PP# 3973

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

OCT 30 1995

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#1F03973 and 1H05611. Abamectin (Avermectin B_1) for Use in/on Almonds and Walnuts. Registrant's Response to Conclusions/Deficiencies Outlined in Memo of G.J. Herndon Dated 5/19/94.

MRID# 435989-00.
DP Barcode# D214699, D214701.
CBTS# 15490, 15491.

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In a letter received by the Agency on 3/30/95, Merck and Co., Inc. is responding to deficiencies cited in the memo of G.J. Herndon dated 5/19/94 concerning PP#1F03973 and 1H05611. The original petition, PP#1F03973/1H05611, involved tolerances on both head lettuce and tree nuts. In a later submission, the head lettuce registration and tolerances were removed and addressed in their own petition (see memo of G.J. Herndon dated 11/16/94 concerning PP#4F4373).

AB Abamectin .043

In PP#1F03973/1H05611, Merck and Co., Inc. is requesting the establishment of permanent tolerances for abamectin (avermectin B_1) insecticide/miticide and its delta-8,9-isomer in/on the following commodities:

Commodity	Tolerance (ppm)
Almonds	0.005
Walnuts	0.005
Almond Hulls	0.10

Conclusions and Recommendations

With the current submission, all of CBTS's concerns/deficiencies surrounding PP#PP#1F03973/1H05611 have been resolved. Therefore, CBTS has no objections to RD issuing a Section 3 registration for use of AGRI-MEK 0.15 EC (EPA Reg. # 618-98) on almonds and walnuts and the following associated tolerances:

Commodity	Tolerance (ppm)
Almonds	0.005
Walnuts	0.005
Almond Hulls	0.10

Note to RCAB:

A DRES run should be initiated using the following values.

Acute and Chronic Residue Values to be Used in the Dietary Risk Assessment of Avermectin

DRES entry	Entry for **ACUTE** Risk Assessment (ppm)	Entry for **CHRONIC** Risk Assessment (ppm)
almonds	0.005	0.00125
beef fat	0.014	0.006
beef lean	0.002	0.002
beef kidney	0.005	0.002
beef liver	0.020	0.008
beef dried	0.002	0.002
beef meat byproducts	0.020	0.008
milk sugar	0.001	0.00025
milk fat	0.004	0.001
milk, non-fat solids	0.004	0.001
walnuts	0.005	0.00125

Detailed Considerations

The Deficiencies listed below were cited by CBTS in the memo of G.J. Herndon dated 5/19/94 concerning PP#1F03973 and 1H05611. Responses were received from the registrant on 3/30/95 and are reviewed below.

Deficiency 1 from the 5/19/94 Memo.

The registrant should delete footnotes a) and b) from the AGRI-MEK 0.15 EC proposed label (see Attachment) for almonds and walnuts.

Registrant's Response to Deficiency 1.

The registrant has provided revised draft labeling.

CBTS's Comments and Conclusions Concerning Deficiency 1.

The issue surrounding Deficiency 1 involves the issue of label language for concentrated orchard sprays. In the review of proposed label for use of avermectin on tree nuts (PP#1F3973, memo of G.J. Herndon dated 11/26/91), CBTS noted that, for concentrated orchard sprays, the amount of active ingredient applied should be proportional to tree size. This issue was also discussed in meetings with Merck on 9/8/94 and 2/28/95. Merck has submitted a draft proposal to the Agency that addresses this issue generically for all their tree crops.

The draft labeling was reviewed in a separate memo (memo of G.J. Herndon dated 10/6/95, titled "Revised Labels for Addressing the Application of Abamectin to Tree Crops"). The new labeling satisfies CBTS's concerns over the potential over-application of avermectin to orchards containing small trees when using low-volume (concentrate) sprays. **Deficiency 1 has been resolved.**

Deficiency 2 from the 5/19/94 Memo.

CBTS continues to recommend that the dosage for concentrated sprays be based on tree size (as outlined in the 11/26/91 memo of G.J. Herndon).

Registrant's Response to Deficiency 2.

The registrant has provided revised draft labeling.

CBTS's Comments and Conclusions Concerning Deficiency 2.

See CBTS's Comments and Conclusions Concerning Deficiency 1 above. **Deficiency 2 has been resolved.**

Deficiency 3 from the 5/19/94 Memo.

The registrant made no mention of the conditions under which the samples were held during transit from the field to the lab. This time period was as long as 18 days in transit. CBTS would like the registrant to comment on whether the samples were kept frozen during this time.

Registrant's Response to Deficiency 3.

The registrant has submitted MRID# 435989-00, which provides the sample conditions and shipping information which were missing from the original submission.

CBTS's Comments and Conclusions Concerning Deficiency 3.

The submitted data/records substantiate that the field samples were maintained in frozen condition during transport from the field to the laboratory. **Deficiency 3 has been resolved.**

cc: circu, PP#1F03973, RF, E. Haeberer (section head), G.J. Herndon.

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Branch Chief: M. Metzger: 10/30/95.

H7509C: CBTS: G.J. Herndon: 305-6362: CM#2, Rm. 804C: 10/19/95.