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6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 12/1/04

Subject: Abamectin. PP#2H5642. Petition for the Establishment of Permanent Tolerances for Section 3 Registration for Use in Food Handling Establishments. Summary of Analytical Chemistry and Residue Data.

DP Barcode:	D310414	Decision No:	298517
PC Code:	122804	MRIDs:	44878101, 44933401, 44933402, 44933403
40 CFR 180.	449		

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Executive Summary

General Information. Abamectin is a mixture of avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops. Abamectin acts as an insecticide by interfering with the nervous system of the insect, causing the insect to become paralyzed. Available mechanistic data indicate a neurotoxic mechanism of action, related to interference with GABA-mediated neurotransmission.

Use Pattern Information. Avert® Prescription Treatment 310 has been proposed for use in food handling establishments. Avert® PT310 is a dust formulation which contains 0.05% active ingredient (ai). Two hundred bait placements can be obtained from each 30 g tube of Avert® PT310, meaning each bait placement (application point) contains 150 mg Avert® PT310. The directions indicate that 4-24 bait placements can be made per 100 sq ft of treatment area. The maximum of 24 bait placements per 100 sq ft of treatment area equals 36 mg Avert® PT310/sq ft (0.018 mg ai/sq ft).

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Residue Profile. The qualitative nature of the abamectin residues in food in food handling establishments is adequately understood based on metabolism studies on cottonseed, citrus, and celery. The available studies indicate that the metabolism of abamectin in plants results in a complex mixture of residues. The majority of the terminal residue is composed of several unidentified polar degradates. The parent compound, its delta-8,9-isomer, and the alpha 8-OH degradate have been identified in plants, with only the parent and its delta-8,9-isomer each accounting for at least 10% of the total residue. For the tolerance assessment and risk assessment, the residues of concern in these crops are the parent compounds (avermectin B_{1a} and B_{1b}) and their delta-8,9-isomers (also known as 8,9-Z-isomers).

The qualitative nature of abamectin residues in ruminants is adequately understood based on a goat metabolism study. The residues of concern in ruminants for the tolerance expression and risk assessment are the parent compounds (avermectin B_{1a} and B_{1b}) and their delta-8,9-isomers. If the tolerances for residues in meat and milk need to be raised at some future time due to registration of abamectin on additional feed items, the 24-hydroxymethyl metabolite may need to be included in the tolerance expression and appropriate enforcement methods developed.

Since no significant poultry feed items (as indicated in OPPTS 860.1000, Table 1) are associated with registered/pending uses, no poultry metabolism study has been required and none is needed for the proposed use in food handling establishments.

The results of a confined rotational crop study indicated that avermectin residues accumulated in some rotational crops at levels up to 10-12 ppb; however, the radioactivity was due to polar degradates that were of little toxicological concern as compared to the parent compound avermectin B_1 and/or the delta-8,9-isomer. Therefore, field rotational crop studies have not been required. Rotational crop studies are not pertinent to the proposed use in food handling establishments.

Tolerances have been established in 40 CFR §180.449(a) for the combined residues of the insecticide avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer in/on the following plant commodities at levels ranging from 0.005 to 0.20 ppm: almond, cotton seed, cucurbits (cucumber, melons, and squashes), potato, and walnut at 0.005 ppm; tomato at 0.01 ppm; apple, citrus, grape, pear, pepper, and strawberry at 0.02 ppm; "celeriac, roots," "celeriac, tops," celery, and "lettuce, head," at 0.05 ppm; "almond, hulls," "apple, wet pomace," "citrus, dried pulp," and "citrus, oil" at 0.10 ppm; cotton gin byproducts at 0.15 ppm, and "hop, dried cone" at 0.20 ppm. Tolerances are also established in 40 CFR §180.449(a) for the following livestock commodities: milk at 0.005 ppm, "cattle, fat" at 0.015 ppm; and "cattle, meat" and "cattle, meat byproducts" at 0.02 ppm. No tolerances are established on poultry commodities.

Time-limited tolerances are established in 40 CFR §180.449(b) for residues of the miticide avermectin B_1 and its delta-8,9-isomer in/on avocado at 0.02 ppm, basil at 0.05 ppm, and spinach at 0.05 ppm in connection with use of the pesticide under Section 18 emergency exemptions. These tolerances will expire on 12/31/06.

HED recently conducted a Human Health Risk Assessment for new uses on plums/prunes, leafy vegetables, fruiting vegetables, the herb subgroup (except chives), avocado, mint, and food handling establishments (K. O'Rourke et al, 11/2/04). In connection with that review, permanent tolerances are pending on the "vegetable, leafy, except *Brassica*, group 4" at 0.10 ppm; the "vegetable, fruiting, group 8" at 0.020 ppm; avocado at 0.020 ppm; mint at 0.010

ppm; "herbs, subgroup 19A (except chives)" at 0.030 ppm; plum at 0.010 ppm; and "plum, prune, dried" at 0.025 ppm.

Codex has recommended several MRL's for plant and cattle commodities (*Pesticide Residues in Food-1997, Part 1).* The Codex residue definition (step 8/CXL) is "sum of avermectin B_{1a}, avermectin B_{1b}, 8,9-Z-avermectin B_{1a} and 8,9-Z-avermectin B_{1b} for plants, and the sum of avermectin B_{1a} and 8,9-Z-avermectin B_{1a} for cattle commodities. The Codex limits of determination (equivalent to HED's limits of quantitation, LOQ's) for plant and livestock commodities are ≤0.01 ppm. (For plants, the LOQ ranges from 0.002 to 0.005 ppm for each of two peaks, one peak representing avermectin B_{1a} and its 8,9-Z-isomer and the other peak representing avermectin B_{1b} and its 8,9-Z-isomer. For cattle meat, the Codex LOQ is 0.01 ppm.) The tolerance expression in Canada for plants is "avermectin B_{1a}, avermectin B_{1b}, and the 8,9-Z-isomers." The tolerance expression in Mexico for plants is avermectina.

The petitioner, Whitmire Micro-Gen Research Laboratories, Inc., proposed establishment of a tolerance of 0.001 ppm for residues of abamectin and/or its delta-8,9-isomer on food products in food handling establishments. The data collection methods were validated by concurrent recoveries at the 0.001 ppm level for abamectin. (Residues of avermectin B_{1a} and 8,9-Z-avermectin B_{1a} were determined; residues of avermectin B_{1b} and 8,9-Z-avermectin B_{1b} were not determined since they were not expected to be detectable.) The methods used for data collection can analyze the residues of concern for risk assessment and are adequate for data collection based on acceptable concurrent recoveries. Analytical methods for enforcement of residues from the use of abamectin are available in PAM II for citrus and processed fractions (Method I), ginned cottonseed (Method IA), and bovine tissues and milk (Method II). These methods are adequate for enforcement of the tolerances on plants at LOQ's (for the sum of both peaks) of 0.005 or 0.01 ppm. Tolerances (40 CFR 180.449) are established at 0.005 ppm for milk, 0.015 ppm for cattle fat, and 0.02 ppm for meat and meat by-products of cattle. [EPA conducted a method validation for meat and milk (PP#8F3592, DEB 3929, F. Boyd, 9/2/88)]. Tolerances should be established at 0.01 ppm in/on all food items in food handling establishments (other than those already covered by higher tolerances as a result of use on growing crops and other than milk, for which the established 0.005 ppm tolerance is adequate; and other than meat and meat byproducts of goat, hog, horse, poultry, and sheep, for which a tolerance should be established at 0.02 ppm.) The limit of detection (LOD) for all food items in food handling establishments is 0.001 ppm for each analyte, equivalent to 0.002 ppm for plant and livestock commodities.

Recommendations

Pending receipt of a revised Section F, there are no residue chemistry data gaps that would preclude registration of Avert® PT310 for use in food handling establishments and the establishment of permanent tolerances for the combined residues of the insecticide avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer in/on food items in food handling establishments as follows:

0.02 ppm for meat and meat byproducts of goat, hog, horse, poultry, and sheep;

0.01 ppm for all other food items (other than those already covered by higher tolerances as a result of use on growing crops and other than milk).

The established tolerances of 0.005 ppm for milk and 0.02 ppm for *cattle, meat* and *cattle, meat byproducts* are adequate.

The limit of detection (LOD) for all food items in food handling establishments is 0.001 ppm for each analyte, equivalent to 0.002 ppm for plant and livestock commodities.

HED will conduct a risk assessment for this use.

Residue Chemistry Deficiencies

860.1550 Proposed Tolerances

A revised Section F is needed to propose tolerances for meat and meat byproducts of goat, hog, horse, poultry, and sheep at 0.02 ppm, and for all other food items (other than those already covered by higher tolerances as a result of use on growing crops and other than milk) in food handling establishments at 0.01 ppm.

Background

The petitioner, Whitmire Micro-Gen Research Laboratories, Inc., proposed establishment of a tolerance of 0.001 ppm for residues of abamectin and/or its delta-8,9-isomer on food products in food handling establishments.

Abamectin is a mixture of avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer. Abamectin is a natural fermentation product of the soil bacterium *Streptomyces avermitilis*. Abamectin is an insecticide/miticide used to control mites, leafminers, and other insects in commercially important crops. Abamectin acts as an insecticide by interfering with the nervous system of the insect, causing the insect to become paralyzed. Available mechanistic data indicate a neurotoxic mechanism of action, related to interference with GABA-mediated neurotransmission.

Tolerances have been established in 40 CFR §180.449(a) for the combined residues of the insecticide avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer in/on the following plant commodities at levels ranging from 0.005 to 0.20 ppm: almond, cotton seed, cucurbits (cucumber, melons, and squashes), potato, and walnut at 0.005 ppm; tomato at 0.01 ppm; apple, citrus, grape, pear, pepper, and strawberry at 0.02 ppm; "celeriac, roots," "celeriac, tops," celery, and "lettuce, head," at 0.05 ppm; "almond, hulls," "apple, wet pomace," "citrus, dried pulp," and "citrus, oil" at 0.10 ppm; cotton gin byproducts at 0.15 ppm, and "hop, dried cone" at 0.20 ppm. Tolerances are also established in 40 CFR §180.449(a) for the following livestock commodities: milk at 0.005 ppm, "cattle, fat" at 0.015 ppm; and "cattle, meat" and "cattle, meat byproducts" at 0.02 ppm. No tolerances are established on poultry commodities.

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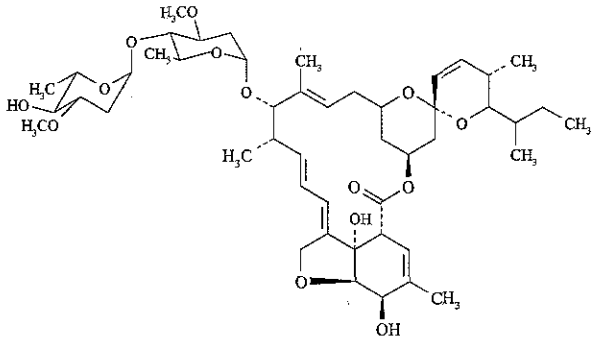
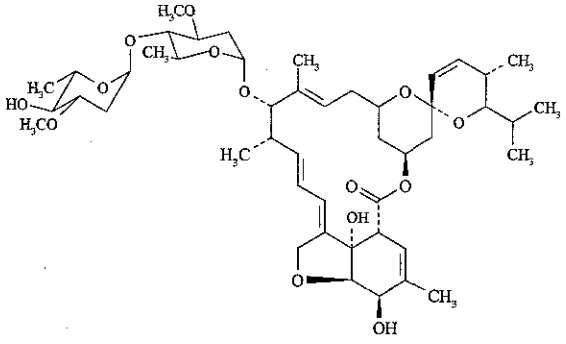
Codex has recommended several MRL's for plant and cattle commodities (*Pesticide Residues in Food-1997, Part 1).* The Codex residue definition (step 8/CXL) is "sum of avermectin B_{1a}, avermectin B_{1b}, 8,9-Z-avermectin B_{1a} and 8,9-Z-avermectin B_{1b} for plants, and the sum of avermectin B_{1a} and 8,9-Z-avermectin B_{1a} for cattle commodities. The Codex limits of determination (equivalent to HED's limits of quantitation, LOQ's) for plant and livestock commodities are ≤0.01 ppm. (For plants, the LOQ ranges from 0.002 to 0.005 ppm for each of two peaks, one peak representing avermectin B_{1a} and its 8,9-Z-isomer and the other peak representing avermectin B_{1b} and its 8,9-Z-isomer. For cattle meat, the Codex LOQ is 0.01 ppm.) The tolerance expression in Canada for plants is "avermectin B_{1a}, avermectin B_{1b}, and the 8,9-Z-isomers. The tolerance expression in Mexico for plants is avermectina.

Table 1. Abamectin Nomenclature.	
Compounds	 Avermectin B_{1a}  Avermectin B_{1b}
Common name	Avermectin B_1
Company experimental name	MK-0936
IUPAC name	mixture of (10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5 '*S*,6*S*,6 '*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6 '-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5 ',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2 '-(5 ',6 '-dihydro-2 '*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside and (10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5 '*S*,6*S*,6 '*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,22-dihydroxy-6 '-isopropyl-5 ',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]pentacosa-10,14,16,22-tetraene)-6-spiro-2 '-(5 ',6 '-dihydro-2 '*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-α-L-*arabino*-hexopyranosyl)-3-*O*-methyl-α-L-*arabino*-hexopyranoside
CAS name	Avermectin B_1
CAS #	65195-55-3 (B_{1a}) & 65195-56-4 (B_{1b})
End-use products/EPs	Agri-Merk 0.15EC (2% EC)

Abamectin technical is an off white to slightly yellow solid.

TABLE 2. Physicochemical Properties

Parameter	Value	Reference[1]
Melting point	155-157 °C	Accession No. 260785, RCB No. 388
Density/specific gravity	1.16 g/cm^3 at 21 °C	Accession No. 260785, RCB No. 388
Water solubility (20°C)	< 0.01 mg/mL in distilled water < 0.001 mg/mL in tap water < 0.001 mg/mL in buffer system pH 6, 7.4 & 9.0 < 0.001 mg/mL in 0.9% NaCl	Accession No. 260785, RCB No. 388
Solvent solubility (mg/mL at 20°C)	> 3 mg/mL in ethanol; >2 mg/mL in isopropyl myristate, chloroform, dimethylacetamide, dimethylformamide, glycerol formal & polyethylene dycol 400.	Accession No. 260785, RCB No. 388
Vapour pressure at 25°C	1.5 x 10^{-9} hPa	Accession No. 260785, RCB No. 388
Dissociation constant (pK_a)	no dissociable moieties	Accession No. 260785, RCB No. 388
Octanol/water partition coefficient Log(K_{ow})	9.9 x 10^{-3}	Accession No. 260785, RCB No. 388

[1] Product Chemistry data were reviewed by Leung Cheng (Accession No. 260785, RCB No. 388, 5/1/1986)

860.1200 Directions for Use

Table 3. Summary of Directions for Use of Abamectin.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (mg ai/sq ft)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Food Handling Establishments						
Apply the dust formulation from plastic tubes equipped with a nozzle and a supplied hand duster. In food areas, application is limited to crack and crevice treatment only. Apply directly to cracks and crevices.	0.05% Dust: Avert® PT310 [1] [499-294]	0.018 [2]	not applicable	not applicable	0	Retreatment interval: 1 week.

[1] Avert® Prescription Treatment 310 is a dust formulation which contains 0.05% ai.

[2] 200 bait placements can be obtained from each 30 g tube of Avert® PT310, meaning each bait placement (application point) contains 150 mg Avert® PT310. The directions indicate that 4-24 bait placements can be made per 100 sq ft of treatment area. The maximum of 24 bait placements per 100 sq ft of treatment area = 36 mg Avert® PT310/sq ft = 0.018 mg ai/sq ft.

