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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN 14 1993

Memorandum:

SUBJECT: PP#0F3880. Amendment dated April 1, 1993 for Abamectin in/on strawberries. Evaluation of Analytical Method and Residue Data. (MRID#'s 427255-00,-01, and -02, CB#'s 11723 and 11724, Barcode# D190265).

FROM: Jerry B. Stokes, Chemist
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

THRU: Phil V. Errico, Section Head III
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

TO: George LaRocca/Adam Heyward, PM-13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Merck Sharp & Dohme Research Laboratories, Merck & Co., Inc., has submitted a cover letter dated April 1, 1993 and additional data in response to a deficiency cited in CBTS review (See memo of 11/5/91, J. Stokes).

Recommendation:

CBTS continues to recommend against this proposed use and the establishment of a 0.02 ppm tolerance for the combined residues of abamectin [avermectin B_1 and its delta 8,9 isomer] in/on strawberries until the petitioner has provided adequate analytical methodology for abamectin residues in/on strawberries and pears.

Detailed Considerations

CBTS Deficiency #6a, memo dated 11/5/91, J. Stokes:

"For three sample shipments (1026R, 1027R, and 6021R) the dates shipped vs. arrival show periods of 9 or 14 days. Were samples in shipment this total time? If so, were samples maintained in a frozen state during these times? The

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petitioner must clarify how the samples were handled and their condition upon arrival at the laboratory. The shipment/arrival and analyses of all samples must be provided for our review."

Petitioner's Response dated 4/1/93:

The petitioner has submitted shipping and freezer storage data for the samples in question.

CBTS Comments/Conclusions:

CBTS considers this deficiency **now** resolved.

Other Comments:

Deficiencies with the analytical methodology have not been addressed.

The method of choice for avermectin B_1 residues on strawberries is No. 8001R1. This method is identical to that proposed for celery (Method No. 10001R1) and pears (Method No. 8000, except for the initial enzymatic step). CBTS has previously decided that although Methods Nos. 1009R3 and 6004 had been submitted to FDA for inclusion in PAM II, the methods and commodities were sufficiently different from celery and pears to require a successful trial of Method No. 8000 before the proposed method No. 8001R1 for strawberries would be acceptable. Method No. 8000 was submitted to the EPA laboratory in Beltsville for method validation in pears.

The following is a summary of the method validation report from the Analytical Chemistry Section, ACB, BEAD. (See memo of M. Law, 2/29/92).

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.

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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.

Petitioner's Response:

The petitioner has not responded to the above comments.

CBTS Comments/Conclusions:

Previously CBTS had commented: "CBTS does not consider the Method No. 8000 for the analysis of avermectin B_1 and 8,9-Z-avermectin B_1 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." (See memo of 4/16/92, J. Stokes).

In addition CBTS stated: "Based upon the residue data for strawberries at the proposed application scheme, the proposed 0.02 ppm tolerance should adequately cover any avermectin B_1 residues in/on treated strawberries. **However**, final conclusions on the acceptability of the data are reserved until the proposed analytical methodology for pears (Method No. 8000) has passed a successful validation." (See memo of 11/5/91, J. Stokes).

The petitioner **must provide** analytical standards to the EPA Repository, and rewrite the proposed enforcement methodology as stated in CBTS's comments 1, 3, and 4 above, and submit it for review.

cc: PP#9F3880; J. Stokes (CBTS); R.F.; Circu.
RDI: PErrico:6/11/93:RLoranger:6/11/93
H7509C:CBTS:JStokes:js:Rm 803:CM#2:305-7561:6/11/93