



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

APR 15 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#6E3378 [RCB Number 701] - Metolachlor
on Tabasco Peppers - Evaluation of Analytical
Methods and Residue Data (Accession Number
261422)

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

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

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: John H. Onley, Ph.D., Section Head *John H. Onley*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Interregional Research Project Number Four (IR-4) Assistant Coordinator, Dr. J.J. Baron, and National Director, Dr. R.H. Kupelian, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of Louisiana, 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 (rac) tabasco peppers at 0.5 part per million (ppm).

Metolachlor tolerances are established for several crops 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), although Residue Chemistry Branch (RCB) has recently recommended in favor of establishment of a 0.5 ppm tolerance for residues of metolachlor on chili peppers grown in New Mexico in conjunction with PP#5E3236 (see M. Firestone memorandum of June 6, 1985).

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

Ciba-Geigy Corporation has submitted a letter dated January 16, 1986 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 tabasco peppers in Louisiana 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 tabasco peppers.
3. RCB concludes that the proposed 0.5 ppm metolachlor tolerance for tabasco peppers grown in the State of Louisiana only is adequately supported by the available residue data and should not be exceeded when metolachlor is applied according to the proposed use.
4. Since tabasco 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 is no Codex, Canadian, or Mexican limit/tolerance for metolachlor on tabasco peppers, RCB does not anticipate a compatibility problem.

Recommendation

Toxicology Branch and Exposure Assessment Branch considerations permitting, RCB recommends for establishment of the proposed 0.5 ppm metolachlor tolerance for tabasco peppers grown in the State of Louisiana.

Should Registration Division approve the proposed limited residue data tolerance reflecting a regional registration, RCB also recommends that the tolerance for metolachlor on tabasco 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 memorandum of April 2, 1979). Technical metolachlor is approximately 95 percent pure. RCB does not expect the impurities to present a residue problem.

The metolachlor formulation proposed for use on tabasco peppers is Dual® 8E (EPA Registration No. 100-597), 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 Tabasco Peppers/Louisiana Only

Apply Dual® 8E by ground equipment only at a rate of 2 pints formulation per acre (2 lb ai/A) as a directed spray in established plants at least 10 weeks after transplanting. Do not apply more than once per growing season. Do not apply within 14 days of harvest.

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 memorandum of December 15, 1983 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 tabasco peppers in Louisiana 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 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 memorandums of July 28 and 29, 1976.

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 gas-liquid chromatography (GLC) under different column conditions.

CGA-49751 residues are partitioned into dichloromethane, washed with 5 percent sodium carbonate, then chromatographed on 16 percent 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 percent 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.

Recovery of CGA-49751 fortified at 0.02 ppm was 66 percent, while recoveries of CGA-37913 fortified at 0.02 and 0.04 ppm were 97 percent and 87 percent, respectively (note: these fortification/recovery data are the same as that reported in PP#5E3236 (Metolachlor on Chili Peppers) - see M. Firestone memorandum of April 26, 1985).

All control values for CGA-49751 were reportedly < 0.01 ppm. Control values for CGA-37913 reportedly ranged from < 0.01 to 0.02 ppm.

RCB concludes that adequate methodology is available for enforcement purposes.

Residue Data

Treated tabasco pepper samples were stored up to 3 months prior to analysis.

A storage stability study was conducted using bell peppers stored frozen for 6 months. A value of 72 percent is reported for a stored sample fortified at 0.02 ppm while a sample fortified the day of analysis reportedly displayed a (method) recovery of 81 percent.

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RCB concludes that adequate storage stability data are available to support the submitted tabasco pepper residue data.

Field trials involving a single Louisiana location (Avery Island) were conducted during the 1982 growing season. Metolachlor was applied a single time with ground equipment to tabasco peppers at a rate of either 2 or 4 lb ai/A (1X or 2X the proposed treatment rate). Tabasco peppers were harvested 7 and 14 days after treatment (note: the minimum proposed PHI is 14 days).

The reported residue data (uncorrected for method recovery) are tabulated below:

Application Rate (lb ai/A)	PHI (days)	Residue Level (ppm):		Total
		CGA-37913	CGA-49751	
2	7	< 0.01-0.03	< 0.01-0.21	< 0.02-0.24
4	7	< 0.01-0.02	0.40-0.44	0.41-0.45
2	14	< 0.01-0.03	0.03-0.08	0.04-0.09
4	14	< 0.01-0.03	0.06-0.25	0.07-0.25

Based on the above data, RCB concludes that the proposed 0.5 ppm metolachlor tolerance for tabasco peppers will not be exceeded when metolachlor is applied according to the proposed use.

Residue in Meat, Fat, Milk, Poultry and Eggs

Since tabasco peppers are not an animal feed item, RCB does not expect a residue problem from secondary residues in animal commodities as a result of the proposed metolachlor use on tabasco peppers.

Other Considerations

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

Attachment 1: International Residue Limit Status Sheet

cc: R.F., Circu, M.Firestone, EEB, EAB, FDA, PMSD/ISB, PP#6E3378
RDI:J.H.Onley:4/4/86:RDSchmitt-4/4/86
RCB:TS-769C:M.Firestone:CM#2:Rm800b:557-1991
typed by KENCO-4/14/86:edited by mpf-4/15/86

Attachment 1

INTERNATIONAL RESIDUE LIMIT STATUS

J. Wes
3/25/86

CHEMICAL: metolachlor

PETITION NO.: 6E3378

CCPR NO.: _____

REVIEWER: Michael P. Firestone

Codex Status

☒ No Codex Proposal Step
6 or above

Residue (if Step 9): _____

Crop(s) _____ Limit (mg/kg) _____

Proposed U.S. Tolerances

Residue: metolachlor 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) _____
tobasco peppers * 0.5

CANADIAN LIMIT

Residue: _____

Crop(s) _____ Limit (ppm) _____

none (on peppers)

MEXICAN TOLERANCIA

Residue: _____

Crop(s) _____ Tolerancia (ppm) _____

none

Notes:

* Regional Registration - Louisiana only

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