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

APR 16 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum:

SUBJECT: PP#9F3787. Abamectin in/on pears. Results of Petition Method Validation. (MRID#'s 411885-15, CBTS#5700).

FROM: Jerry B. Stokes, Chemist
Chemistry Branch I/Tolerance Support
Health Effects Division (H7509C) *July 13 MSL*

THRU: Debra Edwards, Ph. D., Acting Chief
Chemistry Branch I/Tolerance Support
Health Effects Division (H7509C) *Debra Edwards*

TO: George LaRocca/Adam Heyward, PM-13
Insecticide/Rodenticide Branch
Registration Division (H7503C)

Merck & Co., Inc. has proposed a 0.035 ppm tolerance for the combined residues of avermectin B₁ and its delta 8,9-isomer in/on pears. CBTS requested a validation of the analytical methodology, "HPLC-Fluorescence Determination of Avermectin B₁ and its Delta 8,9-isomer in Pears", Method No. 8000.

The following is a summary of the report from the Analytical Chemistry Section, Analytical Chemistry Branch (See Attachment 1 for details of the validation trial).

1. Since the term "delta 8,9 isomer" can be a source of confusion in the discussion of avermectin residues, the petitioner is required to define these residues as 8,9-Z-avermectin B_{1a} and 8,9-Z-avermectin B_{1b} throughout the method.
2. The petitioner must provide the EPA repository with adequate analytical standards according to the Agency requirements.
3. The use of the B_{1a} calibration curve to quantitate both

B_{1a} and B_{1b} is not analytically correct, and will not be acceptable unless the two analytes are demonstrated to produce equivalent HPLC responses in the method.

4. Merck's Method No. 8000 and "Suggestions For The Analyst Performing Merck Residue Method No. 8000" (dated November 18, 1987) must be combined into a single document.

5. The limit of detection for this method was not determined by ACS, but it appears to be less than 1 ppb. Percent recoveries for samples of pears fortified with 32.6 ppb of avermectin B_{1a} were 94 and 102, with 65.2 ppb of avermectin B_{1a} were 101 and 104, with 2.4 ppb of avermectin B_{1b} were 74 and 99, with 4.8 ppb of avermectin B_{1b} were 96 and 88. Percent recoveries for samples of pears fortified with 35 ppb of 8,9-Z-avermectin B_{1a} were 92 and 94, and with 70 ppb of 8,9-Z-avermectin B_{1a} were 94 and 94.

6. Method required a minimum of two full days to prepare and complete analyses of fortified samples. Unknown samples may require a repeat run for quantitation if these are not in the narrow calibration curve.

7. The method marginally meets the requirements for an enforcement method. However, if the above comments are addressed adequately, the method could meet the Agency requirements for the proposed use on pears.

Recommendation:

CBTS does not consider the Method No. 8000 for the analysis of avermectin B₁ and 8,9-Z-avermectin B₁ residues in/on pears acceptable for enforcement purposes. The corrections/comments of the Agency lab, Analytical Chemistry Section must be addressed by the petitioner before CBTS can make a decision as to the adequacy of the method.

Attachment 1: Petition method validation report, M. Law (ACS, ACB, BEAD), dated 2/29/92.

cc with Attachment 1: J. Stokes (CBTS); PP#9F3787; avermectin S. F.

cc without Attachment 1: R.F.; Circu(7)

RDI: PErrico:4/6/92:RLoranger:4/7/92

H7509C:CBTS:JStokes:js:Rm 803A:CM#2:305-7561:4/8/92