PP# 3787

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

SEP 14 1995

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: PP#1F3787. Abamectin (Avermectin B_1) for Use in/on Pears. Results of Beltsville's Method Validation (Memo of E. Greer, Jr. and D. Wright, Jr. dated 5/15/95). No MRID#. DP Barcode# D215484. CBTS# 15592.

From: G. Jeffrey Herndon, Chemist
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

Through: Michael Metzger, Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

To: George LaRocca/Adam Heyward, PM# 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

and

William Hazel, Head
Registration Section
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

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

method was sent back to ACL (memo of G.J. Herndon dated 10/21/94) and the results have been received (memo of E. Greer, Jr. and D. Wright, Jr. dated 5/15/95 - see Attachment I). The purpose of this memo is to address the comments/conclusions raised in the most recent ACL memo.

Conclusions and Recommendations

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).** At this time, however, **CBTS continues to recommend against the issuance of a permanent tolerance on pears.** However, a DRES run can be initiated at a level of 0.02 ppm on pears.

Detailed Considerations

The following Comments were cited by EPA's Analytical Chemistry Laboratory in Beltsville in the memo of E.S. Greer, Jr. and D. Wright, Jr. dated 5/15/95.

Comment #1

The method uses an avermectin B1a calibration curve to quantitate avermectin B1b. Although this technique will probably give acceptable results, it is analytically incorrect. It has also been found to produce a positive bias for the B1b level in spiked samples. This has been demonstrated by data submitted by the registrant and in recovery studies performed at ACL.

CBTS's Comments and Conclusions Concerning Comment #1

In a submission of 3/10/93 in response to the analytical method deficiencies cited in the J. Stokes review of 4/16/92 (see memo of G.J. Herndon dated 12/16/93), Merck provided the following response to a similar concern raised by ACL.

> Avermectin B1b is at most 20% and usually less than 10% of the avermectin content in the formulation and in the incurred residue. Avermectin B1a is at least 80% and usually more than 90% of the avermectin residue. Consequently, the B1b residues are usually not quantifiable and generally not even detectable at the PHI, no matter which calibration curve is used.
>
> B1a and B1b differ by one methylene group connected at the C-25 position. Although B1a and B1b are resolved chromatographically in a reverse phase HPLC system, the quantitation is based on the fluorescent derivative response. The fluorescent part of the molecule is in the

extended conjugation associated with the aromatized ring, which is the same for avermectin B1b and B1a. We have demonstrated the equivalence of the response for B1b to B1a and have previously provided documentation (see Attachment II). The pear method uses the same fluorescent derivative as discussed in Attachment II and the matrix does not present any interferences to affect the fluorescence sensitivity, as illustrated in the validation of the method for B1a and B1b.

Although not 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 up to approximately 100 ng/g (ppb) total. Since the proposed tolerance level in pears is 20 ppb (i.e. <100 ppb), and the pear matrix has been shown not to present any interferences that would affect the fluorescence sensitivity, CBTS considers Merck Method No. 8000, Rev. 4 to be an adequate method for the enforcement of avermectin residues on pears. **CBTS considers Comment #1 resolved.**

Note: If the need arises to raise the tolerance level on pears above 100 ppb, or if Method No. 8000, Rev. 4 is utilized for other commodities (especially other commodities whose tolerance levels exceed 100 ppb or if interferences are seen or expected), Merck will need to revise the method and provide additional validation.

Comment #2

A purified analytical standard of avermectin is not available from the registrant. The registrant supplies a dilute glycerol formal solution of avermectin for this analysis. This issue is addressed in the TMV pre-review included with this report (see Attachment II).

CBTS's Comments and Conclusions Concerning Comment #2

In a submission of 3/10/93 in response to the analytical method deficiencies cited in the J. Stokes review of 4/16/92 (see memo of G.J. Herndon dated 12/16/93), Merck provided the following response to a similar concern raised by ACL.

Abamectin drug substance (bulk technical or solid state) has two characteristics which make it unsuitable for routine use as a reference standard in laboratory analyses - it is a mixed, non-stoichiometric solvate and it is chemically unstable.

