting; however, at maturity, there was no plant size differences between plants grown in treated and control soils. Sugar beets "had severe nematode damage causing some wilt."

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RIN-1937-04

Memorandum for MRID No. 41470601

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Pages 8 through 27 are not included.

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