(11-20-03)

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STUDY REPORTS:

MRID No. 44878101. A. Siirila (3/13/97) Study title: Magnitude of the Residues of Abamectin in Typical Foods Exposed in a Food-Handling Establishment Treated with Avert® PT310. Lab Project Number: CHW 6585-105. Unpublished study prepared by Corning Hazleton, Inc. 550 pages.

MRID No. 44933401. A. Siirila (11/18/96) Study title: Method Validation of Abamectin in Food Items (Amended Report). Lab Project Number: HWI 6585-101. Unpublished study prepared by Hazleton Wisconsin, Inc. 142 pages.

MRID No. 44933402. A. Siirila (1/24/97) Study title: Freezer Storage Stability of Abamectin Residues in Various Food Items. Lab Project Number: CHW 6585-104. Unpublished study prepared by Corning Hazleton, Inc. 95 pages.

MRID No. 44933403. A. Siirila (6/26/97) Study title: Abamectin Food Handling Study (Amended Report) Lab Project Number: HWI 6585-106. Unpublished study prepared by Hazleton Wisconsin, Inc. 205 pages.

EXECUTIVE SUMMARY:

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. The rate of application was at a target 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. 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. The total treatment area was 1655 sq. ft.

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. Samples were collected at five sampling intervals. For each sampling interval, foods were placed in the three placement areas and collected at various times after treatment. For the first sampling interval, foods were exposed for approximately four hours before treatment. After treatment, the first interval samples were collected, and samples from the second and third interval were exposed. After samples from these two intervals were placed, the next treatment was initiated. After the treatment was complete, samples from the fourth interval were exposed. Samples from the second and fourth interval were collected four hours after the the treatment. After collection of the samples, samples from the fifth interval were exposed. Samples from the third and fifth interval were collected the following day, 24 hours after the initiation of the treatment. All food samples were weighed before use in the study. At each sampling interval, unexposed control samples were collected. All exposures were conducted with a minimum of three groups (one at each food placement area).

Samples were stored frozen 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 flourescence detection. The limit of quantitation (LOQ) for all matrices is 1.0 ppb.

Residues of abamectin were less than the LOQ in all control and study samples.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the residue data are classified as scientifically acceptable.

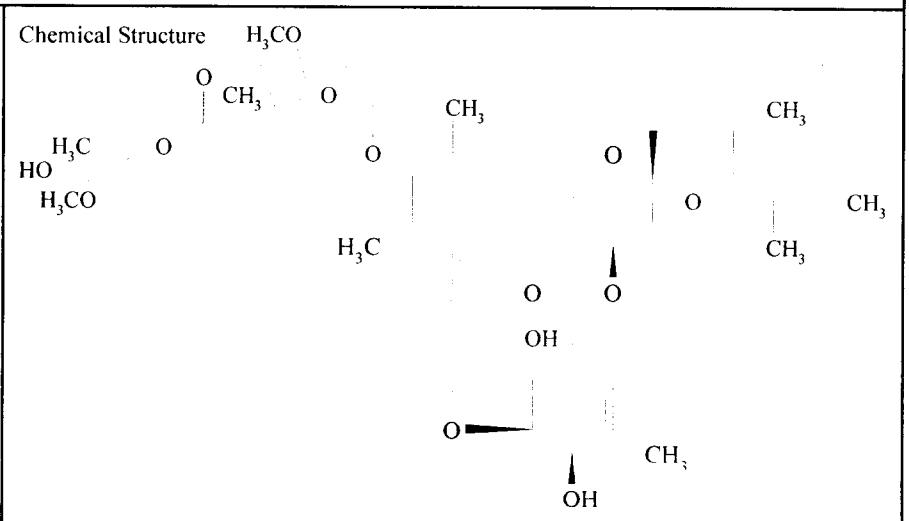
The acceptability of this study for regulatory purposes is addressed in a forthcoming U.S. EPA Residue Chemistry Summary Document for abamectin.

