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

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#1F03973 and 1H05611. Abamectin (Avermectin B_1) for Use in/on Almonds, Walnuts, and Head Lettuce. Registrant's Response to Conclusions/Deficiencies Outlined in Memo of G.J. Herndon Dated 11/26/91.

MRIDs# 429498-01 and 429498-02 (22 volumes).
DP Barcode# D195880.
CBTS# 12660.

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In a letter received by the Agency on 10/1/93, Merck Sharp and Dohme is responding to deficiencies cited in the memo of G.J. Herndon dated 11/26/91 concerning PP#1F03973 and 1H05611. The original petition, PP#1F03973/1H05611, involved tolerances on both head lettuce and tree nuts. With the current submission, the company has responded separately to the head lettuce and tree nut concerns. This review is in response to the **tree nuts** concerns; a separate memo addresses Merck's response to the head lettuce deficiencies (see memo of G.J. Herndon dated 5/19/94; DP Barcode D191433, CBTS# 11901).

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With PP#1F03973/1H05611, Merck Sharp and Dohme 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
Head Lettuce	0.05
Almond Hulls	0.10

Technically, with the exception of the tolerances on fresh tomatoes and tomato pomace, all the tolerances established for avermectin B_1 (40 CFR 180.449, 185.300, and 186.300) have expired (expired on or before 3/31/93). The registrations have been extended and RD is in the process of extending the tolerances until 1997 (private conversation with George LaRocca/Adam Heyward on 5/10/94).

Conclusions

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

2. 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).

3. 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.

Recommendations

Until the deficiencies outlined in Conclusions 1, 2, and 3 are satisfactorily resolved, CBTS cannot recommend in favor of the proposed tolerances. [As noted in a concurrent memorandum (see memo of G.J. Herndon dated 5/19/94; DP Barcode D191433, CBTS# 11901), all deficiencies in this petition related to head lettuce have been resolved].

Note to P.M.: CBTS reiterates our recommendation that the label for application of AGRI-MEK 0.15 EC to **citrus** be revised to include a low volume (concentrated) rate based on tree height, as was included on previous label versions.

Detailed Considerations

The Deficiencies listed below were cited by CBTS in the 11/26/91 memo of G.J. Herndon concerning PP#1F3973/1H5611. Responses were received from the registrant on 10/1/93 and are reviewed below.

Deficiency 3a.

The proposed label for almonds and walnuts does not provide the dosage for full-coverage (dilute) sprays, applied to orchards, in the proper format. The dosage should be expressed as pounds active ingredient per 100 gallons of spray solution applied to runoff. Expressing the dosage in this form accounts for the variation in the quantity of active ingredient applied per acre as a result of the variation in tree size. To calculate this from the fluid ounces (or pounds active ingredient) per acre, the petitioner must provide data on the volume of spray per acre that was required (or would have been required if the trial was not performed to runoff) on the trees, at the time that the field trials were performed, to bring them to the point of runoff. This information will be required from the following, high-volume studies:

Almond
- 001-88-6028R
- 001-88-6035R
- 001-89-6020R

Walnut
- 001-88-6052R
- 001-89-6034R
- 001-88-6027R

Otherwise, full-coverage use must be dropped from the label. In addition, the volume of oil added will need to be expressed as percentage of the spray volume rather than as 1 gallon per acre.

Registrant's Response to Deficiency 3a.

Merck provided additional information from the 6 residue studies. The additional data are shown in Table 1.

Table 1

Additional Information Supporting the Field Trial Data Originally Submitted

Trial #	Tree Age (years)	Tree Height (feet)	Spray GPA	Applied to Runoff?	% Spray Oil*
001-88-6028R	12-15	20-25	400	yes	0.25
001-88-6035R	35	20-25	350	yes	0.29
001-89-6020R	unknown	unknown	400	yes	0.25
001-88-6052R	25	30-35	400	no	0.25
001-89-6034R	12	20	300	yes	0.33
001-88-6027R	unknown	20	400	yes	0.25

* as a percentage of spray volume rather than as 1 gallon per acre

In the one trial in which the spray was not applied to runoff (001-88-6052R), the registrant estimates that 500 gallons may have been needed to wet the foliage to the point of runoff.

Merck has submitted a revised Section B (see Attachment) that adds a new directions for dilute sprays:

> For control of two-spotted, Pacific, and strawberry spider mites, dilute AGRI-MEK 0.15 EC at the rate of 2.5 to 5.0 fl.oz. of formulation into each 100 gallons of spray volume. Paraffinic spray oil should be added at a minimum of 0.25% based on total spray volume. Apply a sufficient volume of the spray solution to obtain thorough coverage to the point of runoff. For control of the European red mite, use 5.0 fl.oz. of formulation per 100 gallons. These rates are based on a standard volume of 400 gallons of dilute spray per acre. If less than 400 gallons of dilute spray solution per acre is applied, use a minimum of 20 fl.oz. per acre for the European red mite and 10 fl.oz. per acre for other mite species in the appropriate spray volume to obtain thorough coverage.

CBTS's Comments and Conclusions Concerning Deficiency 3a.

The language on the proposed label that reads "If less than 400 gallons of dilute spray solution per acre is applied, use a minimum of 20 fl.oz. per acre..." should be changed. Use of the term "minimum" implies that, in certain situations, more product per acre could be applied, yet the label includes the following restriction: "Do not exceed 20 fl.oz. AGRI-MEK 0.15 EC per acre per application or 40 fl.oz. per acre in a growing season".

The Agency has defined dilute sprays as application to the point of runoff and concentrated sprays as anything less than

application to runoff. The intent of dilute sprays is to achieve a uniform concentration of active ingredient per square inch of leaf surface. Therefore, in an orchard comprised of smaller trees (i.e. less canopy or total leaf surface), less total spray volume would be needed to achieve runoff, **but the concentration of active ingredient per gallon of spray volume should remain constant.**

The registrant should delete footnotes a) and b) from the AGRI-MEK 0.15 EC proposed label (see Attachment) for almonds and walnuts. **Deficiency 3a is not resolved.**

Deficiency 3b.

The proposed label for almonds and walnuts does not vary the dosage for concentrated sprays, applied to orchards, based on tree size. CBTS recommends the following label change regarding concentrated spraying of abamectin to tree nuts.

tree height (in feet)	fl.oz. AGRI-MEK/acre	lbs.ai./A.
less than 10	5 - 10	0.006 - 0.012
10 - 18	7.5 - 15	0.009 - 0.018
18 +	10 - 20	0.012 - 0.023

Apply the higher rate for control of heavier insect populations and/or European red mites. Do not apply more than 20 fl.oz./A./application or 60 fl.oz./A. in a 12 month period.

Registrant's Response to Deficiency 3b.

Merck responded:

"We disagree with this proposal by EPA for labeling based on the tree height because, as already indicated in our response to EPA comment 1a (3a of this memo), we feel that the labeling currently proposed for tree nuts should be formatted consistently with that of the EPA-accepted labeling for citrus and pending labeling for pears. We have also reviewed several labels of pesticides commonly used on tree nuts, including the labels for Omite 6E, Vendex 4L, Kelthane EC, and Guthion 2L, and in no case is the rate of pesticide applied specified according to tree height as the EPA reviewer suggested."

CBTS's Comments and Conclusions Concerning Deficiency 3b.

CBTS based their recommendation for varying the amount of active ingredient per acre based on the height of the nut trees in part on the proposed label that was submitted with the Section 3 petition for use of abamectin on citrus (see memo of M.F. Kovacs Jr. dated 4/25/88 concerning PP#8F3592/8H5550). After certain deficiencies were resolved, CBTS recommended that the proposed tolerances on citrus commodities be approved based on the label

that varied the application rate according to tree height. Somehow the part of the label concerning application rate/tree height has been lost in the current AGRI-MEK citrus label - CBTS has no record of recommending for this change. As noted in the memo of G.J. Herndon dated 11/26/91 (see Note to P.M.), CBTS recommended that the label for application of AGRI-MEK 0.15 EC to citrus be revised to include a low volume (concentrated) rate based on tree height, as was included on previous label versions. 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). **Deficiency 3b is not resolved.**

Deficiency 3c.

The proposed label for application of AGRI-MEK 0.15EC to almonds and walnuts must be amended to specify the treatment interval between applications. The field residue data support a minimum treatment interval of 21 days (see Detailed Considerations, Proposed Use).

Registrant's Response to Deficiency 3c.

Merck agreed with this comment and added the following language to a revised Section B:

> "If a second application is necessary to maintain control, do not retreat within 21 days."

CBTS's Comments and Conclusions Concerning Deficiency 3c.

Deficiency 3c is resolved.

Deficiency 7a.

No new storage stability studies were provided with this petition. The storage study data from previous submissions on citrus and tomatoes are not adequately representative of almond nuts, walnuts, almond hulls, and head lettuce, nor are they adequate in duration. Therefore, at a minimum, the registrant must provide all currently available storage stability data on any RAC that show that avermectin B_1a, avermectin B_1b, and the delta-8,9-isomer of avermectin B_1a are stable over a period of at least 26.5 months. Otherwise, the registrant must provide data to show that avermectin B_1a, avermectin B_1b, and the delta-8,9-isomer of avermectin B_1a are stable in a representative leafy vegetable commodity (lettuce, celery, or spinach) over a period of 26.5 months and a representative tree nut commodity (almond, pecan, or English walnut) over a 14 month period. In addition, abamectin recoveries must be provided for almond hulls over a 23.5 month period.

In the future CBTS would like to see the petitioner perform storage stability on control samples from each crop group for which field residue data are provided. The storage conditions should reflect the storage conditions of the treated samples with respect to temperature, length of storage, containers, lighting, etc. Stability does not imply 100% recovery so, in order to get a maximum residue value, the residue data should still be corrected for storage study recovery (see Detailed Conclusions, Storage Stability).

Registrant's Response to Deficiency 7a.

The registrant has references additional storage stability data that have been generated other than the citrus and tomatoes referenced in the original memo. New crops include celery (24 months), pears (35 months), strawberries (24 months) and cottonseed (14 months). The composite crops/recoveries are shown in Table 2.

Table 2

Storage Stability Recoveries for Abamectin Residues in Various Crop Matrices (stored at ≤ -10°C)

Matrix	Length of Frozen Storage (months)	Fortification Level (ppm) and Compound	Method Recovery at Longest Time Interval#	Storage Stability Recovery at Longest Time Interval*
celery	24	0.010 - B1a	70%	79%
		0.206 - B1a		70%
		0.015 - B1b		87%
		0.010 - Δ8,9 isomer		70%
pears	35	0.010 - B1a	95%	84%
		0.071 - B1a		86%
		0.005 - B1b		72%
		0.010 - Δ8,9 isomer		94%
strawberries	24	0.010 - B1a	105%	98%
		0.071 - B1a		102%
		0.005 - B1b		109%
		0.010 - Δ8,9 isomer		94%
tomatoes	24	0.010 - B1a	87%	88%
		0.051 - B1a		86%
		0.004 - B1b		90%
		0.009 - Δ8,9 isomer		74%
cottonseed	14	0.010 - B1a	73%	58%
whole oranges	29	0.010 - B1a	86%	89%
		0.052 - B1a		89%
		0.004 - B1b		95%
		0.010 - Δ8,9 isomer		84%
whole grapefruit	29	0.010 -B1a	96%	92%
		0.052 - B1a		82%
		0.004 - B1b		104%
		0.010 - Δ8,9 isomer		85%
whole lemons	29	0.010 - B1a	84%	86%
		0.052 - B1a		86%
		0.004 - B1b		98%
		0.010 - Δ8,9 isomer		83%
orange peel	52	0.025 - B1a	87%	67%
grapefruit peel	47	0.005 - B1a	unk.	85%
		0.025 - B1a		70%
lemon peel	47	0.005 - B1a	88%	93%
		0.025 - B1a		79%

- fresh fortification

* - uncorrected for method recovery

CBTS's Comments and Conclusions Concerning Deficiency 7a.

The additional data provided show that residues of avermectin are stable on frozen cottonseed stored for up to 14 months. This data should be adequate to insure the stability of avermectin residues in the almond and walnut nutmeat samples (generated for the magnitude of the residue study) which were stored frozen for up to 14 months.

The additional data provided show that residues of avermectin are stable on frozen pears strawberries and tomatoes stored for up to 35 months. This data should be adequate to insure the stability of avermectin residues in the almond hull samples (generated for the magnitude of the residue study) which were stored frozen for up to 23.5 months.

Deficiency 7a is resolved.

Deficiency 7b.

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 7b.

The registrant did not respond to this deficiency.

CBTS's Comments and Conclusions Concerning Deficiency 7b.

Deficiency 7b is not resolved.

Deficiency 9.

Pending the results from the requested storage stability study (see Detailed Conclusions, Storage Stability), the proposed almond nut, almond hull, walnut, and head lettuce tolerances may not be adequate. A final decision on the appropriate tolerance levels will be made after the storage stability data are submitted.

Registrant's Response to Deficiency 9.

No response was necessary.

CBTS's Comments and Conclusions Concerning Deficiency 9.

The storage stability data show adequate stability of avermectin residues in various matrices, which cover treenuts and head lettuce. **Deficiency 9 is resolved.**

Deficiency 10.

There are no feed items associated with the proposed use of abamectin on head lettuce, almond nuts, and walnuts and therefore these commodities should not create problems with secondary residues in meat, poultry, milk, and eggs. However, almond hulls are a feed item of ruminants. Pending the results from the requested storage stability study (see Detailed Considerations, Storage Stability), the established cattle meat and/or meat by-products tolerances may need to be revised. In any case, a new cattle fat tolerance of 0.015 ppm will need to be proposed in a revised Section F.

Registrant's Response to Deficiency 10.

The registrant has submitted a new Section F that includes a cattle fat tolerance of 0.015 ppm.

CBTS's Comments and Conclusions Concerning Deficiency 10.

The storage stability data show adequate stability of avermectin residues in various matrices, which cover treenuts and head lettuce. The existing cattle meat and meat by-product tolerances, in addition to the proposed cattle fat tolerance of 0.015 ppm, should be adequate to cover residues from the existing uses of avermectin, as well the proposed uses requested in PP#1F3973/1H5611. **Deficiency 10 is resolved.**

Attachment - Proposed label for application of AGRI-MEK 0.15 EC to almonds and walnuts

cc (without Attachment): circu., E. Haeberer (section head).

cc (with Attachment): PP#1F03973, RF, G.J. Herndon.

RDI: Section Head: E. Haeberer: 5/17/94,
Branch Senior Scientist: R.A. Loranger: 5/18/94.

H7509C: CBTS: G.J. Herndon: 305-6362: CM#2, Rm. 804C: 5/17/94.

Chemistry Review dated 5/19/94 (100-895 & 100-898)

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Pages 11 through 15 are not included in this copy.

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