860.1300 Nature of the Residue - Plants

DER Reference List: None
MARC Decision Memo Reference: None

No new plant metabolism data were submitted with this tolerance petition. Metabolism studies on cottonseed, citrus, and celery (PP#'s 5G3500, 5G3287, and 8F3649, respectively) have previously been submitted. In addition, a report titled "Comparative Degradation of Avermectin B_{1a} in Cotton Leaf, Citrus Fruit, Celery, and In Vitro" was also submitted (PP#9F3703, S. Willett, 12/15/89). The available studies indicate that the metabolism of abamectin in plants results in a complex mixture of residues. The majority of the terminal residue is composed of several unidentified polar degradates. The parent compound, its delta-8,9-isomer, and the alpha 8-OH degradate have been identified in plants, with only the parent and its delta-8,9-isomer each accounting for at least 10% of the total residue. The polar degradates generated on citrus (7-day PHI) and in vitro (30 hour sample) have been tested for toxicity and were found to be of no toxicological significance at the levels tested (TOX memos 7080 and 7081, W. Dykstra, 3/15/89; PP#8F3592, F. Boyd, 6/21/89; D203373, G. J. Herndon, 3/29/95).

Conclusions: The qualitative nature of the abamectin residues in the food in food handling establishments is adequately understood based on the metabolism studies on cottonseed, citrus, and celery. For the tolerance assessment and risk assessment, the residues of concern in these crops are the parent compounds (avermectin B_{1a} and B_{1b}) and their delta-8,9-isomers (also known as 8,9-Z-isomers).

860.1300 Nature of the Residue - Livestock

DER Reference List: None
MARC Decision Memo Reference: None

No additional livestock metabolism data were submitted with this petition. A goat metabolism study has previously been submitted (PP#7G3468, L. Cheng, 2/11/87; PP#9F3703, S. Willett, 12/15/89). No poultry metabolism study has been submitted.

Conclusions. The qualitative nature of abamectin residues in ruminants is adequately understood based on a goat metabolism study. The residues of concern in ruminants for the tolerance expression and risk assessment are the parent compounds (avermectin B_{1a} and B_{1b}) and their delta-8,9-isomers. If the tolerances for residues in meat and milk need to be raised at some future time due to registration of abamectin on additional feed items, the 24-hydroxymethyl metabolite may need to be included in the tolerance expression and appropriate enforcement methods developed (PP#8F3592, F. Boyd, 6/21/89; D203373, G. J. Herndon, 3/29/95).

Since no significant poultry feed items (as indicated in OPPTS 860.1000, Table 1) are associated with registered/pending uses, no poultry metabolism study has been required and none is needed for the proposed use in food handling establishments.

860.1340 Residue Analytical Methods

DER Reference List: None

Plant and Livestock Commodities

Eight foods (including soda crackers, cheese slices, whole milk, sliced sandwich meat, butter, lettuce, bread, and cream pie) were analyzed. The analytical methods used and validated were "HPLC-Fluorescence Determination of Avermectin B_1 and its Delta-8,9-Isomer in Ginned Cotton Seed" (used for crackers and bread), "HPLC-Fluorescence Determination of Avermectin B_1 and its Delta-8,9-Isomer in Celery" (used for lettuce), "Abamectin in Cheese" (used for cheese slices, meat slices, and butter), "Abamectin in Milk (used for milk), and "Abamectin in Cream Pie" (used for cream pie). In general, the samples were extracted with acetonitrile/water, hexane, or methanol. The residues were cleaned up, derivatized into two fluorescent compounds, and quantitated by high performance liquid chromatography (HPLC) with a fluorescence detector. Residues are determined by the methods as combined residues of avermectin B_{1a} and 8,9-Z-avermectin B_{1a} (one peak on the chromatogram) and combined residues of avermectin B_{1b} and 8,9-Z-avermectin B_{1b} (a second peak on the chromatogram). The petitioner reported that the LOQ for

avermectin B_{1a}/8,9-Z-isomer was 0.001 ppm for all foods in food handling establishments. The petitioner also indicated that the smaller peak (avermectin B_{1b}/8,9-Z-isomer), at ≤20% of the larger peak, would be expected to be nondetectable when the larger peak was nondetectable.

