

063 AB



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

OCT 17 1995

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Avermectin B₁ in/on Pears. PP# 1F3787.

FROM: Brian Steinwand *BS*
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head *E. A. Doyle*
Dietary Risk Evaluation Section
SAB/Health Effects Division *W. J. Burd*

TO: G. LaRocca/A. Heyward, PM Team 13
Registration Division (7505C)

Action Requested

Provide a dietary exposure analysis to estimate the chronic and acute dietary exposure and risk from Avermectin B₁ in/on pears. The petition requests but CBTS recommends against the establishment of tolerances of 0.02 ppm on pears (See memo, G. Herndon, 9/14/95).

Discussion

The registrant originally requested a 0.035 ppm tolerance on pears, and the proposed enforcement method was sent to EPA's Analytic Chemistry Lab (ACL) to be validated. ACL noted several deficiencies in the method which were later resolved (See memo, G. Herndon, 12/16/93). CBTS continues to recommend against the issuance of a permanent tolerance on pears at 0.02 ppm until some data deficiencies can be resolved. However, a DRES run should be initiated (See memo, G. Herndon, 9/14/95).

There are no known animal feed stock uses for pears; secondary residues in meat, milk, poultry and eggs are not expected to be a problem (Personal communication, G. Herndon, 10/10/95).

For the purposes of this analysis, the new tolerance on cucurbits was upgraded to pending status.



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.0004 mg/kg bwt/day, based on a NOEL of 0.12 mg/kg bwt/day from a two generation rat reproduction study with an uncertainty factor of 300 that demonstrated decreased litter size and increased pup deaths. The RfD Peer Review Committee noted that "the greater uncertainty factor is supported by the severity of the effects (pup death) and steep dose-response...." (See memo, R. Gardner, 7/8/93). DRES is not aware of any carcinogenic concerns for Avermectin B₁.

The endpoint for acute dietary risk assessment is the Developmental NOEL (0.06 mg/kg/day) from the mouse developmental toxicity study (See memo, R. Gardner, 7/8/93). The effect level in this study (≥ 0.1 mg/kg/day) is based upon increased incidence of cleft palate.

Residue Information

Tolerances for Avermectin B₁ residues in/on agricultural and animal commodities are published in 40 CFR §180.449 and §186.300. One hundred percent crop treated assumptions were made for all commodities. Anticipated residue (AR) data for cucurbits were supplied by CBTS (See memo, G. Herndon, 9/21/95).

Results

A summary of the residue information and ARs included in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using anticipated residue level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) and the Anticipated Residue Contribution (ARC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Tables 2 and 3.

Chronic Exposure Analysis

Exposure from Existing ARs for Avermectin B₁:

<u>Subgroup</u>	<u>Exposure (mg/kg/day)</u>	<u>ARC</u>
U.S. Population	0.000012	3.1
Non-Nursing Infants (< 1 yr old)	0.000017	4.4

Proposed new ARs on pears:

U.S. Population	0.000001	.245
Non-Nursing Infants (< 1 yr old)	0.000013	3.1

If the new ARs on pears are approved:

U.S. Population	0.000013	3.4
Non-Nursing Infants < 1 yr old)	0.000030	7.5

The chronic analysis for Avermectin B₁ is not a worst case estimate of dietary exposure, and includes some residues at anticipated levels and 100 percent of the commodities assumed to be treated with Avermectin B₁. Based on the risk estimates calculated in this analysis, it appears that chronic dietary risk from the uses recommended is not of concern.

Acute Exposure:

The DRES detailed acute analysis estimates the distribution of single-day exposures for the overall U.S. population and certain subgroups. The analysis evaluates individual food consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of Avermectin B₁ in the commodity supply. Since the toxicological endpoint to which exposure is being compared in this analysis is developmental toxicity, females (13+ years), is the sub population of particular interest.

