



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

Please file with petition 1013

TP52

MAY -9 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Avermectin on Tomatoes at 0.01 ppm (PP#9F3703):
Estimates of dietary exposure and risk.

FROM: James P. Kariya *Kariya*
Dietary Risk Evaluation Section
Health Effects Division (7509C)

TO: George LaRocca/Adam Heyward, PM-13
Fungicide-Herbicide Branch
Registration Division (7505C) *LaRocca*

Action requested

Estimation of dietary exposure and risk due to proposed use of Avermectin B₁ on tomatoes at 0.01 ppm. This appears to be a broadening of the current tolerance on tomatoes, which applies to "fresh tomatoes" only.

Toxicological endpoints

For chronic exposures, a Reference Dose (RfD) of 0.0004 mg/kg/day has been assigned to Avermectin based on a No Observed Effect Level of 0.12 mg/kg/day in a two-generation rat reproduction study in which decreased viability of pups (decreased litter size and increased pup deaths) was observed. An Uncertainty Factor of 300 was applied. This UF is higher than is usually assigned when a NOEL is available. The Peer Review Committee noted that "the greater uncertainty factor is supported by the severity of the effects (pup death) and steep dose-response" (Memorandum, R. Gardner to G. LaRocca and J. Ellenberger, 7-8-93, entitled "Developmental and Reproductive Toxicity Peer Review of Avermectin.")

Avermectin is a developmental toxicant in mice. The NOEL is 0.06 mg/kg/day for acute dietary exposures. The appropriate Margin of Exposure to consider is 100. (Ibid.)

DRES is not aware of any carcinogenicity concerns for Avermectin.



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Residues

Tolerances

The only raw agricultural commodity tolerance in the Code of Federal Regulations (180.449) and the Tolerance Index System is for fresh tomatoes at 0.01 ppm. A feed additive tolerance exists for tomato pomace at 0.07 ppm (CFR 186.300), but this is not of direct concern to DRES. It is relevant only inasmuch as tomato pomace is a feed item and thus may affect the human diet through meat and milk.

DRES has been informed that the time-limited tolerances which expired on March 31, 1993 are being extended to April 1996 and should be considered when assessing dietary exposure and risk (note from G. LaRocca to J. Kariya, 4-18-94). Thus, the following time-limited tolerances were kept in the DRES input file:

Citrus fruits.....	0.02	ppm
Citrus oil.....	0.1	ppm
Cottonseed.....	0.005	ppm
Cattle meat and meat byproducts...	0.02	ppm
Milk.....	0.005	ppm

(The feed additive tolerance of 0.1 ppm on dried citrus pulp was also assumed to be extended, although this affects human dietary exposure only through the meat and milk tolerances noted above.)

The time-limited meat and milk tolerances associated with the citrus tolerance are expected to be sufficient to cover residues resulting from use of tomato pomace as a feed item (memorandum, S. Willett to G. LaRocca/A. Heyward, 4-22-91).

The citrus oil tolerance was applied to the DRES items related to citrus peel, since there are no items specific to citrus oil. Note that this is a change from previous DRES runs on Avermectin, where the 0.02 ppm tolerance for citrus fruits had been mistakenly used.

A tolerance of 0.02 ppm on strawberries is pending (PP#0F3880).

A tolerance of 0.05 ppm on celery is also pending (PP#8F3649). The term "celery" was interpreted by DRES to be the general category "celery" described in CFR 180.1(h) rather than the specific commodity "celery". As a consequence, the Raw Agricultural Commodity (RAC) "fennel" was included in the dietary exposure and risk analysis. This is a change from previous DRES runs, in which fennel had not been considered. Both RACs are marked "approved" in the DRES file. (The assumption has no practical consequence since there is currently no consumption estimate for fennel.)

This DRES analysis pertains to the tolerance of 0.01 ppm on tomatoes which was recommended by Chemistry Branch/Tolerance Support (memorandum, Stephanie H. Willett to G. LaRocca/A. Heyward, 5-4-90). Since tomatoes with avermectin residues could be used for processing if this tomato petition is approved, the DRES items related to processed tomato items were included in the analysis as "approved" items. (Note that at the time of the last DRES run, DRES was unaware that the previous tomato tolerance was limited to "fresh tomatoes", and therefore included all tomato items in the exposure and risk analysis. Changing the items to "new" from "published" keeps the DRES file in line with the actual state of Avermectin tolerances.)

