



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

NOV 5 1991

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum:

SUBJECT: PP#OF3880. Avermectin B₁ in/on strawberries. Evaluation of Analytical Method and Residue Data. (MRID#'s 415405-00, 415405-01, -02, -03, -04, -05, -06, -07, -08, -09, -10, -11, -12, -13, -14, -15, -16, -17, -18, and -19, DEB#6998).

FROM: Jerry B. Stokes, Chemist
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

THRU: Robert S. Quick, Acting Chief
Chemistry Branch/Tolerance Support
Health Effects Division (H7509C)

TO: George LaRocca, PM-15
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch
Health Effects Division (H7509C)

Merck Sharp & Dohme Research Laboratories, Merck & Co., Inc., proposes a tolerance be established for the residues of the miticide avermectin B₁ and the delta 8,9 geometric isomer of avermectin B_{1a} in/on strawberries at 0.02 ppm. (A synonym for avermectin B₁ is abamectin). Avermectin B₁ is defined as a mixture of avermectins containing $\geq 80\%$ avermectin B_{1a} (5-0-demethyl avermectin A_{1a}) and $\leq 20\%$ avermectin B_{1b} (5-0-demethyl-25-de(1-methyl propyl)-25-(1-methylethyl) avermectin A_{1a}). Tolerances, all with expiration dates of 3/31/93, are established for residues of avermectin B₁ and its delta 8,9 isomer in/on cottonseed (0.005 ppm), citrus whole fruit (0.02 ppm), cattle meat (0.02 ppm), cattle meat byproducts (0.02 ppm), and milk (0.005 ppm). Food additive tolerances are established, all with expiration date 3/31/93, for citrus oil (0.10 ppm) and citrus pulp, dried (0.1 ppm).

Tolerances are pending for residues of avermectin B₁ and its delta 8,9-isomer in/on r.a.c.'s of tomatoes (0.005 ppm), celery (0.035), and pears (0.035 ppm). A temporary tolerance for apples (0.035 ppm) is pending. Food additive tolerances are pending for tomato pomace (0.07 ppm dry, 0.01 ppm wet).

Summary of Comments/Conclusions:

1. The manufacturing process has been adequately discussed and impurities are not likely to be a residue problem.
2. The directions for use are adequate.
3. The nature of the residue, avermectin B₁ and its delta 8,9 isomer, is adequately understood.
4. Additional animal metabolic data are not needed.
5. The analytical methodology for strawberries is acceptable only if Method No. 8000 (pears) passes a successful petition method validation.
- 6a. Storage stability will be translated from pears to strawberries for the proposed use.
- 6b. Shipment vs. arrival dates must be clarified for three samples. Shipment/arrival and analyses dates must be provided for all samples.
7. Residue data are adequate to support the proposed 0.02 ppm tolerance for strawberries.
8. Secondary residues are not expected in meat, milk, poultry, or eggs from the proposed use on strawberries.
9. There are no compatibility problems with Codex, or Canadian, or Mexican limits.

Comments/Conclusions:

1. The manufacturing process has been adequately discussed in previous tolerance requests. CBTS concludes that impurities are not likely to be a residue problem.
2. The directions for use are adequate.
3. Plant metabolism data were not submitted with this petition. Data were previously submitted for celery, cottonseed, and citrus. CBTS has expressed the possible need for additional plant studies to support other commodities, particularly if the use pattern differs significantly from those on cotton,

citrus, celery, or tomatoes. However, the nature of the residue is understood for the purposes of this tolerance in/on strawberries. The residues of concern are avermectin B₁ and its delta 8,9 isomer.

4. Animal metabolism data were not submitted with this petition. No animal feed items are associated with strawberries.
- 5a. The proposed analytical methodology (Method No. 8001R1) is identical to that proposed for celery (Method No. 10001R1) and pears (Method No. 8000, except for an initial enzymatic step). Method No. 8000 is currently undergoing a method validation on pears at the EPA laboratory at Beltsville. An independent laboratory method validation on the pear method had been submitted in PP#9F3787.