The Margin of Exposure (MOE) is a measure of how close the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). Generally, acute dietary margins of exposure greater than 100 tend to cause no dietary concern. The high end MOE value of 1000 (See Table 4) is above the acceptable level and demonstrates no acute dietary concern.

Attachments

cc: DRES; Caswell 063AB; RCAB; CBTS I (G. Herndon)

TABLE 1

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 10/10/95

PAGE: 1

CHEMICAL

STUDY TYPE

EFFECTS

REFERENCE DOSES

DATA GAPS/COMMENTS

STATUS

Avermectin B1 Caswell #063AB CAS No. 65195-55-3 A.I. CODE: 122804 CFR No. 180.449	2gen reprod- rat NOEL= 0.1200 mg/kg 0.00 ppm LEL= 0.4000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Incr retinal folds in weanlings, decr viability & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of carcinogen.	AD1 UF -->300 OPP RfD= 0.000400 EPA RfD= 0.000400	No data gaps. UF of 300 due pup deaths in critical study & maternal developmental toxicity in teratology studies. Mouse teratogen.	HED reviewed 07/11/86 HED reassess 06/12/87 EPA reassess 03/30/89 EPA verified 04/20/89 WHO reviewed 1992 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
01016AA	STRAWBERRIES	10 RAW-FRESH OR NFS	0F3880	P 0.020000	0.020000		100.00	0.020000
01016AA	STRAWBERRIES	21 COOKED-NFS	0F3880	P 0.020000	0.020000		100.00	0.020000
01016AA	STRAWBERRIES	70 RAW-FROZEN	0F3880	P 0.020000	0.020000		100.00	0.020000
02001AA	CITRUS CITRON	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.000850	PROCESSING	100.00	0.000850
02002AA	GRAPEFRUIT-UNSP	00 NOT SPECIFIED	8F3592	P 0.020000	0.000850	PROCESSING	100.00	0.000850
02002AB	GRAPEFRUIT-PULP	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000500	PROCESSING	100.00	0.000500
02002AB	GRAPEFRUIT-PULP	21 COOKED-NFS	8F3592	P 0.020000	0.000500	PROCESSING	100.00	0.000500
02002JA	GRAPEFRUIT-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.000850C	PROCESSING	100.00	0.000850
02002JA	GRAPEFRUIT-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.000850C	PROCESSING	100.00	0.000850
02003AA	KUMQUATS	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.004000	PROCESSING	100.00	0.004000
02004AA	LEMONS-UNSPEC	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.002500	PROCESSING	100.00	0.002500
02004AB	LEMONS-UNSPEC	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.002500	PROCESSING	100.00	0.002500
02004AB	LEMONS-PULP	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000500	PROCESSING	100.00	0.000500
02004AB	LEMONS-PULP	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.000500	PROCESSING	100.00	0.000500
02004AB	LEMONS-PEEL	10 RAW-FRESH OR NFS	8F3592	P 0.100000	0.002500	PROCESSING	100.00	0.002500
02004AB	LEMONS-PEEL	21 COOKED-NFS	8F3592	P 0.100000	0.002500	PROCESSING	100.00	0.002500
02004JA	LEMONS-JUICE	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02004JA	LEMONS-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02004JA	LEMONS-JUICE	21 COOKED-NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02004JA	LEMONS-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005AA	LEMONS-UNSPEC	00 NOT SPECIFIED	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005AA	LEMONS-UNSPEC	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005AA	LEMONS-UNSPEC	21 COOKED-NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005AA	LEMONS-UNSPEC	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005JA	LIMES-JUICE	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005JA	LIMES-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005JA	LIMES-JUICE	21 COOKED-NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02005JA	LIMES-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02006AA	ORANGES-UNSPEC	00 NOT SPECIFIED	8F3592	P 0.020000	0.010000	PROCESSING	100.00	0.010000
02006AA	ORANGES-UNSPEC	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.010000	PROCESSING	100.00	0.010000
02006AA	ORANGES-UNSPEC	21 COOKED-NFS	8F3592	P 0.020000	0.010000	PROCESSING	100.00	0.010000
02006AA	ORANGES-UNSPEC	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.010000	PROCESSING	100.00	0.010000
02006JA	ORANGES-PEEL	22 COOKED-FRESH-BAKED	8F3592	P 0.100000	0.010000	PROCESSING	100.00	0.010000
02006JA	ORANGES-PEEL	31 COOKED-FRESH OR CANNED	8F3592	P 0.100000	0.010000	PROCESSING	100.00	0.010000
02006JA	ORANGES-PEEL	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.001000	PROCESSING	100.00	0.001000
02006JA	ORANGES-PEEL	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.001000	PROCESSING	100.00	0.001000
02006JA	ORANGES-PEEL	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.001000	PROCESSING	100.00	0.001000
02006JA	ORANGES-PEEL	21 COOKED-NFS	8F3592	P 0.020000	0.001000	PROCESSING	100.00	0.001000
02006JA	ORANGES-PEEL	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.001000	PROCESSING	100.00	0.001000
02007AA	TANGELLOS	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
02008AA	TANGELLOS	15 RAW-FRESH OR NFS	8F3592	P 0.020000	0.000250C	PROCESSING	100.00	0.000250
04003AA	PEARS-FRESH	31 COOKED-FRESH OR CANNED	1F3787	N 0.020000	0.008000		100.00	0.008000
04003AA	PEARS-FRESH	51 COOKED-CANNED	1F3787	N 0.020000	0.008000		100.00	0.008000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 10/10/95

PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Avermectin B1 Caswell #063AB CAS No. 65195-55-3 A.I. CODE: 122804 CFR No. 180.449	2gen reprod. rat NOEL= 0.1200 mg/kg 0.00 ppm LEL= 0.4000 mg/kg 0.00 ppm ONCO: Negative- 2 species.	Incr retinal folds in weanlings, decr viability & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of carcinogen.	ADI UF -->300 OPR RfD= 0.000400 EPA RfD= 0.000400	No data gaps. UF of 300 due pup deaths in critical study & maternal developmental toxicity study in teratology studies. Mouse teratogen.	HED reviewed 07/11/86 HED reassess 06/12/87 HED reassess 03/30/89 EPA verified 04/20/89 WHO reviewed 1992 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET. #	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
04003AA	PEARS-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	1F3787	N 0.020000	0.008000		100.00	0.008000
04003DA	PEARS-DRIED	10 RAW-FRESH OR NFS	1F3787	N 0.020000	0.035000C		100.00	0.035000
04003DA	PEARS-DRIED	21 COOKED-NFS	1F3787	N 0.020000	0.035000C		100.00	0.035000
08020AA	HOPS	21 COOKED-NFS	4E04419	A 0.500000	0.500000		100.00	0.500000
10002AA	CANTALOUPE-UNSP	00 NOT SPECIFIED (NO CONSUMPTION)	4F04354	A 0.005000	0.001300		100.00	0.001300
10002AB	CANTALOUPE-PULP	21 COOKED-NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10003AA	CASABAS	10 RAW-FRESH OR NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10004AA	CRESHAWS	00 NOT SPECIFIED (NO CONSUMPTION)	4F04354	A 0.005000	0.001300		100.00	0.001300
10005AA	HONEYDEW MELONS	10 RAW-FRESH OR NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10007AA	PERSON MELONS	00 NOT SPECIFIED (NO CONSUMPTION)	4F04354	A 0.005000	0.001300		100.00	0.001300
10008AA	WATERMELON	10 RAW-FRESH OR NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10010AA	CUCUMBERS	21 COOKED-NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10010AA	CUCUMBERS	11 RAW-FRESH OR NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10010AA	CUCUMBERS	21 COOKED-NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10010AA	CUCUMBERS	21 COOKED-NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10011AA	PUMPKIN	22 COOKED-FRESH-BAKED	4F04354	A 0.005000	0.001300		100.00	0.001300
10011AA	PUMPKIN	62 COOKED-FRESH OR FROZEN-BAKED	4F04354	A 0.005000	0.001300		100.00	0.001300
10013AA	SQUASH-SUMMER	10 RAW-FRESH OR NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10013AA	SQUASH-SUMMER	21 COOKED-NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10014AA	SQUASH-WINTER	10 RAW-FRESH OR NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10014AA	SQUASH-WINTER	21 COOKED-NFS	4F04354	A 0.005000	0.001300		100.00	0.001300
10017AA	BITTER MELON	31 COOKED-FRESH OR CANNED	4F04354	A 0.005000	0.001300		100.00	0.001300
10020AA	TOMELGOURD	00 NOT SPECIFIED (NO CONSUMPTION)	4F04354	A 0.005000	0.001300		100.00	0.001300
11003AA	PEPPERS, SWEET	10 RAW-FRESH OR NFS	3F4258	A 0.010000	0.002000		100.00	0.002000
11003AA	PEPPERS, SWEET	21 COOKED-NFS	3F4258	A 0.010000	0.002000		100.00	0.002000
11003AB	CHILI PEPPERS	00 NOT SPECIFIED (NO CONSUMPTION)	3F4258	A 0.010000	0.002000		100.00	0.002000
11003AD	PEPPERS-OTHER	10 RAW-FRESH OR NFS	3F4258	A 0.010000	0.002000		100.00	0.002000
11003AD	PEPPERS-OTHER	21 COOKED-NFS	3F4258	A 0.010000	0.002000		100.00	0.002000
11005AA	TOMATOES-WHOLE	51 COOKED-CANNED	3F4258	A 0.010000	0.002000		100.00	0.002000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	1E3943	P 0.010000	0.002000	IMPORT TOL	100.00	0.002000
11005AA	TOMATOES-WHOLE	31 COOKED-NFS	1E3943	P 0.010000	0.002000	IMPORT TOL	100.00	0.002000
11005AA	TOMATOES-WHOLE	21 COOKED-FRESH OR CANNED	1E3943	P 0.010000	0.002000	IMPORT TOL	100.00	0.002000
11005JA	TOMATOES-JUICE	10 RAW-FRESH OR NFS	9F3703	P 0.010000	0.000420C		100.00	0.000420
11005JA	TOMATOES-JUICE	21 COOKED-NFS	9F3703	P 0.010000	0.000420C		100.00	0.000420
11005RA	TOMATOES-PUREE	10 RAW-FRESH OR NFS	9F3703	P 0.010000	0.000800C		100.00	0.000800
11005RA	TOMATOES-PUREE	21 COOKED-NFS	9F3703	P 0.010000	0.000800C		100.00	0.000800
11005RA	TOMATOES-PUREE	31 COOKED-FRESH OR CANNED	9F3703	P 0.010000	0.000800C		100.00	0.000800

