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

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

26 APR 1985

MEMORANDUM

SUBJECT: PP#5E3236 [RCB Number 878]. Metolachlor on Chili Peppers. Evaluation of Analytical Methods and Residue Data (Accession Number 073472).

FROM: Michael P. Firestone, Ph.D., Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Hoyt L. Jamerson, Minor Uses Officer
Process Coordination Branch
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Note: This review has been expedited per the request of Mr. Douglas D. Campt, Registration Division, Director (see memo dated April 15, 1985).

Interregional Research Project Number 4 Associate Coordinator, Dr. M. E. Burt, and National Director, Dr. R. H. Kupelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of New Mexico, request the establishment of a tolerance for the herbicide metolachlor (2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide) 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 in or on the raw agricultural commodity (r.a.c.) chili peppers at 0.5 ppm.

Metolachlor tolerances are established for several r.a.c.'s under 40 CFR 180.368 at levels ranging from 0.02 to 3 ppm. Several metolachlor tolerances are pending, including PP#4F3000 (apples), PP#3F2958 (tree nuts), PP#3F2957 (stone fruits), PP#2F2720 (liver and kidney of cattle, goats, hogs, horses and sheep), and PP#3F2951 (sorghum).

RCB previously recommended for approval of a Section 18 Emergency Exemption for metolachlor on bell peppers grown in the state of New Mexico (see R. Loranger memo of 7/12/83 re: 83-NM-07).

The Metolachlor Registration Standard was completed by the Office of Pesticides and Toxic Substances in September, 1980.

Ciba-Geigy Corporation has submitted a letter from C. F. Brinkley to H. L. Jamerson of EPA, authorizing the use of previously submitted metolachlor data available in the Agency files in support of the proposed tolerance on chili peppers.

Conclusions

1. The nature of the residue, discussed in the Metolachlor Registration Standard (September, 1980), is considered adequately understood for the purposes of supporting the proposed use on chili peppers in New Mexico only. The residues of concern in both plants and animals consist of the parent compound and metabolites (free plus bound) 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol-(CGA-37913) and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-2-morpholine (CGA-49751).

2. Adequate methods are available for enforcing the proposed metolachlor tolerance on chili peppers.

3a. Based on the residue data generated on chili peppers (i.e., one field trial reflecting various PHI's), RCB could recommend for approval of the proposed 0.5 ppm metolachlor tolerance on chili peppers grown in the state of New Mexico only provided the petitioner is willing to submit a revised Section B/label in which the proposed PHI is increased from 39 days to 65 days.

3b. Should the petitioner seek approval of a PHI of less than 65 days, additional residue data supporting such a use will be required.

4. Since chili peppers are not an animal feed item, RCB does not expect a residue problem from secondary residues in animal commodities.

5. An International Residue Limit Status sheet is attached to this review. Since there are no Codex, Canadian or Mexican limits/tolerances for metolachlor on chili peppers, RCB does not anticipate a compatibility problem.

Recommendation

At this time, RCB recommends against establishment of the proposed 0.5 ppm metolachlor tolerance on chili peppers grown in the state of New Mexico only.

However, provided the petitioner is willing to extend the proposed PHI from 39 to 65 days (see Conclusion 3a), RCB could recommend in favor of establishing such a tolerance.

Should Registration Division approve the proposed limited residue data tolerance reflecting a regional registration, RCB also recommends that the tolerance for metolachlor on chili peppers be included in a separate subsection under 40 CFR 180.368. This limited residue data tolerance would be referenced along with all future limited residue data tolerances to a new subsection (n) under 40 CFR 180.1 which would define the Agency's interpretation of "limited residue" data tolerances. An appropriate interpretation for 40 CFR 180.1, subsection "n" would be:

> "Certain tolerances are based on geographically limited residue data. These limited residue data tolerances are included in separate subsections of 40 CFR 180.101 through 180.999. In order to expand the area of usage on these crops, additional residue data will be required. Persons seeking geographically broader registration on these crops should contact the appropriate EPA product manager concerning whether additional residue data are required."

Detailed Considerations

Manufacture and Formulation

The manufacturing process for metolachlor and the composition of the technical material are discussed in RCB's review of PP#8F2081 (see A. Smith memo of 4/2/79). Technical metolachlor is approximately 95% pure. RCB does not expect the impurities to present a residue problem.

The metolachlor formulation proposed for use on chili peppers is Dual® 8E, an emulsifiable concentrate containing 8 lb ai per gallon. The inerts in this formulation are all cleared under 40 CFR 180.1001(c) or (d).

Proposed Use on Chili Peppers

For control of yellow nutsedge and annual grasses in chili peppers, apply metolachlor either preplant (incorporate by mechanical means, leach with irrigation water or rainfall) or apply as a directed spray to chili plants when the first true pepper leaves are present or up to 39 days prior to harvest. Apply at a rate of 2 pt Dual 8E (2 lb ai) per acre in 20 to 50 gal of water by ground equipment only. Only 1 (one) application per season is allowed, and the use is limited to New Mexico only.

RCB concludes that the petitioner will need to increase the proposed PHI from 39 days to 65 days (see also Residue Data Section of this review).

Nature of the Residue

No new metabolism studies were included in the subject petition, however, the nature of the residue has been discussed in RCB's previous reviews of metolachlor as well as in the Metolachlor Registration Standard dated September 1980.