Anticipated Residues

There are two sets of Anticipated Residues for Avermectin: one set applies to chronic exposures, and one set applies to acute exposures.

ARs for chronic exposure

The following values were obtained from a memo by V.F. Boyd to J.R. Tomerlin dated 6-29-89 and entitled "PP#8F3592/FAP#8H5550 - Avermectin B₁ (Abamectin) on Citrus - Anticipated Residues of Avermectin in Citrus Juice and Milk - Chronic Exposure":

citrus (whole fruit)	0.012 ppm
citrus juice	0.006 ppm
cottonseed	0.001 ppm

DRES' default concentration factors for citrus juices were turned off because there are specific Anticipated Residues for juices.

Note that the Anticipated Residue for milk which was given in Boyd's 6-29-89 memo was not used. This is because the feed items considered when deriving the AR were cottonseed and citrus pulp; tomato pomace was not considered at the time the AR was derived. Since tomato pomace is listed in the "Pesticide Assessment Guidelines, Subdivision O" (EPA-640/9-82-023, October 1982) as a possible feed item for cattle, it was not considered appropriate to use the 1989 ARs for milk in the absence of specific directions from Chemistry Branch on this matter. This is a change from previous DRES runs, in which the AR for milk had been mistakenly used even after the tomato feed-item tolerance had been approved.

ARs for acute exposure

Anticipated Residues for acute exposure were obtained from memoranda dated 9-23-92 and 9-24-92 from Debra Edwards to J. Kariya. Specifically, the following values were used:

orange pulp.....	0.003	ppm
orange juice.....	0.01	ppm
orange peel.....	0.07	ppm
grapefruit pulp.....	0.003	ppm
grapefruit juice.....	0.01	ppm

Again, because there are specific Anticipated Residues for juice, the concentration factors that DRES normally uses when assessing residues that apply to the whole fruit were ignored.

As in the chronic Anticipated Residue analysis, the acute ARs for milk that are cited in the 9-23-92 memo were not used because they did not consider tomato pomace as a possible feed item. Milk was assessed at the tolerance value of 0.005 ppm. This is a change from previous DRES runs, in which the milk AR value had been mistakenly used even though the use on tomatoes as a feed item had been approved.

Results

Assuming tolerance level residues

Using tolerance-level residues and assumptions that 100% of every crop to which Avermectin may be applied is treated, the total Theoretical Maximum Residue Contribution (TMRC) for the general population and the two most highly exposed subgroups in DRES are as follows (as percents of RfD):

	Published tols only	Processed tomatoes only	All published, approved, new
General population.....	34.4%	?	36.1%
Non-nursing infants less than 1 year old..	115.2%	?	116.0%
Children 1 through 6 years old.....	87.9%	?	90.7%

The TMRC from processed tomatoes alone has not been calculated. However, it is less than 1.7%, 0.8%, and 2.8% of the RfD for the respective subgroups. (These percents of the RfD are the TMRCs for celery, strawberries, and processed tomatoes combined.)

Acute toxicity assuming tolerance-level residues has not been evaluated.

Assuming anticipated residues

Using anticipated residues (and 100% crop treatment), the results are as follows, for chronic exposure (as percents of RfD):

	Published tols only	Processed tomatoes only	All published, approved, new
General population.....	24.8%	0.8%	26.5%
Non-nursing infants less than 1 year old..	94.3%	0.3%	95.1%
Children 1 through 6 years old.....	61.5%	1.5%	64.2%

The Anticipated Residue Contribution (ARC) from processed tomatoes alone is < 0.000003 mg/kg/day, 0.000001 mg/kg/day, and 0.000006 mg/kg/day for the respective subgroups. This represents the incremental difference between the existing tolerance on fresh tomatoes and the proposed tolerance on all tomatoes.

For acute exposure, high-end exposure to females 13 years or older (the standard DRES subpopulation which most closely approximates the population of concern, which is "women of childbearing age") is expected to result in a Margin of Exposure (defined as the ratio of the No Observed Effect Level to the expected exposure) of 167 when all uses (published, approved, and new) are considered.