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 10/10/95

PAGE: 3

CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Avermectin B1 Caswell #063AB CAS No. 65195-55-3 A.I. CODE: 122804 CFR No. 180.449		2gen reprod- rat NOEL= 0.1200 mg/kg 0.00 ppm LEL= 0.4000 mg/kg 0.00 ppm ONCO: Negative- 2 species.		Incr retinal folds in weanlings, decr viability & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of carcinogen.		ADI UF -->300 OPP RfD= 0.000400 EPA RfD= 0.000400		No data gaps. UF of 300 due pup deaths in critical study & maternal developmental toxicity in teratology studies. Mouse teratogen.		HED reviewed 07/11/86 HED reassess 06/12/87 HED reassess 03/30/89 EPA verified 04/20/89 WHO reviewed 1992 On IRIS.	
FOOD CODE	FOOD	FOOD FORM	PET. #	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)			
11005RA	TOMATOES-PUREE	32 COOKED-FRESH OR CANNED-BAKED	9F3703	P 0.010000	0.000800C		100.00	0.000800			
11005RA	TOMATOES-PUREE	51 COOKED-CANNED	9F3703	P 0.010000	0.000800C		100.00	0.000800			
11005TA	TOMATOES-PASTE	21 COOKED-NFS	9F3703	P 0.010000	0.002400C		100.00	0.002400			
11005TA	TOMATOES-PASTE	22 COOKED-FRESH-BAKED	9F3703	P 0.010000	0.002400C		100.00	0.002400			
11005TA	TOMATOES-PASTE	31 COOKED-FRESH OR CANNED	9F3703	P 0.010000	0.002400C		100.00	0.002400			
11005UA	TOMATOES-CATSUP	21 COOKED-NFS	9F3703	P 0.010000	0.002200C		100.00	0.002200			
13002AA	CELERY	10 RAW-FRESH OR NFS	8F3649	P 0.050000	0.011000		100.00	0.011000			
13002AA	CELERY	21 COOKED-NFS	8F3649	P 0.050000	0.011000		100.00	0.011000			
13016AA	FENNEL	00 NOT SPECIFIED (NO CONSUMPTION)	8F3649	P 0.050000	0.011000		100.00	0.011000			
13020AA	LETTUCE-UNSPEC	10 RAW-FRESH OR NFS	4F4373	P 0.050000	0.009000		100.00	0.009000			
13045AA	LETTUCE-HEAD	10 RAW-FRESH OR NFS	4F4373	P 0.050000	0.009000		100.00	0.009000			
13045AA	LETTUCE-HEAD	21 COOKED-NFS	4F4373	P 0.050000	0.009000		100.00	0.009000			
270030A	COTTONSEED-OIL	18 PROCESSED OIL	7F3500	P 0.005000	0.000200		100.00	0.000200			
270030A	COTTONSEED-OIL	18 PROCESSED OIL	7F3500	P 0.005000	0.000500		100.00	0.000500			
500000B	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	8F3592	P 0.005000	0.001000C		100.00	0.001000			
500000B	MILK-NON-FAT SOL	21 COOKED-NFS	8F3592	P 0.005000	0.001000C		100.00	0.001000			
500000B	MILK-NON-FAT SOL	51 COOKED-CANNED	8F3592	P 0.005000	0.001000C		100.00	0.001000			
500000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	8F3592	P 0.005000	0.001000C		100.00	0.001000			
500000FA	MILK-FAT SOLIDS	21 COOKED-NFS	8F3592	P 0.005000	0.001000C		100.00	0.001000			
500000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	8F3592	P 0.005000	0.001000C		100.00	0.001000			
500000SA	MILK SUG (LACT)	51 COOKED-CANNED	8F3592	P 0.005000	0.000250		100.00	0.000250			
53001BA	BEEF-MEAT BYP	21 COOKED-NFS	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001BA	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED,...	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001BA	BEEF-MEAT BYP	21 COOKED-CANNED	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001BB	BEEF-OTH ORGAN	21 COOKED-NFS	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001BB	BEEF-OTH ORGAN	51 COOKED-CANNED	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001DA	BEEF-DRIED	21 COOKED-NFS	8F3592	P 0.020000	0.002000		100.00	0.002000			
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.006000		100.00	0.006000			
53001FA	BEEF-FAT	21 COOKED-NFS	8F3592	P 0.020000	0.006000		100.00	0.006000			
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.006000		100.00	0.006000			
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	8F3592	P 0.020000	0.006000		100.00	0.006000			
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	8F3592	P 0.020000	0.006000		100.00	0.006000			
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	8F3592	P 0.020000	0.006000		100.00	0.006000			
53001KA	BEEF-KIDNEY	21 COOKED-NFS	8F3592	P 0.020000	0.002000		100.00	0.002000			
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.008000		100.00	0.008000			
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.002000		100.00	0.002000			
53001MA	BEEF-LEAN	21 COOKED-NFS	8F3592	P 0.020000	0.002000		100.00	0.002000			
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.002000		100.00	0.002000			
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	8F3592	P 0.020000	0.002000		100.00	0.002000			

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 10/10/95

PAGE: 4

CHEMICAL		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Avermectin B1 Caswell #063AB CAS No. 65195-55-3 A.I. CODE: 122804 CFR No. 180.449		2gen reprod- rat NOEL= 0.1200 mg/kg LEL= 0.4000 mg/kg 0.00 ppm		Incr retinal folds in meanlings, decr viability- ty & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of carcinogen.		ADI UF -->300 OPP RfD= 0.000400 EPA RfD= 0.000400		No data gaps- UF of 300 due pup deaths in critical study & mat- ernal developmental tox- icity in teratology stud- ies. Mouse teratogen.		HED reviewed 07/11/86 HED reassess 06/12/87 HED reassess 03/30/89 EPA verified 04/20/89 WHO reviewed 1992 On IRIS.	
FOOD CODE	FOOD	FOOD FORM		PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)		
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED		exp. 4/96	8F3592 P 0.020000	0.002000		100.00	0.002000		

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 10/10/95

PAGE: 1

CHEMICAL INFORMATION		STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
Avermectin B1 Caswell #0033AB CAS No. 65195-55-3 A.I. CODE: 122804 CFR No. 180.449		2gen reprod- rat NOEL= 0.1200 mg/kg 0.00 ppm LEL= 0.4000 mg/kg 0.00 ppm ONCO: Negative- 2 species.		Incr retinal folds in weanlings, decr viability & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of carcinogen.		ADI UF -->300 OPP RfD= 0.000400 EPA RfD= 0.000400		No data gaps. UF of 300 due pup deaths in critical study & maternal developmental toxicity in teratology studies. Mouse teratogen.		HED reviewed 07/11/86 HED reassess 06/12/87 HED reassess 03/30/89 EPA verified 04/20/89 WHO reviewed 1992 On IRIS.	
POPULATION SUBGROUP		TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC		DIFFERENCE		EFFECT OF ANTICIPATED RESIDUES			
		CURRENT TMRC*	NEW TMRC**	AS PERCENT OF RFD	AS PERCENT OF RFD	ARC	%RFD				
U.S. POPULATION - 48 STATES		0.000155	0.000161	40.373500	1.507000	0.000016	3.93700				
U.S. POPULATION - SPRING SEASON		0.000153	0.000159	39.746000	1.498000	0.000017	4.14800				
U.S. POPULATION - SUMMER SEASON		0.000154	0.000161	40.194500	1.816500	0.000016	4.07875				
U.S. POPULATION - FALL SEASON		0.000157	0.000163	40.658250	1.414750	0.000015	3.76250				
U.S. POPULATION - WINTER SEASON		0.000158	0.000163	40.847250	1.258000	0.000015	3.74775				
NORTHEAST REGION		0.000173	0.000180	45.007500	1.832000	0.000017	4.35425				
NORTH CENTRAL REGION		0.000158	0.000164	40.951250	1.423000	0.000016	3.94175				
SOUTHERN REGION		0.000132	0.000136	34.050500	1.054000	0.000013	3.25025				
WESTERN REGION		0.000169	0.000177	44.176000	1.921000	0.000018	4.55025				
HISPANICS		0.000198	0.000204	50.879000	1.444500	0.000018	4.48950				
NON-HISPANIC WHITES		0.000155	0.000161	40.290750	1.601250	0.000016	4.05700				
NON-HISPANIC BLACKS		0.000136	0.000140	34.931250	0.816250	0.000011	2.83075				
NON-HISPANIC OTHERS		0.000187	0.000194	48.387000	1.739750	0.000018	4.41225				
NURSING INFANTS (< 1 YEAR OLD)		0.000134	0.000163	40.754500	7.182000	0.000017	4.25775				
NON-NURSING INFANTS (< 1 YEAR OLD)		0.000464	0.000498	124.495750	8.434000	0.000031	7.63500				
FEMALES (13+ YEARS, PREGNANT)		0.000121	0.000123	30.853750	0.682750	0.000011	2.68325				
FEMALES 13+ YEARS, NURSING		0.000136	0.000142	35.614250	1.584500	0.000014	3.52450				
CHILDREN (1-6 YEARS OLD)		0.000371	0.000379	94.781000	1.906250	0.000026	6.44850				
CHILDREN (7-12 YEARS OLD)		0.000237	0.000243	60.627250	1.336000	0.000019	4.79800				
MALES (13-19 YEARS OLD)		0.000154	0.000158	39.392750	0.920000	0.000014	3.58200				
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.000131	0.000134	33.514000	0.738250	0.000012	3.00075				
MALES (20 YEARS AND OLDER)		0.000106	0.000114	28.491250	2.036000	0.000017	4.12825				
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.000109	0.000113	28.347750	1.058250	0.000012	3.06325				

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.

TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Avermectin B1
 USING ANTICIPATED RESIDUES
 CASWELL #063AB

DATE: 10/10/95

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000012	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	3.118	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	<0.000001	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	0.245	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000013	MG/KG/DAY
THE NEW ARC WILL OCCUPY	3.363	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000002	MG/KG/DAY
THIS ARC WILL OCCUPY	0.574	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000016	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	3.937	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000017	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	4.338	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000013	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	3.156	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000030	MG/KG/DAY
THE NEW ARC WILL OCCUPY	7.494	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000001	MG/KG/DAY
THIS ARC WILL OCCUPY	0.141	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000031	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	7.635	% OF THE ADI.

TABLE 4

DETAILED ACUTE ANALYSIS INCLUDING AR/S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:04 Tuesday, October 10, 1995 23

NAME: AVERNECTIN STUDY RDV MOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.
*CASWELL NO: 063AB CFR NO: CFR A 00000.0012 000100 Reproductn Rat Systemic *
*CAS NO: 65195-55-3 SHAUGHNESSY NO: 122804 B C *
*STATUS CODES: *
*RDV INFO: The LD value used in this analysis is 0.0001 mg/kg of BODY WEIGHT/DAY *
FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

-FEMALES(13+ YRS)

ESTIMATES BASED ON		ESTIMATED % OF POTENTIAL		MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY															
TOLERANCES:		PERSON DAYS THAT ARE USER-DAYS		MG/KG BODY WEIGHT/DAY		AS PERCENT OF RDV													
ANTICIPATED RESIDUES:		0.00		0.000000		0.00													
0		99.74		0.000010		10.36													
ESTIMATED % OF POPULATION USER-DAYS WITH RESIDUE CONTRIBUTION EXCEEDING X TIMES THE RDV, FOR X=		0		.2		.4		.6		.8		1		1.2		1.4		1.6	
TOLERANCES:		0		0		0		0		0		0		0		0		0	
ANTICIPATED RESIDUES:		100		12		2		0		0		0		0		0		0	
0		0		0		0		0		0		0		0		0		0	
TOLERANCES:		0		0		0		0		0		0		0		0		0	
ANTICIPATED RESIDUES:		100		12		2		0		0		0		0		0		0	
0		0		0		0		0		0		0		0		0		0	

Exposure = RDV x X
= 0.0001 x 0.6
High End Exposure = 0.00006
MOE = Noel ÷ Exposure
= 0.06 mg/kg/day ÷ 0.00006 mg/kg/day
MOE = 1000
Mean MOE = NOEL ÷ Mean
= 0.06 ÷ 0.00001
= 6,000