In plants (corn, soybeans), the major metabolic pathway involves conjugation with glutathione, formation of the mercaptan, conjugation of the mercaptan with glucuronic acid, hydrolysis of the methyl ester, and conjugation of the alcohol with a neutral sugar (see K. Arne memo of 12/15/83 re: PP#3F2957).

In animals (goats, rats), metolachlor is rapidly eliminated with only trace residues remaining in tissues (primarily liver). Conjugated residues in urine consist of the same bound metolachlor metabolites as those found in plants (although the natural compounds to which these metabolites are bound are different for plants and animals).

The nature of the residue is considered adequately understood for the purposes of supporting the proposed use on chili peppers in New Mexico only. The residues of concern in both plants and animals consist of the parent compound metolachlor (free plus bound) and its metabolites (free plus bound) 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol (CGA-37913) and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholine (CGA-49751).

Analytical Methodology

The method used to generate the residue data submitted in this petition and the previous Section 18 submission (83-NM-07) is Ciba-Geigy method AG-338 entitled "Analytical Method for Residues of Metolachlor Plant Metabolites Determined as CGA-37913 and CGA-49751 After Acid Hydrolysis." This method is a variation of method AG-286, which has successfully undergone a method trial (see R. Watts memos of 7/28/76 and 7/29/76).

In brief, metolachlor and its metabolites (free plus bound) are hydrolyzed by acid (6N HCl) reflux to CGA-37913 and CGA-49751, which are then determined separately by GLC under different column conditions.

CGA-49751 residues are partitioned into dichloromethane, washed with 5% sodium carbonate, then chromatographed on 16% moisture silica gel column. Residues of CGA-49751 are then converted to the chloroethanol derivative which is partitioned into hexane and cleaned up on a 16% moisture silica gel column. Quantitation is by GLC using a nitrogen-phosphorous ionization detector in the nitrogen mode.

Residues of CGA-37913 are partitioned into hexane following the addition of a sodium hydroxide solution. The residues are then cleaned up by the use of successive chromatographic columns - first on alumina (18% moisture) and then on silica gel. Quantitation is by GLC using a nitrogen-phosphorous ionization detector in the nitrogen mode.

Control values varied between <0.01 to 0.02 ppm.

In the 83-NM-07 submission, recoveries of CGA-49751 fortified at 0.04 and 0.06 ppm were 110% and 91%, respectively, while CGA-37913 recovery was not determined. In the present submission, recovery of CGA-49751 fortified at 0.02 ppm was 66%, while recoveries of CGA-37913 fortified at 0.02 and 0.04 ppm were 97% and 87% respectively.

RCB concludes that adequate methods are available for enforcement purposes.

Residue Data

In conjunction with the subject petition, one field trial was conducted in New Mexico in which single postemergence foliar applications were made to chili peppers at the rate of 2 lb ai/A (the maximum proposed rate) and samples were harvested at either a 109, 88, 63 or 39-day PHI. Samples were stored frozen for up to 4 months prior to analysis. Storage stability data for metolachlor in corn reportedly demonstrates no appreciable residue loss for up to 13 months when stored at -15°C.

In conjunction with 83-NM-07 (Section 18) submission, one field trial was conducted in Texas in which a single postemergence foliar application was made to bell peppers at a rate of 1.5 or 3 lb ai/A 90 days prior to harvest.

The residue data are presented below:

State	Application Rate (lb ai/A)	PHI (days)	Residue Level (ppm) CGA-37913	CGA-49751[a]	total
NM (chili peppers)	2.0	109	<0.01	<0.01	<0.02
		88	<0.01	0.02	0.03[b]
		63	<0.01	<0.01	<0.02
		39	<0.01	0.53	0.54[b]
TX (bell peppers)	1.5	90	<0.01	0.05	0.06[b]
	3.0	90	<0.01	<0.01	<0.02

a) corrected for recovery.
b) <0.01 ppm is equivalent to 0.01 ppm for the purposes of calculating the total residue level.

Based on the above residue data generated on chili peppers (one field trial reflecting various PHI's), RCB could recommend for approval of the proposed 0.5 ppm metolachlor tolerance on chili peppers grown in the state of New Mexico only provided the petitioner is willing to submit a revised Section B/label in which the proposed PHI is increased from 39 days to 65 days.

Should the petitioner seek approval of a PHI of less than 65 days, additional residue data generated on metolachlor-treated chili peppers supporting such a use will be required.

Residue in Meat, Fat, Milk, Poultry and Eggs

Since chili peppers are not an animal feed item, RCB does not expect a residue problem from secondary residues in animal commodities.

Other Considerations

An International Residue Limit Status sheet is attached to this reivew. Since there are no Codex, Canadian or Mexican limits/tolerances for metolachlor on chili peppers, RCB does not anticipate a compatibility problem.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL: Metolachlor

PETITION NO.: 5E3236

CCPR NO.:

REVIEWER: Michael P. Firestone

F. Hoes 4/16/85

Codex Status

☑ No Codex Proposal Step 6 or above

Residue (if Step 9):

Crop(s) | Limit (mg/kg)

Proposed U.S. Tolerances

Residue: metolachlor (2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl) acetamide) and its metabolites determined as 2-[(2-ethyl-6-methylphenyl) amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone

Crop(s)	Tol. (ppm)
chili peppers	0.5

CANADIAN LIMIT

Residue:

Crop(s)	Limit (ppm)
none (on chilli peppers)	

MEXICAN TOLERANCIA

Residue:

Crop(s)	Tolerancia (ppm)
none	

Notes: