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

NOV 16 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8F3649 - Avermectin B_1 (AVM B_1) on Celery - Evaluation of Analytical Method, Residue Data, and Metabolism - MRID Nos. 224705-223065; RCB Nos. 4094 and 4095

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and

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THRU: Charles L. Trichilo, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (TS-769C)

Merck Sharp and Dohme proposes the establishment of permanent tolerances for residues of avermectin B_1 (AVM B_1) (abamectin) and its delta 8,9-isomer on the raw agricultural commodity (RAC) celery at 0.035 ppm.

No permanent tolerances for residues of avermectin (AVM), an insecticide produced by a strain of Streptomyces avermitilis have yet been established. However, a permanent tolerance request of 0.005 ppm for residues of AVM B_1 and its delta 8,9-isomer on cottonseed is currently pending (PP#7F3500, memorandum of C. Deyrup, July 29, 1987).

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Permanent tolerances are also pending on the following (PP#8F3592/FAP#8H5550, memorandum of M. Kovacs, April 25, 1988):

Commodities	Tolerance
Citrus whole fruit (RAC)	0.005 ppm
Cattle - meat and meat byproducts	0.005 ppm
- milk	0.001 ppm
Dried citrus pulp	0.03 ppm
Citrus oil	0.10 ppm

Summary of Deficiencies Remaining to be Resolved

1. A revised label including mixing instructions and application directions (i.e., spray volume) is needed.

2. Polar degradates in celery are similar to those in citrus and cotton, and are of the same quantity (up to 70% of residues). Toxicological evaluation of these degradates may be of concern to the Toxicology Branch (TB).

3. A complete storage stability study is needed for validation of the residue data.

4. Based on the residue data presented, if validated, the petitioner needs to submit a revised Section F raising the proposed 0.035 ppm level to 0.05 ppm for AVM B_1 and its delta 8,9-isomer.

Recommendations

DEB cannot recommend for the requested AVM tolerances in celery (0.035 ppm) until the following outstanding deficiencies cited in Conclusion 2, 5, and 7 are satisfied, and TB evaluation on the toxicological significance of the polar degradates has been finalized.

Conclusions

1. The manufacturing process and resulting technical grade AVM B_1 are adequately documented. The formulated material to be used for celery is AGRIMEK~ 0.15 EC Miticide/Insecticide. This is a new name for AGRIMEC 0.15 EC, which contains inert ingredients cleared for use under section 180.1001.

2. The proposed use for celery states that the maximum rate will be 0.02 lb ai/A with a maximum of 10 applications per growing season, and harvesting no sooner than 7 days after the last application. However, the labeling does not include mixing instructions or directions for spray volume and coverage per acre. A revised Section B including these labeling directions will be needed.

3a. The nature of the residue in celery will be adequately delineated if more identification work is not needed for the polar degradates. At this time, the residues of concern in celery are AVM B_1a and its delta 8,9-isomer. The alpha 8-OHB_1a was identified as a part of the polar degradates, but contributes a maximum of 7 percent to the total residues (a maximum of 0.07 x 0.05 ppm = 0.0035 ppm less than analytically quantifiable). There are nine or more other entities contributing to the polar degradates (each < 10% or less than 0.005 ppm based on tolerance), although the polar degradates represent a substantial (as much as 70% of residues in the celery stalk at 7 days preharvest interval [PHI]) portion of AVM residues. TB may have concern regarding the safety evaluation of these polar degradates in celery. Evidence is presented to show the polar degradates to be similar to those found in cotton and citrus.

3b. No new animal metabolism data were presented in this submission. However, data were presented to show that the alpha 8-OH metabolite identified in celery is also identifiable in the liver tissue of rats.

DEB is still not convinced that a tritium label goat study is satisfactory for permanent tolerance setting. The nature of residues in animals is not adequately determined.

4. The analytical method used for celery is Method No. 10001, Revision 1, March 11, 1987; it is essentially the same as Method Nos. 1009R01 and 1009R02 previously validated for citrus. The current method was validated also by two outside laboratories. The analytical method is considered adequate for use as a monitoring method.

5. The residue data are adequate in number, geographic distribution, and are reflective of the proposed use to consider the setting of a tolerance level. However, the storage stability data (85% recovery at 3 months of freezer storage) are inadequate for validating the analytical data derived from samples stored up to 18 months. Further reporting of the ongoing storage stability study will be necessary.

6. Since celery is not used as feed or forage for cattle or poultry, there are no meat, milk, poultry, or egg considerations involved with this petition.

7. A request for a tolerance of 0.035 ppm residues of AVM on celery is insufficient, according to the data presented. If the residue data in 5. above is validated by storage stability, then a revised Section F requesting 0.05 ppm tolerance for AVM residues will be needed.

8. An International Residue Limit Status sheet is attached.

Detailed Considerations

Manufacturing Process

AVM B_1 is produced by a fermentation process using a strain of Streptomyces avermitilis. The technical product is extracted from the broth and purified by recrystallization. A more detailed description of the manufacturing process was given in DEB's May 1, 1986 review of EPA 618-OL (memorandum of L. Cheng). The technical product is a mixture of AVM B_1a and B_1b; the structures of these AVMs, which differ by the presence of an additional methylene group, are depicted in Attachment 2. The ratio of AMV B_1a to B_1b is > 80:20. The technical also contains about 1 percent of unidentified impurities related to the AVMs. TB is not concerned with the AVM-related impurities (PP#5G3287/FAP#5H5474, memorandum of W. Dykstra, March 3, 1986).

Formulation

The formulation to be used on celery is AGRI-MEK (formerly AGRIMEC) 0.15 EC Miticide/Insecticide which contains 2 percent AVM. One gallon of the emulsifiable concentrate (EC) contains 0.15 lb AVM B_1 as the active ingredient. AGRI-MEK 0.15 EC is the same formulation as MK-936 0.15 EC for which all inert ingredients were cleared for use under section 180.1001 (PP#6G3320, AVM on cottonseed, memorandum of A. Smith June 23, 1986).

This is also the same formulation proposed for use on citrus.

The label describes abamectin as:

> Avermectin B_1, [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-di (1-methylpropyl)-25-(1-methylethyl) avermectin A_1a)]

Proposed Use

Celery

AGRI-MEK 0.15 EC is an emulsifiable concentrate containing 0.15 lb ai/U.S. gallon which when mixed with water according to the Directions for Use, controls Liriomyza leafminers and spider mites (two-spotted and carmine) on celery.

Mix with water as indicated below and apply by ground equipment as a foliar spray to insure good upper and lower leaf coverage. Use 8 fl oz/A for low to moderate infestations and 16 fl oz/A for severe infestations. For spider mites, apply when mites first appear and repeat as necessary to maintain control. For leafminers, apply when adult flies are first observed and repeat applications at 7-day intervals or as necessary to maintain control.

Pests	fl oz/acre
Leafminers and Spider Mites	8.0 - 16.0

Use Restrictions - Celery

- Do not apply more than 160 fl oz on a given celery crop during its full cropping period.
- Do not apply within 7 days of harvest.

NOTE: AGRI-MEK 0.15 EC MAY BE USED WITHOUT ANY WETTING AGENT. WHEN NECESSARY TO IMPROVE THE WETTING OF FOLIAGE AND TO SMOOTH OUT SPRAY DEPOSITS, THE NONIONIC SURFACTANT LEAF ACT 80A IS RECOMMENDED.

The proposed use calls for a maximum 16 fl oz (0.02 lb ai/A) per application with a maximum of 10 applications or 160 fl oz (0.20 lb ai/A) per growing season. Applications are to be made by ground equipment and a 7-day PHI is specified.

The proposed use mentions that the desired quantity of formulation should be mixed with water according to "Directions for Use" or "Directions Below." No such directions are included on the label. Directions for mixing of the formulation with water and amounts of spray to be applied per acre will be necessary.

Nature of the Residue in Plants

A metabolism study of H^3 and C^{14} labeled AVM B_1 is presented. Foliar application of H^3-AVM was made at rates of 0.01 (0.5X) and 0.1 (5X) lb ai/A to immature and mature celery plants. A total of four applications at 7-day intervals, beginning 1 week after transplant, was made to the immature plants with sampling at 0, 1, 2, 4, and 6 weeks after the last application. A total of 10 foliar applications at 7-day intervals, beginning 3 weeks after transplant, was made to the mature plants with sampling at 0, 1, 3, 7, 14, and 21 days after last application. C^{14}-AVM was applied at the rate of 0.01 lb ai/A to mature celery plants in the same manner as for H^3-AVM. Sampling of the C^{14}-treated plants was performed just after the last of 10 applications (0 day) and 1 week later (7 days).

H^3-activity following application of 0.01 lb ai/A to immature celery resulted in 2740 ppb concentration in leaves and 550 ppb in stalks at 0-day, dissipating to 11.5 ppb in leaves and 4.1 ppb in stalks at 6 weeks after the last of four applications. Application of 0.1 lb ai/A H^3-AVM resulted in approximately 10X these concentrations of H^3-activity in immature plant leaves and stalks.

In a similar manner, the 0.5 and 5X rates of H^3-AVM resulted in H^3 residues in the mature celery following the last of 10 applications at 0.1 lb ai/A (5X) with concentrations of 2140 ppb in leaves and 400 ppb in stalks at 0-day, dissipating to 458 ppb in leaves and 50.9 ppb in stalks at 3 weeks.

C^{14}-activity following 0.75X application of C^{14}-AVM resulted as follows: 9570 ppb in immature plant leaves at 0-day and 519 ppb at 14 days; 1160 ppb in immature celery stalks at 0-day and 141 ppb at 14 days; 514 ppb in mature celery leaves at 0-day and 197 ppb at 14 days; 36.6 ppb in mature stalks at 0-day and 20 ppb at 14 days.

Upon extracting celery with acetone, the distribution of radioactivity in leaves and stalks is presented in Table 1. Chromatographic separation and identification of metabolites resulted in the data presented in Table 2.

The half-life of H^3-AVM in celery was determined to be approximately 5 to 9 days. The total radioactivity extracted with acetone from leaves ranged from 70 to 97 percent at 0-day with approximately 96 percent in immature leaves and 70 percent in mature leaves (Table 1). The extractable activity dissipates to 58 to 68 percent at 3 to 6 weeks in the leaves. A similar distribution is noted in celery stalks with less dissipation (75 to 83%) of acetone extractables at 3 to 6 weeks.

The data would indicate a fairly rapid degradation of AVM to polar constituents with moderate translocation of radioactivity into the stalk. This is substantiated by the distribution data recorded in Table 2. However, in Table 2 it is also obvious that AVM is rapidly metabolized in the leaves but much less rapidly degraded in the stalk. These data also show that the edible stalk of celery at maturity contains 50 to 65 percent of residues as polar degradates and 30 to 40 percent of the residues as AVM B_1a and its delta 8,9-isomer (1 to 8%).

Cochromatography of degradates with standards was performed on HPLC using a Zorbax C18 column (C18 HPLC) to elute the cyclohexane and aqueous fractions from the partitioning of the acetone extract. The polar, moderately polar, and B_1a fractions were also rechromatographed by HPLC using a Zorbax silica column (SIHPLC).

In this manner, it was possible to identify the alpha 8-OH compound, in addition to B_1a and the delta 8,9-isomer. The 8-OH compound was always less than 7 percent of the total residues as seen in Table 3. These tabulated results also show that in addition to the 8-OH compound, delta 8,9-isomer, and B_1a there are at least nine other unidentified but discrete major components comprising the total residues. Most significant is the fact that no residue, with exception of B_1a, contributes more than 10 percent to the total acetone-extractable residue from celery.

Using the H^3 (5X rate) AVM and the C^{14} (0.75X rate) AVM mature celery samples from a PHI of 7 days, characterization of the unextractable radioactivity was pursued. The data in Table 4 show that AVM residue levels in leaves and stalks ranged from 1134 to 20 ppb in the samples selected. After acetone extraction, most (58 to 81%) of the radioactive residue is removed. This leaves 19 to 42 percent of the

HED/DEB review dated 11/16/88 (100-895 & 100-898)

Page _____ is not included in this copy.

Pages 8 through 9 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Table 3. Estimation of the % contribution of identified and unidentified residues to the total residues from ^{3}H-avermectin B_1a-treated celery. CVP is known to consist of multiple components which were not examined in the present studies. Values in parenthesis are from Moye et al., PLM #1. Values marked "Remainder" or "Wash" consist of radioactivity above background not present as discrete components. Minor differences between sum of indicated values for individual moderately polar or polar residues and stated sum are due to rounding errors.

Fraction	Day 0 Stalk	Day 7 Stalk	Day 7 Leaf
Polars	21.7 (22.3)	41.0 (31.4)	60.2 (63.7)
CVP	11.9	30.3 [23.2][2]	46.2
C1	1.4	1.8 [1.4]	2.0
C2	5.3	2.5 [1.9]	3.0
C1	n.d	1.3 [1.0]	1.8
C2	n.d	2.0 [1.5]	1.6
Remainder	3.0	3.0 [2.3]	5.6
Moderately Polars	13.0 (18.5)	29.1 (19.2)	13.9 (18.8)
S1	0.4	0.5 [0.3]	0.4
S2	3.9	9.4 [6.2]	2.2
S3	1.5	0.0 [0.0]	2.2
S4[1]	2.9	6.9 [4.6]	2.1
S5	1.6	3.2 [2.1]	4.3
S6	0.0	0.0 [0.0]	1.7
Remainder	2.7	9.1 [6.0]	0.8
Avermectin B_1a	54.6 (56.6)	23.9 (44.0)	10.5 (14.8)
Delta-8,9 B_1a	2.7 (2.7)	1.1 (5.4)	3.4 (2.7)
Wash	8.0	4.9	12.0

[1]S4 is 8-alpha-hydroxy B_1a (8-OH).
[2]Calculated from (Values) - The values in brackets represent the estimated contribution of individual B_1a residues for an undegraded sample of Day 7 celery stalk using the relative proportions of individual polar and moderately polar residues obtained for the apparently degraded sample of Day 7 stalk and the relative proportions of total polar and moderately polar residues obtained for a fresh sample of Day 7 stalk (Moye et al., PLM #1). Thus for CVP, 30.3/41.0 x 31.4 = 23.2%; for S1, 0.5/29.1 x 19.2 = 0.3, etc.

Table 4
Avermectin Residues in Mature Celery Following Application of:

		^{3}H-Avermectin at 0.10 lb/acre	^{14}C-Avermectin at 0.015 lb/acre
Leaves		Mean ppb	Mean ppb
Day[a]	0	2140	514
	1	2170	
	3	1650	
	7	1134	197
	15	554	
	22	458	
Stalks			
Day[a]	0	400	36.6
	1	331	
	3	204	
	7	238	20.0
	15	43.8	
	22	50.9	

[a]Days after last avermectin application.

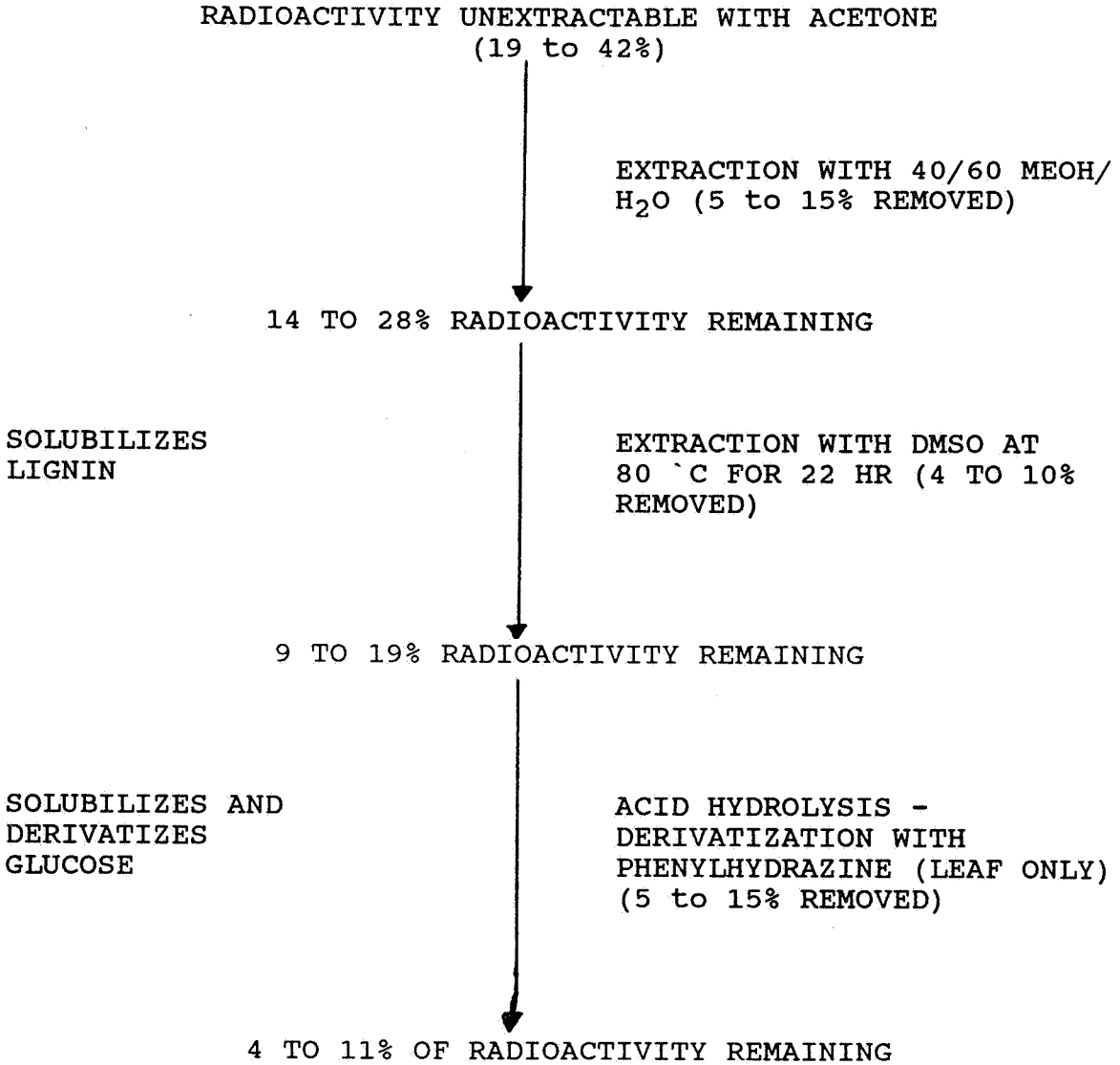
radioactive residue in the extracted plant material (485 to 7 ppb),based on original sample weight. The nonextractable activity was subjected to MeOH/H_2O extraction and solubilization of lignin with DMSO. These extracts were subjected to HPLC and the remaining celery mats were examined to determine the quantity of radioactive residue as glucose.

Figure 1 shows the distribution of radioactivity in the unextractable celery. Characterization of this radioactivity shows trace amounts of AVM B_1a and a polar component. Up to 15 percent of the activity remaining in the celery mats is incorporated into glucose. The remaining unextractable residue (4 to 11%) probably represents the incorporation of AVM radioactivity in smaller (2 to 5 carbon) fragments of natural products.

In summary, metabolism of radiolabeled AVM in celery adequately describes the nature of the residue as AVM B_1a, the delta 8,9-isomer, the alpha 8-OH compound and polar degradates (nine or more entities, all less than 10% of residue). The polar degradates give rise to 2 to 6 carbon

Figure 1

SUCCESSIVE REMOVAL OF ^{14}C AND ^{3}H UNEXTRACTABLE RESIDUES FROM CELERY[a]



[a]Expressed as percent of total residue.

fragments (natural products) including glucose and its polymers. The residues of concern are concluded to be the parent compound and its delta 8,9-isomer at this time.

Nature of the Residue in Animals

No animal metabolism studies were submitted with this petition.

Rat metabolism data were submitted in conjunction with PP#4F3065 (Avermectin on Range and Pasture Grass, memorandum of F. Boyd, September 13, 1984), PP#5F3287 (Avermectin on Citrus, memorandum of L. Cheng, December 19, 1985) and PP#78G3468 (Avermectin on Citrus, memorandum of L. Cheng February 11, 1987).

The major metabolite identified in rats was 3" desmethyl AVM with a minor metabolite < 10 percent of the total radioactive residue identified as 24-hydroxymethyl AVM.

The delta 8,9-isomer is a photolysis product of AVM and has been found on oranges, cotton leaves, and celery leaves. It is not found in animals. Therefore, the petitioner investigated the metabolism of the delta 8,9-isomer by rats. Metabolites analogous to those detected in the AVM study were found, namely the corresponding 24-hydroxymethyl and 3" desmethyl isomers. The delta 8,9-isomer and its metabolites accounted for 92 to 98 percent of the extractable activity from rat tissues.

In this submission a minor celery metabolite, alpha 8-OH AVM was identified. This metabolite has not been found in animals. Using chromatography of rat liver extract with an 8-OH standard as well as a reverse isotope dilution assay (RIDA), an investigation is reported as to whether H^3-alpha-8 OH B_1a is produced as a metabolite of H^3 AVM B_1a in rats. Approximately 3.4 percent of the radioactive residue in liver tissue from male rats sacrificed 2 days after treatment with 1.4 mg/kg of H^3 AVM is alpha 8-OH B_1a. Thus the 8-OH compound is a metabolite in the rat.

Goat metabolism studies were submitted with PP#5F3065 and PP#5G3287.

The major metabolite identified in goat tissues was 24-hydroxymethyl AVM also known as metabolite A in both the rat and goat studies. No metabolite B (3" desmethyl AVM), the major metabolite found in rats, was reported in any tissues. The petitioner cites studies which report that ivermectin (22,23-dihydro AVM), which is registered for use on animals, gives rise to the 3" desmethyl analog of AVM in swine.

DEB concluded that the goat metabolism study, which used ^{3}H-AVM, was adequate to support a temporary tolerance on citrus, meat, and milk (PP#7G3468, memorandum of L. Cheng, February 11, 1987).

However, DEB is not convinced that the tritium label is suitable for the establishment of permanent tolerances.

Analytical Method

The analytical method employed is Method No. 10001, Revision 1, March 11, 1987, "HPLC-Fluorescence Determination of Avermectin B_1 and its Delta 8,9-Isomer in Celery." This method is essentially the same as Nos. 1009RO1 and 1009RO2 used for analysis of citrus. The citrus method has been validated by ACS/COB/BEAD (J. Wilner ACS/COB September 30, 1987 memorandum to E. Zager, DEB).

The limit of sensitivity is 5 ng/g (5 ppb) and the limit of detection is 2 ng/g (2 ppb) for B_1a and its delta 8,9-isomer. Recoveries averaged 78 to 92 percent for B_1a at 50 to 2.5 ppb fortification. For the delta 8,9-isomer, recoveries over the same range of fortification averaged 52 to 57 percent.

The residue data presented in this submission were generated by two different analytical laboratories, Hazleton Laboratories America, Inc., Madison, Wisconsin and Analytical Development Corporation, Colorado Springs, Colorado. The outside laboratories' validation of the method and its similarity to the EPA-validated method for citrus, obviates the need for evaluation of Method No. 10001, Revision 1, by the COB/EPA lab.

Residue Data for Celery

A total of 16 field trials are reported from 1986 to 1987 in four States, Florida (7), California (7), Texas (1), and Michigan (1). All trials employed X (0.02 lb ai/A) and 2X rates, according to proposed labeling, with 10 applications at weekly intervals and sampling for dissipation of residues, primarily at 0, 1, 3, 5, 7, and 14 days after last application. Six of the field trials (including an aerial application) employed AGRI-MEK 0.15 with and without Leaf ACT 80A surfactant, as recommended on the proposed label. A single aerial trial is reported from South Bay, Florida in 1987; all other 15 trials employed ground application. The proposed label restricts application to ground equipment. The proposed labeling does not include mixing and application volume instructions; however, all trials, with exception of two, report the use of 50 to 75 gal/A (GPA) of spray mixture.

The two exceptions are the aerial application at 3 GPA and the Texas trial where 20 GPA were applied from a tractor-mounted boom sprayer. Labeling instructions for spray mixture and spray volume will be needed in a revised Section B. A total of 10 varieties of celery are included in these 16 trials.

These field trial data including all raw, summary, environmental, and quality assurance considerations are presented in 18 bound volumes. Pertinent data for tolerance setting are summarized in Table 5. These data show a sizeable dissipation from 0-day (maximum of 645 ppb, Monterey, CA) to a 7-day residue of 35.6 ppb (maximum from Monterey, CA). There is little difference in residue levels with or without the surfactant, Leaf Act. The Oxnard, CA trial with a PHI of 3 days had a maximum level of 17.5 ppb, comfortably within the range of 7-day PHI residues.

Data on trimmed versus untrimmed celery are presented, but not included in Table 5. These data show a significant difference in residues at 0-day (considerably higher in the untrimmed samples), with no significant difference in residues at 70-day PHI due to trimming of the RAC.

The residue data are consistent with the proposed labeling. These data are adequate in number of trials and geographic distribution to be representative of environmental differences across two growing seasons and the celery-growing area.

Storage Stability Data

A storage stability study protocol for 2 years' duration is reported. The extent of storage time reported with this presentation is 3 months. The average recovery of B_1a from celery after 3 months' storage is 85 percent, at a 10 ppb fortification level. However, more than 50 percent of the above residue trial data are derived from samples of celery held in frozen storage 6 to 18 months prior to analysis.

It is concluded that complete reporting from the ongoing storage stability study will be necessary before the above residue data, summarized in Table 5, can be validated.

Meat, Milk, Poultry, and Eggs

Since celery is not utilized as a feed, nor is it foraged, by poultry and livestock there are no meat, milk, poultry, and egg considerations involved with the tolerance request.

Table 5

Summary of Residue Data (ppb) for Abamectin on Celery Treated at 0.02 lb ai/A, with 10 Applications

Trial Location	Interval To Harvest (Days)	Range of $B_1a/8,9$ in Untrimmed Celery (ppb) Without Leaf Act	With Leaf Act
1986 Field Trials			
Belle Glade, FL	0	75.2-108	
	7	7.2-18.1	
Belle Glade, FL	0	20-131	
	7	NQ[1/]	
Zellwood, FL	0	128-142	
	7	NQ-7.9	
Belle Glade, FL	0	9.4-65.2	
	7	NQ	
Oxnard, CA	0	39.7-66-3	
	7	ND[2/]-6.3	
Santa Maria, CA	0	205-574	
	7	8.8-15.8	
Oxnard, CA	0	63.2-88.5	
	7	6.6-10.6	
Salinas, CA	0	32.2-65.2	
	7	NQ-7.2	
Monterey, CA	0	184-645	
	7	8.7-35.6	
1987 Field Trials			
Donna, TX	0	398-700	
	7	7.8-8.7	
Zellwood, FL	0		NQ-7.6
	7		ND

1/NQ = Not quantitated, value between 2 and 5 ppb.
2/ND = Not detected, value less than 2 ppb.

Table 5

Summary of Residue Data (ppb) for Abamectin on Celery Treated at 0.02 lb ai/A, with 10 Applications (cont'd)

Trial Location	Interval To Harvest (Days)	Range of $B_1a/8,9$ in Untrimmed Celery (ppb)	
		Without Leaf Act	With Leaf Act
1987 Field Trials			
Oxnard, CA	0	86-205	126-212
	3	6.3-17.5	NQ-10.6
Santa Maria, CA	0	123-160	117-192
	7	NQ	NQ-10.1
Zellwood FL	0	225-386	214-308
	7	7.2-29.1	NQ-18.2
South Bay, FL*	0	105-198	125-144
	7	11.1-23.1	8.8-12.5
Marcellus, MI	0	78.8-134	76.2-121
	7	5.6-22.4	5.7-9.6

*Aerial application by helicopter.

Other Considerations

Neither Codex, Canada, nor Mexico have established tolerances for residues of AVM on celery. There will be no compatibility problem if the proposed tolerance on celery is established. An International Residue Limit Status Data sheet is attached.

Attachment 1 - International Residue Limit Status
Attachment 2 - Avermectin B_1a and B_1b Structure

cc: TB, Circu, RF, PP#8F3649, Reviewer-Boyd, PMSD/ISB, PM#15

RDI:J.H.Onley,11/3/88;R.D.Schmitt,11/3/88
TS-769:F.Boyd:CM#2:Rm804:X77484:11/2/88: - Edited by vg
53868:Boyd:C.Disk:KENCO:11/04/88:DD:vo:ek:rw

ATTACHMENT 1

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL AVERMECTIN

CODEX NO. _____

CODEX STATUS:

☑ No Codex Proposal Step 6 or above

Residue(if Step 8): _____

Crop(s)	Limit (mg/kg)

PROPOSED U.S. TOLERANCES:

Petition No. PP#8F3649

RCB Reviewer F. Boyd

Residue: AVERMECTIN B, and its delta 8,9-isomer

Crop(s)	Limit (mg/kg)
Celery	0.035

CANADIAN LIMITS:

☑ No Canadian limit

Residue: _____

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

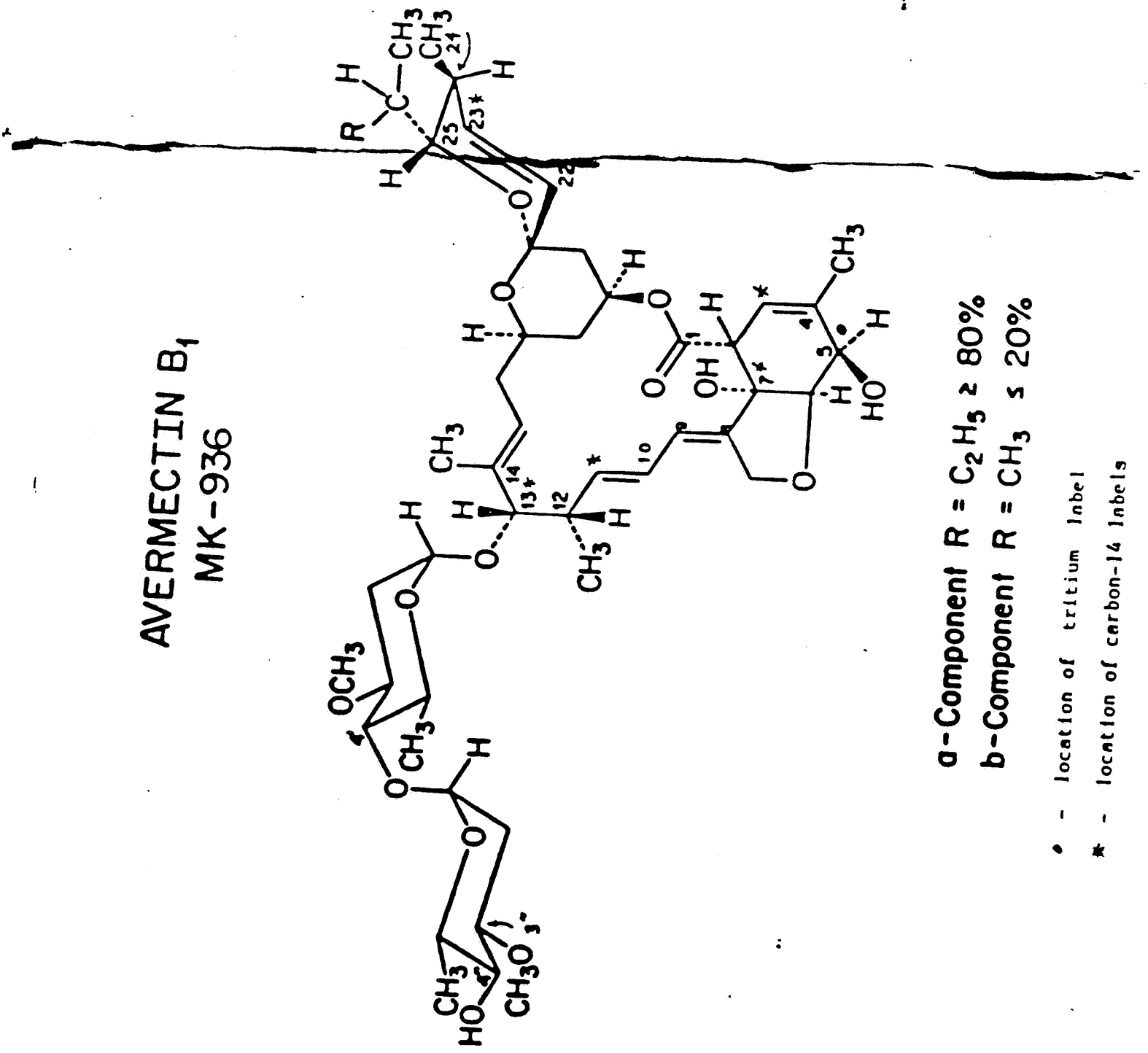
☑ No Mexican limit

Residue: _____

Crop(s)	Limit (mg/kg)

NOTES:

ATTACHMENT 2
PP#8F3592/FAP#8H5550



AVERMECTIN B_1
MK-936

a-Component R = C_2H_5 ≥ 80%
b-Component R = CH_3 ≤ 20%

• - location of tritium label
* - location of carbon-14 labels