COMPLIANCE:

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

A. BACKGROUND INFORMATION

TABLE A.1. Test Compound Nomenclature

Compound	Chemical Structure
Avermectin B1a	

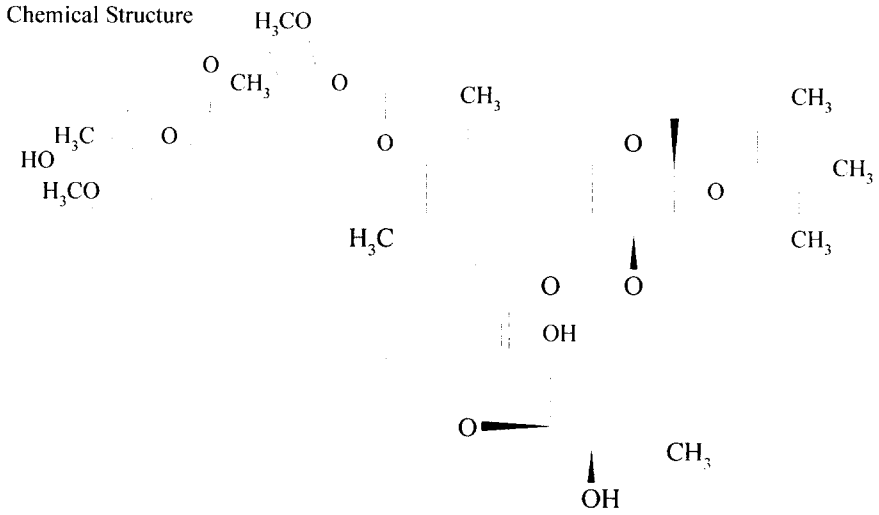
Compound Avermectin B1b	Chemical Structure 
Common name	Abamectin
IUPAC name	(10E,14E,16E,22Z)-(1R,4S,5?S,6S,6?R,8R,12S,13S,20R,21R,24S)-6?-[(S)-sec-butyl]-21,24-dihydroxy-5?,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene)-6-spiro-2?-(5?,6?-dihydro-2?H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-?-L-arabino-hexopyranosyl)-3-O-methyl-?-L-arabino-hexopyranoside and (10E,14E,16E,22Z)-(1R,4S,5?S,6S,6?R,8R,12S,13S,20R,21R,24S)-21,22-dihydroxy-6?-isopropyl-5?,11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]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-?-L-arabino-hexopyranosyl)-3-O-methyl-?-L-arabino-hexopyranoside
CAS name	Avermectin B1
CAS #	71751-41-2
End-use product/EP	Avert® PT 310
CFR Reference	40 CFR §180.449

TABLE A.2. Physicochemical Properties

Parameter	Value	Reference (MRID#)
Melting point/range	155-157	
pH	No Acidic or Basic Group	
Density	1.16 @ 21	
Water solubility (25 °C)	≤ 0.01 mg / mL (distilled water) < 0.001 mg / mL (tap water)	

TABLE A.2. Physicochemical Properties		
Parameter	Value	Reference (MRID#)
Solvent solubility (g/L at 20 °C)	> 0.002 g / L Chloroform > 0.002 g / L Dimethylacetamide > 0.002 g / L Dimethylformamide > 0.003 g / L Ethanol > 0.002 g / L Glycerol formal > 0.002 g / L Isopropyl myristate > 0.002 g / L Polysorbate 80 > 0.002 g / L Polyethylene Dycol 400	
Vapor pressure at 25 °C	1.5×10^{-9}	
Octanol/water partition coefficient Log(K_{OW})	9.9×10^{3}	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Study Site and Use Pattern.

Establishment	Establish-ment Type	EP[1]	Application						Residue-transfer Route
			Method	Rate, Units	Retreat. Interval (Days)	No. of Applics.	Total Rate, Units	Coapplied Adjuvants	
Food-handling	Restaurant	Avert® PT 310	Direct application to cracks and crevices	30g/500 sq. ft.	7	3	90g/500 sq.ft.	N/A	volatilization and sorption/condensation

[1]EP = End-use Product

B.2. Analytical Methodology

Abamectin is a mixture of two homologs containing not less than 80% avermectin B1a and not greater than 20% avermectin B1b. Avermectin B1b is at most 20% of the active ingredient and total B1b residues in test systems are generally low. Thus, the expected homolog of abamectin present in samples was avermectin B1a. When avermectin B1a is below the LOQ, avermectin B1b would also be well below the LOQ. In general, 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 flourescence detection. HED notes that since this is a common moeity method, this method will also determine residues of avermectin B1b and its delta-8,9-isomer. Also, since the tolerance expression on 40 CFR §180.449 is expressed in terms of the combined residues of avermectin B1a, avermectin B1b and the delta-8,9-isomer and there were no residues above the LOQ, there is no need to anlyze or report them separately for purposes of this action only.