Conclusions. The methods used for data collection can analyze the residues of concern for risk assessment and are adequate for data collection based on acceptable concurrent recoveries. Analytical methods for enforcement of residues from the use of abamectin are available in PAM II for citrus and processed fractions (Method I), ginned cottonseed (Method IA), and bovine tissues and milk (Method II). These methods determine residues in plant and livestock commodities at limits of quantitation (LOQ's) of 0.005 ppm for milk, 0.02 ppm for meat and meat byproducts, and ≤0.01 ppm for other food items in food handling establishments. The limit of detection (LOD) of the methods is 0.001 ppm for each analyte, equivalent to a 0.002 ppm for plant and livestock commodities.

60.1360 Multiresidue Methods

DER Reference List: None

The 1990 Pestrak data base indicates that abamectin and its metabolites are not recovered or not likely to be recovered by FDA multiresidue methods. Therefore, the multiresidue methods can not be used to determine residues for dietary exposure assessment and can not be used as the primary enforcement method.

860.1380 Storage Stability

DER Reference List: 44878101, 44933401, 44933402, and 44933403

Residue samples were stored frozen from 13 to 182 days (approx. 6 months) before analysis.

Storage stability data were submitted for each of the eight food matrices. Each food (lettuce, crackers, bread, cream pie, sliced cheese, sliced meat, butter, and whole milk) was fortified with abamectin [with the assigned purity of 0.893% avermectin B_{1a} (w/w) and 0.044 % avermectin B_{1b} (w/w)] at 0.01 ppm. After fortification, the foods were stored in a freezer at -30°C to -10°C for 8-12 months. Recoveries of avermectin B_{1a} and its delta-8,9-isomer were determined. Based on acceptable recoveries, residues of abamectin were stable for 8-12 months in the eight food matrices.

The available storage stability data are adequate to support the storage conditions and intervals of samples from the food handling study.

860.1400 Water, Fish, and Irrigated Crops

Abamectin is not presently registered or proposed for use on water, fish, and irrigated crops.

860.1460 Food Handling

DER Reference List: 44878101, 44933401, 44933402, and 44933403

Table 4. Summary of Residues from the Crop Field Trials with Abamectin.[1]

Crop Matrix	Applic. Rate (mg ai/sq ft)	PHI (hours)	Residues (ppm)				
			Mean	Std. Dev.	HAFT	Min.	Max.
Food Handling Establishments (proposed use = 0.018 mg ai/sq ft/application, 0-day PHI)							
Food in Food Handling Establishments	0.018 mg ai/sq ft[2]	0-24	<0.001	NA	<0.001	<0.001	<0.001[3]

[1] The study determined the peak comprising abamectin B_{1a} /8,9-Z-isomer. The second peak comprising abamectin B_{1b} /8,9-Z-isomer was not determined in the study since it represents ≤20% of the ai.
[2] 36 mg Avert PT310/ft^2 = 0.018 mg ai/sq ft.
[3] All residues were <0.001 ppm in MRID 44878101. A second report (MRID 44933403) was not reviewed because the field phase of the study was not conducted under Good Laboratory Practices.

The study was conducted in the food preparation and handling areas of a restaurant which was not in operation during the study. All food preparation and storage equipment were in the restaurant and in place during the conduct of the study. Ventilation fans and heating systems were in operation as they would be during normal working conditions and the temperature was maintained at typical restaurant conditions.

Avert® PT 310 (containing 0.05% abamectin as the active ingredient) was applied by a licensed pesticide applicator in a total treatment area of 1655 sq. ft. The rate of application was a target rate of one tube (30g) per 500 sq. ft. The application was repeated at 7 days and 14 days after the first application for a total of three treatments. The application rate was 27.05 g, 34.50 g, and 33.08 g per 500 sq. ft. for the first, second, and third treatment, respectively. The petitioner reported that this application rate is equivalent to 0.0143 g, 0.0182 g, and 0.0174 g of active ingredient (abamectin) per 500 sq ft for the first, second, and third treatment, respectively.

Eight foods, including soda crackers, cheese slices, whole milk, sliced sandwich meat, butter, lettuce, bread, and cream pie were selected for the study. These specific foods were chosen because they represent the types of foods that could be available in an operating food-handling establishment. They also cover the range from non-fatty (soda crackers and lettuce) to fatty (butter, meat, cheese slices) foods and high moisture (lettuce, meat, and cheese slices) to low moisture (soda crackers, and butter) foods.

Three sites in the restaurant were identified as food placement areas. One of these areas was near the center of the food preparation, on top of the grill and a serving table. Another area consisted of a serving cart, serving counter, and the deep fat fryer located along an exterior wall of the building. The last area consisted of a stainless steel table and the top of two ovens located along an interior wall on the opposite side of the food preparation area.

Abamectin was applied into cracks and crevices according to label directions on three separate occasions. Foods were placed in the three placement areas for each sampling interval. Samples were collected at five sampling intervals for each treatment, ranging from 4 hours before treatment to 24 hours after treatment. At each sampling interval, unexposed control samples were also collected.

Samples were stored frozen for 13 to 182 days before analysis. The analytical methods used involved extracting abamectin from the matrix using acetonitrile/water, hexane, or methanol, cleaning up the sample extract, derivatizing into a fluorescent compound, and quantitation by HPLC with fluorescence detection. The reported limit of quantitation (LOQ) for all matrices was 0.001 ppm (1.0 ppb). Residues of abamectin in all controls and treated samples were reported as <0.001 ppm in MRID 44878101.

Conclusions. The residue data are adequate to indicate that abamectin residues in food in food handling establishments will be below 0.005 ppm in milk, below 0.02 ppm in meat and meat byproducts of cattle, goat, hog, horse, poultry, and sheep; and below 0.01 ppm in/on all other food items in food handling establishments. The limit of detection (LOD) for all food items in food handling establishments is 0.001 ppm for each analyte (avermectin B_{1a}/8,9-Z-isomer and avermectin B_{1b}/8,9-Z-isomer), equivalent to 0.002 ppm for plant and livestock commodities. Adequate storage stability data were submitted.

860.1480 Meat, Milk, Poultry, and Eggs

No feeding studies have been submitted with this petition. Tolerances have been established on cattle commodities at 0.015 ppm in fat, 0.02 ppm in meat and meat byproducts, and 0.005 ppm in milk. No tolerances have been established for poultry commodities.

Foods in food handling establishments are not significant livestock feeds.

860.1500 Crop Field Trials

Crop field trials are not pertinent to the proposed use in food handling establishments.

860.1520 Processed Food and Feed

Processing studies are not pertinent to the proposed use in food handling establishments.

860.1850 Confined Accumulation in Rotational Crops
and
860.1900 Field Accumulation in Rotational Crops

DER Reference List: None

The results of a confined rotational crop study indicated that avermectin residues accumulated in some rotational crops at levels up to 10-12 ppb; however, the radioactivity was due to polar degradates that were of little toxicological concern as compared to the parent compound avermectin B_1 and/or the delta-8,9-isomer (memo of P. Mastradone dated 4/24/88). Therefore, field rotational crop studies have not been required (PP#7F3500, #8F3592, and #5E4566, DP Barcodes: D230333, D230352, D230880, G. Herndon, 1/10/97).

Rotational crop studies are not pertinent to the proposed use in food handling establishments.

860.1550 Proposed Tolerances

HED has determined that the nature of the residue in plants and livestock is adequately understood. The residues of concern in plant and livestock commodities are abamectin, avermectin B_1 [≥80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and ≤20% avermectin B_{1b} (5-*O*-demethyl-25-de (1-methylpropyl)-25-(1-methylethyl) avermectin A_1)], and its delta-8,9-isomer for tolerances and risk assessment.