Abamectin drug substance contains up to 7.0% ethanol and 17.0% water. These solvents are not present in a

fixed ratio (arising from defined solvates) and are therefore subject to facile variation (loss of ethanol and/or water, or uptake of water) depending on the environment (temperature and humidity) in which the drug substance is stored and handled. In addition, abamectin is not chemically stable and is subject to solid-state oxidative decomposition.

Both of the unfavorable characteristics have been overcome through the development of an abamectin glycerol formal solution for use as a routine laboratory reference standard. Abamectin, and associated ethanol and water, are completely soluble in glycerol formal at the concentration employed. Glycerol formal is non-volatile and non-hygroscopic, and therefore, solvation variations after dissolution of abamectin are eliminated. In addition, glycerol formal has desirable stabilization properties and inhibits the oxidation degradation of abamectin.

When the abamectin glycerol formal solution was prepared, the B1a and B1b isomer concentrations were accurately determined versus a specially prepared solid reference lot which is no longer available (because of the unfavorable characteristics previously mentioned). The solution was subdivided into individual amber glass containers, each with an amount convenient for multiple analyses, and stored frozen to insure stability. The solution is dilute, permitting the accurate weighing of a convenient amount which does not require excessive dilution to prepare working standards with concentrations appropriate for use in trace residue analyses. Refrigerated, or preferably frozen, shipment and storage is desirable to maintain the standard's integrity.

The abamectin glycerol formal solution standard is suitable for its intended use, and has been successfully employed by several Merck laboratories and numerous contract laboratories which conduct residue analyses both in the US and internationally. The glycerol formal standard solution is of defined purity and sufficiently concentrated for all residue determinations, including the method described for pears. Finally, there is no solid abamectin standard that is available or suitable for use.

As might be expected from the similarities in the structure, the avermectin B1a delta 8,9-Z isomer has similar characteristics. Consequently, a solution of avermectin B1a delta 8,9-Z isomer standard in glycerol formal has been prepared and is used. However, we have determined that the avermectin B1a delta 8,9-Z isomer

yields the same derivative as is obtained from the parent avermectin B1a so that it is not necessary to use the delta 8,9-Z isomer standard, except during the initial validation of the method

Based on a conversation with Merck (phone conversation with L. Grosso of 9/5/95), Merck is in the process of formulating a neat avermectin standard. However the work has not been completed. Based on the inherent properties (unstable, hygroscopic) of the abamectin standards, the concentration levels of the supplied standards relative to the proposed tolerance level in pears (0.02 ppm), and the process by which abamectin is manufactured (fermentation process using a strain of Streptomyces avermitilis), CBTS considers the supplied standard solutions in glycerol to be adequate for enforcement purposes, **until a neat avermectin standard is formulated. CBTS considers Comment #2 resolved.**

Comment #3

The method states that all standards should be stored in a freezer at -10°C, but the EPA repository at RTP ships this material at ambient temperature. The "History of Standard" sheet that the repository includes with the standard states that the material must be kept frozen. ACL feels that the standard as supplied by the repository is not suitable for enforcement purposes because of the potential for degradation. ACL used an analytical standard solution supplied by the registrant that was received packed in dry ice.

CBTS's Comments and Conclusions Concerning Comment #3

This Deficiency is not a fault of the registrant. The RTP repository is not under the purview of the Office of Pesticide Programs. **CBTS considers Comment #3 resolved.**

Comment #4

It was stated in a previous TMV report that the method and the "Suggestions to the Analyst" document should be consolidated so that all of the information needed to run the procedure is contained in a single document. It appears that the registrant simply tacked the two documents together, so that the analyst still has to refer back and forth to two separate sections while conducting the analysis.

CBTS's Comments and Conclusions Concerning Comment #4

The registrant should integrate the two documents, as per ACL's request. **CBTS does not consider Comment #4 resolved.**

Comment #5

ACL performed a validation of Merck method #8000 for the analysis of avermectin on pears in FY 91. Numerous problems (included those listed above) were associated with the method and were addressed in the TMV report. The present method (#8000 rev. 4) is almost identical to method #8000 and still includes most of the same deficiencies. The TMV pre-review should be referred to for a detailed discussion of these issues.

CBTS's Comments and Conclusions Concerning Comment #5

These items are addressed in the current memo and in the memo of G.J. Herndon dated 12/16/93. **CBTS considers Comment #5 resolved.**

Comment #6

The Sigma brand pectinase specified in the method is no longer available. Sigma supplies a substitute (Cat. No. 9032-75-1). The registrant was notified of this situation and concurred with the use of this alternate product. The method should be modified to reflect this change.

CBTS's Comments and Conclusions Concerning Comment #6

The registrant should modify the method to reflect the alternate pectinase product. **CBTS does not consider Comment #6 resolved.**

Comment #7

The limit of detection was estimated to be 0.003 ppm calculated as three times the baseline noise.

CBTS's Comments and Conclusions Concerning Comment #7

Comment #7 is not a deficiency.

Comment #8

A set of six samples can be analyzed in three 8 hour days including instrumental analysis time.

CBTS's Comments and Conclusions Concerning Comment #8

Comment #8 is not a deficiency.

Comment #9

This method generally meets the requirements in Subdivision O, Section 171-4(b) of the Residue Chemistry guidelines provided the above comments and those included in the attached pre-review are addressed.

CBTS's Comments and Conclusions Concerning Comment #9

Based on the previous comments, **CBTS considers Comment #9 resolved.**

Attachment I - Tolerance Method Validation of Abamectin on Pears, memo of E. Greer, Jr. and D. Wright, Jr. dated 5/15/95.

Attachment II - TMV Pre-Review of Abamectin on Pears, B.J. Puma, 1/27/95.

cc (without Attachments): circu., SF, E. Haeberer (section head), H. Hundley (7503W).

cc (with Attachments): PP#1F3787, RF, G.J. Herndon.

RDI: TPSII Team: 9/11/95,
Branch Senior Scientist: R.A. Loranger: 9/11/95,
Branch Chief: M. Metzger: 9/12/95.

H7509C: CBTS: G.J. Herndon: 305-6362: CM#2, Rm. 804C: 9/7/95.

Attachment I

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

Analytical Chemistry Section
Building 306, BARC-East
Beltsville, Maryland 20705

MAY 15 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 9F03787. Tolerance Method Validation of Abamectin (Avermectin B1) on Pears

FROM: Everett S. Greer, Jr., Team Leader
Dallas Wright, Jr., Chemist
Analytical Chemistry Section

THRU: Harvey K. Hundley, Head
Analytical Chemistry Section

THRU: Donald A. Marlow, Chief
Analytical Chemistry Branch

TO: Elizabeth Haeberer, Head
Tolerance Petition Section II
Chemistry Branch I-Tolerance Support
Health Effects Division

INTRODUCTION

The Analytical Chemistry Section was requested by the Chemistry Branch I, Tolerance Support to conduct a method validation on the insecticide/miticide abamectin. Merck & Co., Inc. Method No. 8000.Rev. 4 ("HPLC-Fluorescence Determination for Avermectin B1 and 8,9-Z-Avermectin B1 in Pears and Apples") was used for the analysis of pears spiked with avermectin B1a at the 0.01 ppm and 0.02 ppm levels.

METHOD SUMMARY

Pear samples are treated with pectinase followed by extraction with 50:50 acetonitrile/water. The aqueous extract is cleaned up on a C-8 SPE column and the avermectin B1 is eluted with acetonitrile. The acetonitrile solution is extracted with hexane and the hexane fraction is further cleaned up on an aminopropyl SPE column. The analyte is eluted with a methylene chloride/acetone mixture. The eluant is taken to dryness and

derivatized to a fluorescent compound with dimethylformamide, trifluroacetic anhydride and 1-methylimidazole. The reaction mixture is cleaned up on a silica SPE column, and the eluant is taken to dryness and dissolved in methanol. The analyte is quantitated by HPLC using a fluorescence detector.

COMMENTS

1. The method uses an avermectin B1a calibration curve to quantitate avermectin B1b. Although this technique will probably give acceptable results, it is analytically incorrect. It has also been found to produce a positive bias for the B1b level in spiked samples. This has been demonstrated by data submitted by the registrant and in recovery studies performed at ACL.

2. A purified analytical standard of avermectin is not available from the registrant. The registrant supplies a dilute glycerol formal solution of avermectin for this analysis. This issue is addressed in the TMV pre-review included with this report.

3. The method states that all standards should be stored in a freezer at -10° C.,but the EPA repository at RTP ships this material at ambient temperature. The "History of Standard" sheet that the repository includes with the standard states that the material must be kept frozen. ACL feels that the standard as supplied by the repository is not suitable for enforcement purposes because of the potential for degradation. ACL used an analytical standard solution supplied by the registrant that was received packed in dry ice.

4. It was stated in a previous TMV report that the method and the "Suggestions to the Analyst" document should be consolidated so that all of the information needed to run the procedure is contained in a single document. It appears that the registrant simply tacked the two documents together, so that the analyst still has to refer back and forth to two separate sections while conducting the analysis.

5. ACL performed a validation of Merck method No. 8000 for the analysis of avermectin on pears in FY 91. Numerous problems (included those listed above) were associated with the method and were addressed in the TMV report. The present method(No. 8000, Rev. 4) is almost identical to method No. 8000. and still includes most of the same deficiencies. The TMV pre-review should be referred to for a detailed discussion of these issues.

6. The Sigma brand pectinase specified in the method is no longer available. Sigma supplies a substitute (Cat No. 9032-75-1). The registrant was notified of this situation and concurred with the use of this alternate product. The method should be modified to reflect this change.

7. The limit of detection was estimated to be 0.003 ppm calculated as three times the baseline noise.

8. A set of six samples can be analyzed in three 8 hour days including instrumental analysis time.

9. This method generally meets the requirements in Subdivision O, Section 171-4(b) of the Residue Chemistry guidelines provided the above comments and those included in the attached pre-review are addressed.

Commodity	Chemical Added	PPM Added	PPM Found	Percent Recovery
Pears	Avermectin B1a	Control	N.D.	-
		Control	N.D.	-
		0.01	0.0104	104
		0.01	0.0096	96
		0.02	0.0128	64
		0.02	0.0154	77

Modifications to method (major or minor):

See comments section of report.

Special precautions to be taken:

None

Source of analytical standard:

Merck & Co., Inc.

If derivatized standard is used, give source:

Prepared as per method

Instrumentation for quantitation:

HPLC/Fluorescence detection

Instrumentation for confirmation:

N/A

If instrument parameters differ from those given in the method, list parameters used:

A Brownlee RP-18, 1.5 cm x 3.2 mm Id. guard column was used instead of the 3 cm guard column specified in the method. This resulted in shorter retention times than those reported by the registrant.

Commercial sources for any special chemicals or apparatus:

N/A

Additional comments:

See report

Chromatograms:

Copies of controls, low and high level fortifications, and standard curve included.

Attachment II

TMV Pre-Review of Abamectin in/on Pears

Reviewer: Bart J. Puma BJP

Date: January 27, 1995

Project Code: B95-13

Analyte: Avermectin B_{1a} (the main component of abamectin)

Method: HPLC-Fluorescence Determination for Avermectin B_1 and 8,9-Z-Avermectin B_1 in Pears and Apples, Merck & Co., Inc., Method No. 8000, Rev. 4

An earlier version of Method No. 8000 was tested at ACL (see project file B90-38) on pear homogenate samples fortified with 0.0, 35.0, and 70.0 ppb of abamectin (a mixture of two avermectin B_1 homologs containing not less than 80% avermectin B_{1a} and not more than 20% avermectin B_{1b}) and 0.0, 35.0, and 70.0 ppb of the 8,9-Z isomer of avermectin B_{1a}. (Note: In this pre-review, the abbreviations B1a, B1b, and 8,9-Z-B1a stand for avermectin B_{1a}, avermectin B_{1b}, and 8,9-Z-avermectin B_{1a}, respectively.) Based on the petitioner's assay of the abamectin standard, the samples spiked with 35.0 and 70.0 ppb abamectin received 32.6 and 65.2 ppb B1a and 2.4 and 4.8 ppb B1b, respectively. Although recoveries of B1a, B1b, and 8,9-Z-B1a were satisfactory and no interferences were detected at the 1 ppb level for the individual analytes in unfortified samples, our petition method validation (PMV) report of 2/29/92 advised Chemistry Branch I - Tolerance Support (CBTS) of several problems with accepting the method for tolerance enforcement (see items 1,2,3,4, and 6 under Comments in the PMV report).

The petitioner's revised method was submitted with detailed responses to the method deficiencies outlined in our PMV report. CBTS considers the deficiencies resolved and has asked ACL to conduct a PMV of the revised method on pear samples fortified with 0, 10, and 20 ppb B1a in order to assess recoveries of B1a (only) at lower levels than previously tested. The revised method retains the analytical procedure of the earlier version, but includes additional data demonstrating its performance at lower than previously validated levels of B1a, B1b, and 8,9-Z-B1a in pears and extending its applicability to these residues in apples. [Note: Neither version of the method is supported by independent laboratory validation data, but the need for such data is a policy matter beyond the scope of this pre-review.]

Since the analytical procedure has not changed, I would expect the revised method to provide results similar to those obtained in our earlier PMV, even at the lower B1a fortification levels requested for the new PMV. However, I believe that neither the revised method nor the petitioner's responses to our

comments resolve the deficiencies discussed in our PMV report, except for the nomenclature problem noted in Comment 1. In order to arrive at a common understanding of what is needed in an abamectin tolerance enforcement method, I believe that we at EPA should get together to discuss the remaining method deficiencies among ourselves and then with representatives of Merck & Co. The following comments are numbered to correspond to the items under Comments in our PMV report and are intended to supplement them, not to supplant them.

1. The anomalous term "8,9 isomer of abamectin" in the earlier method has been replaced by the recommended names 8,9-Z-avermectin B_{1a} and 8,9-Z-avermectin B_{1b} in the revised method. A similar nomenclature change is needed in EPA's expression of abamectin tolerances in 40 CFR §180.449, §185.300, and §186.300, wherein tolerances are given for "combined residues of avermectin B_1 and its delta-8,9-isomer", which expression is incorrect both in chemistry and grammar.

2. The need for purified analytical reference standards is so fundamental in analytical chemistry that it should not be necessary to explain it, especially as applied to a proposed regulatory method! Merck has offered excuses for failing to provide proper reference standards, but has not explained how, in the absence of such standards, EPA (or anyone else, including Merck) can assay the certified abamectin standard solutions that were submitted to ACL and the EPA pesticides repository. Merck says that when the abamectin standard solution in glycerol formal was prepared, the concentrations of B1a and B1b were accurately determined versus a specially prepared reference lot which is no longer available. Does this mean that no other specially prepared reference lot is available? If so, how does Merck retest the standard solutions yearly as indicated in a letter sent to ACL with certificates of analysis for the standard solutions of abamectin and 8,9-Z-B1a? If the EPA repository is to supply regulatory laboratories with dilute standard solutions of abamectin in glycerol formal for use in enforcing tolerances, EPA will need a suitable reference standard and methods for assaying both the pure material and the dilute abamectin standards in order to ensure the integrity of the latter. The fact that the latest abamectin and 8,9-Z-B1a standard solutions currently available from the EPA repository were provided by Merck in 1988 indicates that it would be ~~it would be~~ difficult, if not impossible, to provide legitimate scientific support for any regulatory action based on the use of these standards for residue analysis.

One of the reasons Merck gives for using glycerol formal as solvent for the standard solutions is that it is non-hygroscopic. This is strange because glycerol formal is listed in various suppliers' catalogs as either hygroscopic (Aldrich Chemical; TCI America) or moisture sensitive (Lancaster Synthesis) and is reported to be hygroscopic in Dictionary of Organic Compounds, 5th Ed., Vol. 2, Item D-07685. What is the evidence to support Merck's claim that glycerol formal is non-hygroscopic?

3. Using the B1a calibration curve to quantitate B1b residues as proposed in the method is bad science and its acceptance in a regulatory method would establish a bad precedent because it is analytically incorrect and introduces a positive bias of about 10% in the results for B1b residues. Although the effect of this positive B1b bias on the overall result for abamectin is small (because B1b is at most 20% of the incurred residue), using a technique with a known bias toward high results would be difficult to support in an enforcement action against a sample slightly above the tolerance level. Acceptable techniques are readily available for B1b quantitation in the method. Merck should use one of these instead of basing the determination of B1b on the calibration curve for another compound that produces a different analytical response than B1b.

4. In response to our recommendation to consolidate the method and "Suggestions for the Analyst...." into a single document containing all the information needed to apply the method, Merck claims to have incorporated the suggestions for the analyst into the text of the method. However, it appears to me that the two documents (slightly revised to use the standard name for 8,9-Z-B1a and to add validation data for apples and pears at lower residue levels) have merely been tacked together, so that it requires the user to check instructions in at least two places for each step of the procedure. Furthermore, discrepancies between the original documents have not been eliminated, as in the storage temperature for standards or the sample fortification technique, and the revision still lacks the item formerly called "protocol AB-P1" and now referenced as "general guideline AB-P1".

6. The need to repeat analyses of samples giving residue responses above the narrow range of the calibration curve would increase the total analysis time for these samples to more than 24 hours. Initially, the method gave no instructions for reserving and storing derivatized sample and standard solutions (this may have been covered in "protocol AB-P1"), so it appeared that repeating an analysis would require derivatization of the half of the cleaned up sample solution that is reserved just before the initial derivatization. The only information then given on repeating an analysis was in this sentence from the "Suggestions..." document: "If the peak height for a sample is larger than the highest standard, this solution should be diluted and reanalyzed (see protocol AB-P1)." Now that the revised method says to reserve the derivatized solutions in a freezer until quantitation is completed, and to dilute and reinject samples which have peak heights above the standard, it can be seen that the "sample" referred to in this quotation from "Suggestions..." relates to the derivatized sample solution rather than the sample itself or the reserved half of cleaned up sample extract separated before derivatization of the other half, but additional information is needed to know whether derivatized sample and standard solutions may be diluted and reinjected after storage out of the freezer, such as in vials of an LC autoinjector, for overnight or longer. Although dilution and reinjection would

shorten the time needed for reanalysis (compared to starting again with the derivatization), reanalysis would be needed for any samples with abamectin residues somewhat above one-half the proposed tolerance level of 20 ppb because the B1a peak height for the first injection of the sample solution would likely exceed that of the highest standard used to prepare the calibration curve. The linearity studies done during our PMV indicate that the calibration curves for B1a and B1b are linear for abamectin standards going to at least ten times greater concentrations than in the highest calibration standard in the method. Merck should consider greatly extending the range of abamectin concentrations used for calibration as this would eliminate the need for reanalysis of samples with abamectin residues at or near tolerance levels, and would allow the determination of B1b from a B1b calibration curve generated from the same abamectin standard runs used to prepare the B1a calibration curve.

ANALYTICAL CHEMISTRY BRANCH
SCREEN FOR RESIDUE METHODS FOR TMV

1. LABORATORY ASSIGNMENT NUMBER: B95-13
2. PP#: 9F03787
3. TECHNICAL REVIEWER: Bart Puma
4. DATE: 1-27-95
5. ANALYTES/LEVEL: avermectin B_{1a} (the principal component of abamectin) at 0.01&0.02 pp
6. COMMODITIES: pears
7. METHOD: "HPLC-Fluorescence Determination for Avermectin B_1 and 8,9-Z-Avermectin B_1 in Pears and Apples", Method No. 8000, Rev. 4, Merck Research Laboratories, Merck&C

The Analytical Chemistry Section has been asked to screen the residue chemistry methods submitted by the registrant in order to determine if they contain the essential requirements identified in the Residue Chemistry Guidelines. Full scientific review and laboratory evaluation of those methods will take place after the initial screen. The following items need to be resolved before the analytical method can be evaluated.

	YES	NO
1. Does the method use exotic equipment and/or supplies that are not commercially available in the U.S.?		✓
2. Does the method require any new equipment before the laboratory work begins?		✓
3. Are chromatograms included?		
a. Is (are) peak(s) of interest sufficiently resolved from other peaks?	✓	
b. Has registrant included chromatograms of analyses at or below tolerance on all crop types for which tolerance is requested by HED?	✓	
c. Do the control samples have reasonably low levels of the analyte in relation to the proposed tolerance?	✓	
d. Is the method sufficiently sensitive and specific to measure and identify the residues at levels specified by HED in the TMV request?	✓	