

6-17-96

MEMORANDUM

SUBJECT: PP#5E4566. Abamectin (AGRI-MEK 0.15EC
Miticide/Insecticide, EPA Reg. No. 618-98) in or on Hops.
Amendment of 2/22/96.

MRID Nos. 439709-01, 440076-01, Chemical Code: 122804.
CBTS Nos. 17113, 17178; DP Barcodes: D225120, D225898.

FROM: William D. Wassell, Chemist
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Health Effects Division (7509C)

THROUGH: Edward Zager, Acting Chief
Chemistry Branch I - Tolerance Support
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TO: Deborah L. McCall, Acting Section Head
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Executive Summary of Deficiencies Remaining to be Resolved:

* None

Summary/Background:

George M. Markle, Associate Director, Interregional Research Project No. 4 (IR-4), State Agricultural Experiment Station, Rutgers University, New Brunswick, NJ on behalf of the IR-4 Project, the Agricultural Experiment Stations of Idaho, Oregon and Washington, the Idaho, Oregon and Washington Hop Commissions and the Hops Growers of America requests the establishment of a tolerance for residues resulting from the use of the miticide/insecticide abamectin [a mixture of avermectins containing $\geq 80\%$ avermectin B_{1a} (5-O-demethyl avermectin A_{1a}) and $\leq 20\%$ avermectin B_{1b} (5-O-demethyl-25-de (1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a})] on hops. The tolerance is requested in terms of the combined residues of the insecticide avermectin B₁ and its delta-8,9-isomer in or on the raw agricultural commodity dried hops at 0.2 ppm.

The current submission is in response to our memo of 2/7/96 (W.D Wassell, 4E4419, D222409) and consists of a revised analytical method and analytical data. In the previous review, we concluded

several minor modifications to the method have been suggested by
ACL/BEAD and the petitioner has been required to rewrite the

method to include these modifications. The petitioner should refer to Deficiencies 4, 6, 7, 8, and 9 for specific instructions concerning rewriting Merck Method M-036. The previously cited deficiencies are restated below followed by the petitioner's response and finally our comments.

Conclusions and Recommendations:

CBTS concludes Merck Method M-036.2 has been revised as per our comments. Deficiencies 4, 6, 7, 8, and 9 from our memo of 2/7/96 (W.D Wassell, 4E4419, D222409) are resolved. Merck Method M-036.2 will be forwarded to the FDA for inclusion in PAM Vol II.

Toxicological considerations permitting, CBTS can now recommend for the establishment of a permanent tolerance for the combined residues of the insecticide avermectin B₁ and its delta-8,9-isomer in or on the raw agricultural commodity dried hops at 0.2 ppm.

Note to PM: This tolerance when granted should be established on the commodity "hops, dried".

A DRES run can be initiated at this time utilizing residue levels of 0.2 ppm for avermectin B₁ and its delta-8,9-isomer in/on dried hops.

Detailed Considerations:

Deficiency 4 (Comment 1, from 5/18/95 Pre-review, E.S. Greer, Jr.)

Method 8000, Rev 4 has a derivatization step that is virtually identical to this method and the "Suggestions to the Analyst..." section describes precautions to be observed when performing this step. If the petitioner feels that these precautions are necessary for Method 8000, Rev. 4, they should be included in this method.

Deficiency 7 (Comment ILV 2, from 9/19/95 Pre-review, Dallas Wright, Jr.)

The ILV report states that the registrant informed them that the avermectins are not stable in hexane, and that the samples must not be stored in hexane overnight. However the method description does not mention that problem, nor does it give any suggested stopping places. If this is crucial to obtaining acceptable recoveries, it must be noted in the method.

Deficiency 8 (Comment ILV 3, from 9/19/95 Pre-review, Dallas Wright, Jr.)

The method states that equivalent equipment may be substituted for those specified in the method. However, the ILV laboratory

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used a different brand of SPE cartridge and found that the recoveries were lower. The method write-up should be changed to indicate that other brands of SPE cartridges may not be suitable for this analysis.

Deficiency 9 (Comment ILV 4, from 9/19/95 Pre-review, Dallas Wright, Jr.)

The ILV laboratory noted that the solid material at the bottom of the tube after centrifuging should not be disturbed when transferring the supernatant liquid. If small particulate matter is transferred with the liquid, it may interfere with subsequent analysis steps. The method write-up does not mention this as a potential problem.

Petitioner's Response:

In response to these deficiencies, the petitioner has submitted a revised analytical method entitled:

Liquid Chromatographic Method for the Quantitation of Total Avermectin B1 and 8,9-Z-Avermectin B1 in Dried Hops Using Fluorescence Detection, M-036.2, dated: 2/21/96 (revision 2), Pages 20 thru 35 of MRID No. 440076-01.

CBTS' Comments/Conclusions:

CBTS concludes the method has been revised as per our comments. **Deficiencies 4, 7, 8, and 9 are resolved.**

Deficiency 6 (Comment 3b, from 5/18/95 Pre-review, E.S. Greer, Jr.)

Derivatized standards of B1b and 8,9 isomer of B1a were used for quantitating recoveries for these compounds. The method uses standard B1a for this purpose. This issue is also addressed in the TMV pre-review.

Petitioner's Response:

The petitioner has submitted a study entitled:

Determination of Molar Absorptivities for Avermectin B1a and Avermectin B1b, by N.A. Johnson, 3/1/96, MRID No. 439709-01.

In this study, the molar absorptivities (at 245 and 254 nm) and response factors (absorbance/weight, at 245 nm) for avermectin B1a and avermectin B1b were measured and compared statistically. Additionally, the response factors for derivatized avermectin B1a and avermectin B1b were determined at 245 nm (UV detection) and at 254 nm (fluorescence detection). The molar absorptivities and

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response factors for the underivatized standards were determined over a concentration range of 2 to 10 ppm and 10 to 100 ppm, respectively. Response factors for derivatized avermectin standards were determined over a range of 0.01 to 0.1 ppm. No significant differences in the molar absorptivities and response factors for avermectin B1a and avermectin B1b and their derivatized counterparts were found.

CBTS' Comments/Conclusions:

Although not strictly analytically correct, Merck has provided sufficient data to show that the quantitation of avermectin B1b residues using the B1a curve will accurately measure the contribution of B1b in the total avermectin residue. **CBTS considers Deficiency 6 resolved.**

cc: WDWassell, RF, Circ., PP#4E4419, H. Jamerson (PM-43, 7505W).

RDI:TPTI: 06/11/96; RALoranger: 06/11/96.

7509C:CBTS:WDWassell:wdw:CM#2:Rm 804U:305-6135:06/05/96.

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Residue Chemistry Review

Subject: PP#5E4566. Abamectin (AGRI-MEK 0.15EC Miticide/Insecticide, EPA Reg. No. 618-98) in or on Hops. Amendment of 2/22/96. MRID Nos. 439709-01, 440076-01, Chemical Code: 122804. CBTS Nos. 17113, 17178; DP Barcodes: D225120, D225898.

Document

Class:

Product

Chem:

Residue 860.1340 Residue analytical method

Chem:

Biochemicals:

DP Barcode: D225120, D225898

MRIDs: 43970901, 44007601

PC Codes: Actives 122804 **Abamectin (ANSI)**

Inerts

Commodities: Hops

Administrative #: 5E04566; 000618-00098

Reviewers: William D. Wassell

Review Edward Zager

Approved on: June 17, 1996

Approver:



WP Document: Abamecti.05⁶

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