The petitioner has proposed the establishment of a permanent tolerance of 0.001 ppm for residues of abamectin and/or its delta 8,9-isomer on food products in food handling establishments. There are no residue chemistry data deficiencies that would preclude the establishment of permanent tolerances for the combined residues of the insecticide avermectin B_1 [a mixture of avermectins containing greater than or equal to 80% avermectin B_{1a} (5-*O*-demethyl avermectin A_1) and less than or equal to 20% avermectin B_{1b} (5-*O*-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_1)] and its delta-8,9-isomer in/on meat and meat byproducts of goat, hog, horse, poultry, and sheep at 0.02 ppm; and in/on all other food items (other than those already covered by higher tolerances as a result of use on growing crops and other than milk, for which the established 0.005 ppm tolerance is adequate) in food handling establishments at 0.01 ppm. The limit of detection (LOD) for all food items in food handling establishments is 0.001 ppm for each analyte (avermectin B_{1a}/8,9-Z-isomer and avermectin B_{1b}/8,9-Z-isomer), equivalent to 0.002 ppm for plant and livestock commodities.

Codex has recommended several MRL's for plant and cattle commodities (*Pesticide Residues in Food-1997, Part 1).* The Codex residue definition (step 8/CXL) is "sum of avermectin B_{1a}, avermectin B_{1b}, 8,9-Z-avermectin B_{1a} and 8,9-Z-avermectin B_{1b} for plants, and the sum of avermectin B_{1a} and 8,9-Z-avermectin B_{1a} for cattle commodities. The Codex limits of determination (equivalent to HED's limits of quantitation, LOQ's) for plant and livestock commodities are ≤0.01 ppm. (For plants, the LOQ ranges from 0.002 to 0.005 ppm for each of two peaks, one peak representing avermectin B_{1a} and its 8,9-Z-isomer and the other peak

representing avermectin B_{1b} and its 8,9-Z-isomer. For cattle meat, the Codex LOQ is 0.01 ppm.) The tolerance expression in Canada for plants is "avermectin B_{1a}, avermectin B_{1b}, and the 8,9-Z-isomers." The tolerance expression in Mexico for plants is avermectina.

The Codex and the USA residue definitions are the same for plants. The Codex definition does not include avermectin B_{1b} and 8,9-Z-avermectin B_{1b} for livestock commodities whereas the USA does include avermectin B_{1b} and 8,9-Z-avermectin B_{1b} in livestock commodities.

Table 5. Tolerance Summary for Abamectin

Commodity	Proposed (P)/ Established (E) Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (*correct commodity definition)*
All food items (other than those already covered by higher tolerances as a result of use on growing crops, and other than milk and meat and meat byproducts) in food handling establishments	0.001 (P)	0.01	
milk	0.005 (E)	0.005	No action is needed since the tolerance of 0.005 ppm on milk is established.
meat and meat byproducts of cattle	0.02 (E)	0.02	No action is needed since the tolerance of 0.02 ppm on *cattle, meat* and *cattle, meat byproducts* is established.
meat and meat byproducts of goat, hog, horse, poultry, and sheep	0.001 (P)	0.02	*goat, meat* *goat, meat byproducts* *hog, meat* *hog, meat byproducts* *horse, meat* *horse, meat byproducts* *poultry, meat* *poultry, meat byproducts* *sheep, meat* *sheep, meat byproducts* The Codex 0.01 ppm LOQ for meat measures only avermectin B_{1a}/8,9-Z-isomer; the US measures avermectin B_{1a} /8,9-Z-isomer and avermectin B_{1b}/8,9-Z-isomer. A US tolerance of 0.02 ppm for cattle meat and meat byproducts is already established.

160.1650 Submittal of Analytical Reference Standards

The analytical reference standards for avermectin B_1 and its 8,9-Z-isomer have been submitted to the USEPA National Pesticide Standards Repository.

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Chemical:	**Abamectin**
PC Code:	**122804**
HED File Code	**11500 Petition Files Chemistry**
Memo Date:	**12/01/2004**
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