Although a successful petition method validation (PMV) has been completed for methodology for citrus and submitted to FDA for inclusion in PAM II as Method I, and likewise, a letter method has been submitted to FDA for cottonseed, these methods and commodities are sufficiently different from celery and pears to require a successful trial of Method No. 8000 before the proposed method No. 8001R1 for strawberries is acceptable.

- 5b. Avermectin has been tested using the multiresidue method protocol A, and the data previously sent to FDA 6/21/89.
- 6a. Storage stability data were not submitted in this petition. The petitioner has submitted adequate storage stability data for pears in PP#9F3787. This data will be translated to strawberries to support the proposed use.
- 6b. For three sample shipments (1026R, 1027R, and 6021R) the dates shipped vs. arrival show periods of 9 or 14 days. Were samples in shipment this total time? If so, were samples maintained in a frozen state during these times? The petitioner must clarify how the samples were handled and their condition upon arrival at the laboratory. The shipment/arrival and analyses of all samples must be provided for our review.
7. Based upon the residue data for strawberries at the proposed application scheme, the proposed 0.02 ppm tolerance should adequately cover any avermectin B₁ residues in/on treated strawberries. However, final conclusions on the acceptability of the data are reserved until the proposed analytical methodology for pears (Method No. 8000) has passed a successful validation (See conclusion 5a), and the response of the petitioner to conclusion 6b has been reviewed.

8. The strawberry is not an animal feed item. Therefore, there is no reasonable expectation of secondary residues in livestock tissue, milk, or eggs from this proposed use of avermectin B₁ on strawberries.
9. There are no Codex, Canadian, or Mexican limits established for avermectin B₁ or the delta 8,9 geometric isomer of avermectin B₁. Therefore, no compatibility problem exists.

Recommendations:

CBTS recommends against the establishment of 0.02 ppm tolerance for the combined residues of avermectin B₁ and its delta 8,9 isomer in/on strawberries because of conclusions 5a, 6b, and 7.

The analytical methodology submitted for pears (Method No. 8000) must pass a successful petition method validation before Method No. 8001R1, submitted for strawberries, will be acceptable, and adequate storage stability data must be submitted to support the residue data.

Detailed Considerations

Manufacture and Formulation

Avermectin B₁ is produced by a fermentation process using a strain of Streptomyces avermilitis. This process yield 4 homologous pairs of closely related compounds: avermectin A₁, A₂, B₁, and B₂. The avermectins are extracted from the culture broth and purified by recrystallization. Avermectin B₁ is the technical grade active ingredient in the formulation to be discussed. The manufacturing process for technical avermectin B₁ and its contents have been discussed previously (PP#4F3065, memo of 9/13/84, V. Frank Boyd; PP#5G3287, memo of 12/10/85, L. Cheng). The TGAI contains ca 1% of unidentified impurities related to the avermectins. The TOX Branch has stated that the impurities are not of concern (PP#5G3287, memo of 3/12/86, W. Dykstra). DEB concludes that the impurities are not likely to be a residue problem, and there are no problems with the manufacturing process.

The formulated product is AGRI-MEK 0.15 EC Miticide/Insecticide. One gallon of the emulsifiable concentrate (EC) contains 0.15 lbs avermectin B₁ as the active ingredient. The inert ingredients are cleared for use under §180.1001.

The label describes the a.i. as avermectin B₁: [a mixture of avermectins containing $\geq$ 80% avermectin B_{1a} (5-0-demethyl avermectin A_{1a}) and $\leq$ 20% avermectin B_{1b} (5-0-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a})]. Avermectin B₁ is 2.0% of the formulated product.

Proposed Use

For control of mites on strawberries at start of new spring growth or when fruit first appear during, the production season apply no more than 16 fl. oz. (0.019 lb. a.i.)/A. Do not exceed 64 fl. oz. (0.076 lb. a.i.)/A/season. Apply in a minimum of 50 gallons of water per acre for concentrated sprays and up to 400 gallons of water per acre for dilute sprays. Only ground equipment should be used. The proposed PHI is 3 days.

