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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 1999

MEMORANDUM

SUBJECT: Emamectin. 99OK0008. PC Code 122806. Section 18 Exemption: Cotton. Anticipated Residues. DP Barcode: D255553.

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Oklahoma has requested an emergency exemption under FIFRA for the use of emamectin on cotton. Emamectin is a mixture of two active homologous compounds, 4"-deoxy-4"-epi-methylamino-avermectin B_{1a} (90% minimum) and 4"-deoxy-4"-epi-methylamino-avermectin B_{1b} (10% maximum). The end use product Denim™ is formulated as the benzoate salt in an emulsifiable concentrate. Along with the exemption request was a cotton residue study intended for a Section 3 registration (MRID 44795001, PP#7F4845).

HED very recently recommended for the establishment of tolerances for residues of emamectin and its metabolites at 0.025 ppm in broccoli, Brussels sprouts, cabbage, cauliflower, head lettuce, and celery (D241907, PP#6F4628, 6-April-1999, M. Rust, S. Weiss, W. Cutchin, and G. Reddy). As a condition of registration, the Agency requires a successful method validation and the registrant is to make any necessary modifications to the method resulting from the BEAD laboratory validation. According to the latest dietary exposure

analysis report, only acute and chronic dietary exposures need to be conducted (D253603, W. Cutchin, 3/5/99).

The proposed use label calls for up to 3 applications made to cotton at 0.0075-0.01 lb active per acre at ≥5-day intervals. Emamectin may be applied in ≥5 gallons of spray volume using ground or aerial equipment; application through an irrigation system is prohibited. A preharvest interval of 21 days has been proposed. The state estimated that a total of 150,000 acres of cotton, primarily in the southwest and west central regions, would be treated. Grazing of livestock in the treated areas is prohibited.

HED's Metabolism Assessment Review Committee concluded that the following residues should be included in the tolerance expression and in the dietary exposure assessment in plants: emamectin, Δ-8,9 isomer of B_{1a} and B_{1b}, AB_{1a} (N-desmethyl B_{1a}), MFB_{1a} (N-formyl B_{1a}), and FAB_{1a} (N-formyl AB_{1a}). It should be noted that B_{1a} and its Δ-8,9 isomer account for >50% of the residue in lettuce, cabbage and corn (Briefing memo to MARC, 9/2/97, J. Stokes).

A cursory review of the residue study indicated that field trials were conducted in AZ, AR, TX, and OK in 1996 and conducted in CA, LA, OK, SC, and TX in 1997. Six applications of emamectin (MK-244 5 SG, a soluble granule formulation) were made at 0.01 lb ai/A with a spray interval of 5 $\pm$ 1 days using ground equipment. Cotton samples were collected (stripper or spindle harvester) 25-32 days after the last application.

Method 244-92-3, Revision 1, "HPLC-Fluorescence Method to Determine the Total Toxic Residue of MK-0244 and Its Metabolites on Vegetables, including Leafy Vegetables and Cole Crops", with modifications and method 244-96-1 (similar to Method 244-92-3) were used for analyzing emamectin residues in gin trash and cottonseed. It should be noted that the method does not resolve B_{1a} or B_{1b} from their respective Δ-8,9 isomer. In cottonseed, concurrent method recoveries ranged from 74-94% for B_{1a} at 2.0 ppb, 52-64% for AB_{1a} at 5.0 ppb, 61-100% for MFB_{1a} at 1.0 ppb, and 70-120% FAB_{1a} at 1.0 ppb. No example chromatograms were submitted for cottonseed; we assume the method recoveries for B_{1b} to be similar to B_{1a}. In gin trash, concurrent method recoveries yielded 71% B_{1a} at 2.5 ppb, 56, 68% B_{1a} at 5.0 ppb, and 89-95% B_{1a} at 50.5 ppb and 72-96% B_{1b} at 5.2 ppb. Sample chromatograms for cotton gin trash were provided and support the assignment of LOQs of 2.0 ppb for B_{1a} and B_{1b}.