The methods used and validated for this report were: "HPLC-Fluorescence Determination of Avermectin B1 and its Delta 8,9 Isomer in Ginned Cotton Seed" (used for crackers and bread), 'HPLC-Fluorescence Determination of Avermectin B1 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). The combined LOQ for the method is 1 ppb.

C. RESULTS AND DISCUSSION

The analytical methods were validated for each matrix (except crackers) at the following levels: control samples and duplicate fortifications at 1.0 ppb, 5.0 ppb, and 20 ppb. The crackers validation consisted of an analysis of control samples and duplicate fortifications at 1.0 ppb, 4.0 ppb, and 20 ppb. The recoveries ranged from 70% to 117% with an average recovery of 89%. The average recovery for each matrix was 80%, 93%, 111%, 89%, 80%, 76%, 99%, and 83% for lettuce, cream pie, meat slices, crackers, bread, cheese slices, milk, and butter, respectively (Table C.1).

Each of the eight food matrices were fortified with abamectin at 10 ppb. Fortified samples were stored in a freezer set to maintain -30°C to -10°C and were analyzed at various intervals. Lettuce, crackers, and bread samples were analyzed intially (0 month) and after approximately 8 months of storage. Cream pie, cheese, and butter samples were analyzed at 0 month and approximately 10 month intervals. Meat and milk samples were analyzed at 0 month and approximately 2, 4, 6, 8, 10, and 12 month intervals. Concurrent fortification recoveries ranged from 67% to 75% for lettuce, 69% to 116% for cream pie, 59% to 112% for cheese, 82% to 102% for sliced meat, 62% to 93% for crackers, 56% to 86% for bread, 87% to 121% for milk, and 67% to 91% for butter. Samples in the food-handling establishment study were stored frozen for 182 days (apporx. 6 months) before analysis. (See table C.2)

No residues of abamectin above the LOQ of 1.0 ppb were detected in any of the treated or control samples.

TABLE C.1. Summary of Concurrent Recoveries of Abamectin in Several Matrices.

Matrix	Analyte	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Lettuce	Abamectin	1 ppb	2	77,77	80±8.2
	Abamectin	5 ppb	2	74,80	
	Abamectin	20 ppb	2	75,96	
Cream Pie	Abamectin	1 ppb	2	86,91	93±4
	Abamectin	5 ppb	2	94,94	
	Abamectin	20 ppb	2	94,98	
Meat Slices	Abamectin	1 ppb	2	110,112	111±3
	Abamectin	5 ppb	2	109,117	
	Abamectin	20 ppb	2	108,108	
Crackers	Abamectin	1 ppb	2	94,91	89±4
	Abamectin	4 ppb	2	82,89	

Matrix	Analyte	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
	Abamectin	20 ppb	2	89,89	
Bread	Abamectin	1 ppb	2	71,70	80±7
	Abamectin	5 ppb	2	82,83	
	Abamectin	20 ppb	2	89,82	
Cheese Slices	Abamectin	1 ppb	2	82,78	76±4
	Abamectin	5 ppb	2	72,77	
	Abamectin	20 ppb	2	73,73	
Milk	Abamectin	1 ppb	2	108,106	99±6
	Abamectin	5 ppb	2	97,95	
	Abamectin	20 ppb	2	96,94	
Butter	Abamectin	1 ppb	2	81,90	83±5
	Abamectin	5 ppb	2	78,84	
	Abamectin	20 ppb	2	78,85	

TABLE C.2. Summary of Storage Conditions

Matrix (RAC or Extract)	Storage Temp. (°C)	Actual Storage Duration (days)	Limit of Demonstrated Storage Stability (months)
Lettuce	-30 to -10	182	8
Cream Pie	-30 to -10	182	10
Sliced Cheese	-30 to -10	182	10
Sliced Meat	-30 to -10	182	10
Crackers	-30 to -10	182	8
Bread	-30 to -10	182	8
Milk	-30 to -10	182	12
Butter	-30 to -10	182	10

D. CONCLUSION

The residue data reflect the proposed use of abamectin on food handling establishments. Abamectin residues were less than 1 ppb in all samples analyzed. Samples were analyzed by an adequate HPLC data collection method. The storage conditions and intervals of samples are supported by adequate storage stability data. Under the conditions and parameters used in the study, the residue data are classified as scientifically acceptable.

E. REFERENCES

None

Template Version March 2003