Nature of the Residue

Plants: No new plant metabolism data were submitted in this petition. Data were previously submitted on celery, cottonseed, and citrus (PP#'s 5G3220, 5G3287, and 8F3649). The petitioner has also submitted a report entitled "Comparative Degradation of Avermectin B_{1a} in Cotton Leaf, Citrus Fruit, Celery and In Vitro" (MRID#408709-19). The degradation of 14C or 3H-avermectin B_{1a} on citrus fruit, cotton leaves, and celery from plant exposed to sunlight was compared to 14C-avermectin B_{1a} degradation on glass under simulated sunlight by HPLC analysis of the residues. Details of the studies were discussed previously (See memos of: 12/15/89, S. Willett, PP#9F3703; 7/89/87, C. Deyrup; 11/16/88, V. F. Boyd; 2/13/89, V. F. Boyd).

In general, the cochromatography of the solvent rinses of the 14C-treated plant with standards, according to the petitioner showed the following:

1. The degradation of avermectin B_{1a} on plants or in vitro appears to be similar and results in a complex mixture.
2. At least 2 avermectin B_{1a} degradates were formed in all systems examined; the conformational isomer of the parent compound, delta 8,9 avermectin B_{1a}, and an oxygenated product of the parent compound, 8-alpha hydroxy avermectin B_{1a}.
3. When the proportion of avermectin B_{1a} is less than 10-15% of the total remaining residue, which usually occurred in a week or less post-application in plants, most of the remaining residue is present as unidentified multiple polar compounds which appear to degrade slowly with extended exposure to sunlight.
4. The studies indicate that photodegradation on plant surfaces rather than metabolism is the major pathway for avermectin B_{1a} disposition in plants.

CBTS previously agreed that the metabolism of avermectin B₁ in plants is complex with the parent compound and its delta 8,9 isomer accounting for 10% or more of the total residue. A small amount has been identified as an alpha-8-hydroxy degradate, and the remaining terminal residue is composed of several unidentified polar degradates. The petitioner has submitted data to show that the residues present in the citrus surface rinses, celery extracts, and cotton leaf rinses and extracts at typical PHI's are similar to in vitro photodegradation products. To support the uses on cotton and citrus, the polar degradates generated on citrus (30X, 7 day PHI) and in vitro (30 hr sample) have been tested for toxicity and were found to be of no toxicological significance at the levels tested (See TOX memos 007080 and 007801 of W. Dykstra dated 3/13/89, and DEB memo of V. F. Boyd dated 6/21/89).

CBTS also commented previously that we do not agree with the petitioner's conclusion that avermectin B₁ is degraded on all plants in a similar manner. The metabolism is complex and may need additional studies. Photodegradation on the exterior plant surfaces is not the only transformation taking place on plants, and may not necessarily always be the major degradative pathway under certain conditions. The petitioner should be prepared to conduct additional plant metabolic studies on other crops to support future uses, particularly if the use pattern differ significantly from those of cotton, celery, citrus and tomatoes. In future studies, 14C-treatment should more closely simulate actual use (e.g. accidental application to soil, and moderate rainfall). The account of the total radioactivity should be improved. A 14C-labelled compound should be used. (See memo of 12/15/89, S. Willett, PP#9F3703).

In this proposed use on strawberries the use pattern is similar to the uses on the above commodities. Therefore, for the purpose of establishment of an avermectin B₁ tolerance in/on strawberries, the metabolism data is adequate. The residue of regulatory concern is avermectin B₁ and the delta 8,9 geometric isomer of avermectin B_{1a}.

Animals: No additional animal metabolism data were submitted in this petition. CBTS had previously commented that if registration on additional feed items causes the dietary burden in livestock to increase, a new 14C goat metabolism may be required. (See memo of 12/15/89, S. Willett, PP#9F3703). However, the strawberry is not considered an animal feed item. Therefore, for the purposes of the establishment of a avermectin B₁ tolerance in/on strawberries, additional animal metabolic data will not be needed.