Combined residues of emamectin, B_{1a}, AB_{1a}, MFB_{1a}, and FAB_{1a} were all nondetectable (17 samples) except for 2 values at <LOQ B_{1a} in cottonseed resulting from 6 x 0.01 lb ai/A and PHIs of 25-32 days (twice the proposed use rate). Residues in gin trash (also twice the proposed use rate) ranged from <2.5 to 41 ppb B_{1a} and <2.5-3.3 ppb B_{1b}. Residue data for cottonseed oil, hulls and meal were not provided.

Residue data for celery, head lettuce, and cabbage described in PP#3G4239 (M. Flood, 23-Mar-1995) and PP#6F4628 (W. Cutchin, 26 Jan, 1999) showed comparable levels of emamectin residues resulting from EC and SG formulations.

We note that B_{1b} is at most at 10% of the active ingredient and AB_{1a}, MFB_{1a}, and FAB_{1a} are very minor metabolites; AB_{1a}, MFB_{1a}, and FAB_{1a} would be considered negligible to B_{1a} when present at nondetectable levels. Therefore, we recommend that the tolerance be set at 2 ppb in cottonseed as a result of the proposed section 18 use. Residue data for gin trash support a tolerance of 25 ppb (half of 41+3.3 ppb). For the processed commodities cottonseed oil, cotton meal, and cotton hulls, we base the tolerance levels on the average field trial residue of 1 ppb in cottonseed multiplied by the maximum theoretical concentration factors (GLN 860.1520); thus 6.0 ppb for cottonseed oil, 2.0 ppb for cotton meal, and 4.0 ppb for cotton hulls.

Undelinted cottonseed, hulls, meal and gin trash may be fed to beef and dairy cattle, and cotton meal may be fed to poultry. However, the exposure of emamectin residues to livestock through these feed items except for gin trash would be negligible; likewise for poultry since gin trash is not usually fed to chickens. The theoretical dietary burden for beef and dairy cattle from treated gin trash in the feed would be (0.025 ppm residue x 20% in the diet ÷ 90% dry matter) 0.0055 ppm.

Cows (3 lactating at each level) were fed emamectin benzoate at 30, 90, and 300 ppb in the feed for 28 days; only B_{1a} and B_{1b} were measured with an LOQ of 2 ppb for each compound in liver, kidney, muscle and fat, and 0.5 ppb in milk (Method 244-95-1, HPLC-Fluorescence Method for the Determination of Emamectin Benzoate (MK-0244) Residues in Bovine Tissue, Milk, Cream and Plasma). Feeding study data showed finite transfer of emamectin only in kidney, liver and marginally in fat at the 30 ppb feeding level, not quantifiable (<0.5 ppb) in milk and not quantifiable (<2.0 ppb) or not detectable (<1.0 ppb) in muscle; B_{1b} was not detectable (<1.0 ppb) in milk or tissues. We estimate the following average B_{1a} residues: 0.25 ppb in milk, 8.6 ppb in liver, 1.4 ppb in fat, 3.7 ppb in kidney, and 0.67 ppb in muscle. The estimated maximum residue values are: 0.5 ppb in milk, 10 ppb in liver, 2.1 ppb in fat, 4.0 ppb in kidney, and 1.3 ppb in muscle.

Since the dietary burden is only about one sixth of the lowest feeding dose, the average residues transferred to milk and tissues should be corrected by 5.5/30. The following values should be used for chronic dietary analysis:

Milk	0.046 ppb
Liver	1.6 ppb
Fat	0.26 ppb
Kidney	0.68 ppb
Muscle	0.12 ppb

The corrected (5.5÷30) maximum residues in milk and tissues should be used for acute dietary analysis:

Milk	0.092 ppb
Liver	1.8 ppb
Fat	0.38 ppb
Kidney	0.73 ppb
Muscle	0.24 ppb

cc:RAB3 Reading File, SF, Section 18 F, Cheng
RD/I:ChemTeam:5/5/99:SDapson:5/10/99
7509C:RAB3:LCheng:CM#2:RM810A:5/3/99:3rab\emamectin\antiresi