PP # 3787

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

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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#1F3787. Abamectin (Avermectin B_1) for Use in/on Pears. Merck's Response of 10/31/95 to the Lone Remaining Deficiency as Outlined in the Memo of G.J. Herndon dated 9/14/95.
MRID# 438325-01. DP Barcode# D220771. CBTS# 16467.

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and

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Merck and Co., Inc. is requesting the establishment of a permanent tolerance for abamectin (avermectin B_1) insecticide/miticide and its delta-8,9-isomer in/on pears at 0.02 ppm.

Merck originally requested a 0.035 ppm tolerance on pears, and the proposed enforcement method (Method No. 8000) was sent to EPA's Analytical Chemistry Lab (ACL) to be validated based on this request. ACL noted several deficiencies in the method (see memo of M. Law and B. Puma dated 2/29/92) which were later resolved (see memo of G.J. Herndon dated 12/16/93). Since that time, Merck has requested a 0.02 ppm tolerance and submitted additional field trial data and a new Section B in support of the lower tolerance. In the memo of G.J. Herndon dated 10/27/94, CBTS recommended in favor of the 0.02 ppm tolerance provided that ACL could show that Method 8000, Rev. 4 was adequate to enforce the new lower tolerance. The

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method was sent back to ACL (memo of G.J. Herndon dated 10/21/94) and the results were received (memo of E. Greer, Jr. and D. Wright, Jr. dated 5/15/95). Based on ACL's comments, CBTS provided the following comments/conclusions:

> CBTS can recommend in favor of a Section 3 registration and permanent tolerance of 0.02 ppm on pears provided that Merck makes the requested changes to Method 8000, rev. 4 as outlined in Comments 4 and 6 of this memo (integrating the method and "Suggestions to the Analyst" and specify the alternative pectinase product).

In the present submission, Merck has provided the following revised method:

> "HPLC-Fluorescence Determination for Avermectin B1 and 8,9-Z Avermectin B1 in Pears and Apples", T.A. Wehner, 10/27/95, Merck Method 8000, Rev. 5 (MRID# 438325-01).

Conclusions and Recommendations

The current submission adequately addresses the comments/conclusions that were raised in the memo of G.J. Herndon dated 9/14/95. TOX considerations permitting, CBTS can recommend that a Section 3 registration be established for the use of AGRI-MEK 0.15 EC Miticide/Insecticide (EPA Reg.# 618-98) on pears. Associated with this registration, the proposed permanent tolerance of 0.020 ppm should be established for residues of avermectin and its delta-8,9-isomer on pears.

A DRES run has already been completed (see memo of B. Steinwand dated 10/17/95).

Merck Method 8000, rev. 5 will be sent to FDA to be incorporated into PAM II as a roman numeral method.

cc: PP#1F3787, RF, SF, circu., G.J. Herndon,
E. Haeberer (Section Head).

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