Analytical Methodology

Analytical methodologies have been previously submitted for citrus, tomato, celery, cottonseed, and pears. Methodology is submitted in this petition for strawberries. In all methods residues of

avermectin B₁ and its delta 8,9 isomer are extracted into organic solvents, passed through cleanup procedures, derivatized, and quantified by reverse phase HPLC with fluorometric detection. The methods are summarized in Table 1.

As evidenced in this table the initial plant extractions and cleanup procedures differ amongst the commodities. Method No. 1009R3 (citrus) has completed a successful validation by the Agency, and has been submitted to FDA for inclusion in PAM II as Method I. Method No. 6004 (cottonseed) has been submitted to FDA for inclusion in PAM II as a letter method since a method trial was not run by the Agency, but the methodology is adequate for enforcement purposes.

The method of choice for avermectin B₁ residues on strawberries is No. 8001R1. This method is identical to that proposed for celery (Method No. 10001R1) and pears (Method No. 8000, except for the initial enzymatic step). The celery method has not been run in the agency laboratory, but Method No. 8000 has been submitted to the EPA laboratory in Beltsville for method validation in pears. All the methods, after differences in the extraction procedures and sample cleanups, use the same derivatization step and reverse phase HPLC analysis of the fluorescent derivatives.

The petitioner has submitted method validation data from an independent laboratory (Hazleton Laboratories America, Inc.) in this petition (MRID# 415405-17). Two fortification levels for avermectin B_{1a} and the delta 8,9 isomer (5.1 and 25.4 ppb, and 5.0 and 25.2 ppb, respectively) and one level for the avermectin B_{1b} (3.8 ppb) were used. Recoveries ranged from 82 to 102 % for avermectin B_{1a} and B_{1b}, and 92 to 98% for the delta 8,9 isomer using Method No. 8001R1. Additional validation data for strawberries, also been submitted (MRID# 415405-18). The strawberry matrix fortifications ranged from 5.0 to 49.8 ppb for avermectin B_{1a}, 5.0 to 50 ppb for avermectin B_{1b}, and 3.7 to 5.2 ppb for the delta 8,9 isomer. Recoveries ranged from 70 to 108% (B_{1a}, 18 samples, 89% ave.), 92 to 103% (B_{1b}, 6 samples, 99% ave.), and 70 to 108% (delta 8,9 isomer, 18 samples, 86% ave.). Control samples were adequate. The limit of detection is 0.02 ppm.

Although Methods Nos. 1009R3 and 6004 have been submitted to FDA for inclusion in PAM II, these methods and commodities are sufficiently different from celery and pears No. 8000 to require a successful trial of Method No. 8000 before the proposed method No. 8001R1 for strawberries is acceptable.

Therefore, for the purposes a tolerance in/on strawberries, the analytical methodology Method No. 8000 (pears) must successfully pass the Agency laboratory validation if Method No. 8001R1 is the proposed enforcement method.

Table 1

Analytical Methodology

Commodity	Method No.	Matrix Extraction	Solvent Partition	Column Cleanup	Solvent Partition	Column Cleanup	Solvent Partition	Solvent Partition	Derivatization: HPLC Analysis
Citrus	1009R3 ^a	Methanol	Isooctane/ methylene chloride	Acidic alumina: methylene chloride/ isopropanol	Hexane	Hexane/ methylene chloride	Hexane/ methylene chloride	Hexane/ methylene chloride	Trifluoro- acetic anhydride/ 1-methyl- imidazole/ dimethyl- formamide;
Cotton- seed	6004 ^b	Methanol	—	Aminopropyl: hexane/toluene/ methylene chloride/ acetone	Isooctane/ methylene chloride	Isooctane/ methylene chloride	Hexane/ methylene chloride	Hexane/ methylene chloride	Trifluoro- acetic anhydride/ 1-methyl- imidazole/ dimethyl- formamide;
Tomato	9003	Methanol	Isooctane/ methylene chloride	Acidic alumina: methylene chloride/ isopropanol	Hexane	Hexane/ methylene chloride	Hexane/ methylene chloride	Hexane/ methylene chloride	Trifluoro- acetic anhydride/ 1-methyl- imidazole/ dimethyl- formamide;
Celery	10001R1	Acetonitrile/ water	—	CB: acetonitrile	Hexane	Hexane/ methylene chloride/ acetone	Hexane/ methylene chloride/ acetone	Hexane/ methylene chloride/ acetone	Methanol/ ammonium hydroxide;
Pear	8000	Pectinase hydrolysis; Acetonitrile/ water	—	CB: acetonitrile	Hexane	Hexane/ methylene chloride/ acetone	Hexane/ methylene chloride/ acetone	Hexane/ methylene chloride/ acetone	Silica column: chloroform; HPLC C18: methanol/ water
Straw- berry	8001R1	Acetonitrile/ water	—	CB: acetonitrile	Hexane	Hexane/ methylene chloride/ acetone	Hexane/ methylene chloride/ acetone	Hexane/ methylene chloride/ acetone	Trifluoro- acetic anhydride/ 1-methyl- imidazole/ dimethyl- formamide;

a A successful PWV has been completed and the method has been sent to FDA for inclusion in PAM II as Method I.

b The method has been submitted to FDA for inclusion in PAM II as Method IA.

Avermectin has been tested using the multiresidue method protocol A, and the data previously sent to FDA (See memo of V. Boyd, 6/21/89).

Storage stability data

Storage stability data as such are not submitted for strawberries. Field samples in most of the field trials were collected and stored frozen for two months or less before analysis (See Table 2). In other trials samples were stored for upto 8 months before analyzed. Apparently samples from trial 1027R and trial 6020R were analyzed after 4 and 3 months (after harvest), respectively, in Merck's in-house laboratory, then analyzed 8 and 7 months (after harvest) by a contract laboratory, Hazleton Laboratories America, Inc.

Comparison data (See MRID#415402, p. 10) between the two different labs gave similar residue results. The residues present when the samples were analyzed 3-4 months appeared stable under frozen conditions upto 7-8 months without any degradation. However, data are not available to show the identity of the residues prior to the 3-4 month period. In addition, in three sample shipments (1026R, 1027R, and 6021R) the dates shipped vs. arrival show periods of 9 or 14 days. Were samples in shipment this total time? If so, were samples maintained in a frozen state during these times? The petitioner must clarify. The shipment/arrival and analyses dates for the Merck laboratory were not provided. This information should be provided for our review.

Storage stability data are available for pears. (MRID#411885-14). Four sets of samples were fortified with avermectin B_{1a} (10.2 or 71.0 ppb), B_{1b} (10.0 ppb), or delta 8,9 isomer (5.3 ppb). Samples were stored frozen and analyzed at 43, 92, 183, and 365 days. Two replicates were run for each fortification (except 3 for 10.2 ppb B_{1a}) with recoveries ranging from 62 to 111%, with averages of 86% for B_{1a}, 89% for B_{1b}, and 93% for delta 8,9 isomer. One sample of B_{1a} gave 0% recovery, but it was questioned if the sample received the initial fortification. A freshly fortified sample (10.2 ppb B_{1a}) run in parallel gave 85% recovery. Control data were adequate. The storage stability data is adequate to support the use on pears.

Therefore, the storage stability data for pears will be translated for strawberries. Additional storage stability data will not be necessary to support the proposed use on strawberries. However, the petitioner should still address the CBTS inquiries cited above.

Residue data

Residue data are submitted for strawberries. Avermectin B₁ residue data has been submitted for strawberries from CA, FL, MI, OR

Table 2

Storage Stability Data, Strawberries

Location/Study ID	Sampling Dates	Shipment/ Arrival (Merck lab)	Analysis by Merck lab	Shipment/ Arrival (Contract lab)	Analysis by Contract lab	Months Storage Before Analysis
CA/001-88-1026R	5/20-27/88	6/2/88 6/16/88	7/14-8/17/88	NA	NA	2
CA/001-88-1027R	6/02-09/88	8/10/88 8/19/88	9/16-29/88	1/4/89 1/5/89	1/26-2/14/89	4 8
CA/001-88-6020R	6/28-7/5/88	8/22/88 8/23/88	9/23-28/88	1/4/89 1/5/89	2/14-23/89	3 7
CA/001-88-6021R	7/21-28/89	8/18/88 9/7/88	9/20-28/88	NA	NA	2
FL/001-89-0004R	2/11-14/89	2/22/89 2/23/89	NA	2/27/89 2/28/89	3/2-10/89	1
FL/001-89-0005R	2/11-14/89	2/22/89 2/23/89	NA	2/27/89 2/28/89	3/9-17/89	1
FL/001-89-0024R	4/28-5/1/89	5/23/89 6/1/89	NA	6/5/89 6/6/89	6/20-24/89	2
CA/001-89-1007R	4/21-24/89	NA	NA	4/26/89 4/27/89	5/24-6/2/89	1
MI/001-89-1018R	6/26-29/89	NA	NA	7/10/89 7/11/89	7/27-8/3/89	1
MI/001-89-1019R	6/26-29/89	NA	NA	7/10/89 7/11/89	8/8-16/89	1.5
OR/001-89-1020R	6/6-9/89	NA	NA	6/20/89 6/21/89	7/5-12/89	1
OR/001-89-1021R	6/21-24/89	NA	NA	6/29/89 6/30/89	7/20-26/89	1
CA/001-89-6003R	7/6-9/89	NA	NA	7/18/89 7/19/89	8/18-23/89	1.5
PA/001-89-3004R	6/8-11/89	8/25/89 8/25/89	NA	8/28/89 8/29/89	9/13-18/89	4
PA/001-89-3005R	6/8-11/89	8/25/89 8/25/89	NA	8/28/89 8/29/89	9/20-26/89	4

NA: data not available in petition submission

Table 3

RESIDUE DATA 1988 FIELD TRIALS

Location/Study ID	lb a.i./A	Spray volume, GPA	No. of applications	Residue range, ppb (PHI in days) ^{a,b}						
				0	1	2	3	7		
CA/001-88-1026R	0.02	200	4	15.3-20.0	8.0-17.7	5.9-8.8	NQ-8.8	ND-NQ		
CA/001-88-1026R	0.04	200	4	37.5-49.5	24.5-44.2	19.8-34.6	14.9-22.3	6.5-8.7		
CA/001-88-1027R	0.02	200	4	9.5-17.7	10.8-15.4	7.9-10.7	5.3-8.4	ND-NQ		
CA/001-88-1027R	0.04	200	4	36.2-49.0	32.7-45.9	28.6-42.4	18.9-24.5	6.8-14.7		
CA/001-88-6020R	0.02	200	4	17.9-24.6	12.2-15.8	7.9-11.7	ND-8.5	NQ		
CA/001-88-6020R	0.04	200	4	41.3-52.6	28.6-40.0	18.9-21.7	20.2-26.1	NQ-6.9		
CA/001-88-6021R	0.02	200	4	10.3-14.8	NR	NR	5.0-11.9	NR		
CA/001-88-6021R	0.04	200	4	NR	NR	NR	NR	NR		

^a Four samples analyzed for each PHI; ND: not detected, < 2 ppb; NG: not quantitated, > 2 ppb, < 5 ppb; residue values represent B_{1a} and its delta-8,9 isomer; NR: not reported.

^b Analyses of avermectin B_{1a} yielded ND to NQ, except for two samples in CA/001-88-1026R: 5.2 and 5.2 ppb

Table 3 cont'

RESIDUE DATA 1989 FIELD TRIALS

Location/Study ID	lb a.i./A	Spray volume, GPA	No. of applications	Residue range, ppb (PHI in days) ^{a,b}		
				0	2	3
FL/001-89-0004R	0.02	89	4	24.0-31.3	NR	5.6-7.1
FL/001-89-0004R	0.04	89	4	57.4-78.7	NR	8.2-20.9
FL/001-89-0005R	0.02	89	4	24.2-35.6	NR	5.1-7.5
FL/001-89-0005R	0.04	89	4	52.5-70.8	NR	9.6-21.1
FL/001-89-0024R	0.02	50	4	13.9-24.7	ND-NQ	ND
CA/001-89-1007R	0.02	50	4	13.0-22.0	6.0-10.0	NQ-7.7
MI/001-89-1018R	0.02	50	5 ^c	ND-NQ ^d	ND-NQ	ND
MI/001-89-1019R	0.02	200	5 ^c	NQ-11.9	ND	ND
OR/001-89-1020R	0.02	200	4	23.6-29.3	7.8-14.0	8.0-10.7
OR/001-89-1021R	0.02	200	4	5.5-10.7	ND-NQ	ND
CA/001-89-6003R	0.02 ^e	50	4	5.6-9.4	NQ	NQ-5.2
PA/001-89-3004R	0.02	45.1-47.1	4	7.2-13.8	NQ	NQ
PA/001-89-3005R	0.02	204-220	4	8.2-15.3	ND-NQ	ND

^a Four samples analyzed for each PHI; ND: not detected, < 2 ppb; NG: not quantitated, > 2 ppb, < 5 ppb; residue values represent B₁₁ and its delta-8,9 isomer.

^b Analyses of avermectin B_{1b} yielded ND to NQ, except for one sample in FL/001-89-0005R: 9.6 ppb.

^c A 10-day interval was between 3rd and 4th application; a 5th application was made 7 days after 4th application.

^d One sample yielded 5.0 ppb.

^e The wrong sample of abamectin was used; trial continued and samples analyzed.

and PA. The data reflect 1X (0.02 lb a.i./A) (15 trials) and 2X (0.04 lb a.i./A) (6 trials) rates at the proposed 3-day PHI. The spray volumes were applied from 45 to 89 gpa and from 200 to 220 gpa. The number of applications per season was 4 in all field trials, except one with 5. At the proposed 3-day PHI, the combined residues of avermectin B₁ and its delta 8,9 isomer, ranged from nondetectable (ND:< 2 ppb) to 11.9 ppb at the proposed 1X rate, and from ND to 26.1 ppb at the 2X rate. Residues of avermectin B_{1b} were ND to NQ (> 2, < 5 ppb) for both the 1X and 2X rates except for two samples (5.2 and 5.2 ppb). The maximum allowed per season is 0.08 lb a.i./A. Details of the residue data are include in Table 3.

Based upon the residue data for strawberries at the proposed application scheme, the proposed 0.02 ppm tolerance should adequately cover any avermectin B₁ residues in/on treated strawberries. However final conclusions on the acceptability of the data are reserved until adequate storage stability data are reviewed.

No processing studies are submitted in this petition. Since tolerances are established only on the r.a.c., strawberries, then processing studies will not be required.

Meat, milk, poultry, and eggs

Temporary tolerances are established for avermectin B₁ and its delta 8,9 isomer in cattle meat and meat byproducts (0.02 ppm) and milk (0.005 ppm) with an expiration date of 3/31/93.

The strawberry is not an animal feed item. Therefore, there is no expectation of secondary residues in livestock tissue, milk, or eggs with this proposed use of avermectin B₁ on strawberries.

Other considerations

There are no Codex, Canadian, or Mexican limits established for avermectin B₁ or the delta 8,9 geometric isomer of avermectin B₁. Therefore, no compatibility problem exists.

cc: PP#9F3880; J. Stokes (CBTS); C. Furlow (PIB/FOD); Avermectin B₁
S.F.; R.F.; Circulation (7)
RDI: PErrico:10/10/91:RLoranger:10/17/91
H7509C:CBTS:JStokes:js:Rm 803A:CM#2:557-1439:10/31/91

INTERNATIONAL RESIDUE LIMIT STATUS

J. Stokes
7/1/91

CHEMICAL Avermectin B₁

CODEX NO. _____

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

PROPOSED U.S. TOLERANCES:

Petition No. PP#0F3880

RCB Reviewer J. Stokes

Residue: Avermectin B₁ and
its delta 8,9 isomer

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
strawberry	0.02

CANADIAN LIMITS:

☒ No Canadian limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit</u> <u>(mg/kg)</u>
----------------	--------------------------------

NOTES: _____