Discussion

Analyses using anticipated levels of avermectin residues (rather than tolerance levels) suggest that the proposed use on tomatoes at 0.01 ppm will not cause exposure to exceed the maximum levels which the Agency generally believes are not likely to be associated with effects from either acute or chronic exposure. Specifically, exposures are expected to be below 100% of the Reference Dose for chronic effects, for all standard subgroups which the Dietary Risk Evaluation System evaluates. The Margin of Exposure for high-end exposure for females 13 years and older is approximately 167, which means that the No Observed Effect Level is approximately 167 times higher than the exposure that women exposed to high levels of Avermectin are expected to receive. The Agency is generally not concerned as long as the NOEL is at least 100 times the expected exposure.

It should be noted that the tolerances for meat and milk are **time-limited**. If the tolerances change, or are not granted permanently, the exposure and risk estimates are likely to change. DRES notes that tolerances for meat and milk should always be made permanent when feed item tolerances are made permanent, to avoid the possibility that the tolerances on meat and milk might expire even though the pesticide can legally be used on feed items.

It should also be noted that the % RfD for non-nursing infants is only slightly below 100. Further tolerances for Avermectin are likely to push the exposure estimate above the RfD. Registration Division may want to ask Chemistry Branch to estimate Anticipated Residues for milk which include consideration of tomato-based feed items. Anticipated Residues for chronic exposure should be separated from Anticipated Residues for acute exposure.

cc: DRES, Caswell 063AB, Tox I, CBTS

CHEMICAL		STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Avermectin B1	2gen reprod- rat	Incr retinal folds in weanlings, decr viability & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of oncogenicity.	AD1	UF	No data gaps.	HED complete 07/11/86
Caswell #063AB	NOEL=	0.1200 mg/kg		OPP RfD=	UF of 300 due pup deaths in critical study & maternal developmental toxicity in teratology studies. Mouse teratogen.	HED reassess 06/12/87
CAS No. 65195-55-3	LEL=	0.4000 mg/kg		EPA RfD=		HED reassess 03/30/89
A.I. CODE: 122804		0.00 ppm				EPA verified 04/20/89
CFR No. 180.449	ONCO: Negative- 2 species.					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	A 0.020000	0.020000		100.00	0.020000
01016AA	STRAWBERRIES	21 COOKED-NFS	0F3880	A 0.020000	0.020000		100.00	0.020000
01016AA	STRAWBERRIES	70 RAW-FROZEN	0F3880	A 0.020000	0.020000		100.00	0.020000
02001AA	CITRUS CITRON	22 COOKED-FRESH-BAKED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002AA	GRAPEFRUIT-UNSP	00 NOT SPECIFIED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002AB	GRAPEFRUIT-PULP	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002AB	GRAPEFRUIT-PULP	21 COOKED-NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002JA	GRAPEFRUIT-JUICE	15 RAW-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02002JA	GRAPEFRUIT-JUICE	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02003AA	KUMQUATS	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AA	LEMONS-UNSPEC	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AA	LEMONS-UNSPEC	22 COOKED-FRESH-BAKED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AB	LEMONS-PULP	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AB	LEMONS-PULP	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004HA	LEMONS-PEEL	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.100000	0.012000	PROCESSING	100.00	0.012000
02004HA	LEMONS-PEEL	21 COOKED-NFS	exp. 4/96?	P 0.100000	0.012000	PROCESSING	100.00	0.012000
02004JA	LEMONS-JUICE	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02004JA	LEMONS-JUICE	15 RAW-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02004JA	LEMONS-JUICE	21 COOKED-NFS	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02004JA	LEMONS-JUICE	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02005AA	LIMES-UNSPEC	00 NOT SPECIFIED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02005AB	LIMES-PULP	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02005HA	LIMES-PEEL	21 COOKED-NFS	exp. 4/96?	P 0.100000	0.012000	PROCESSING	100.00	0.012000
02005JA	LIMES-JUICE	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02005JA	LIMES-JUICE	15 RAW-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02005JA	LIMES-JUICE	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02006AA	ORANGES-UNSPEC	00 NOT SPECIFIED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006AB	ORANGES-PULP	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006AB	ORANGES-PULP	21 COOKED-NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006HA	ORANGES-PEEL	22 COOKED-FRESH-BAKED	exp. 4/96?	P 0.100000	0.012000	PROCESSING	100.00	0.012000
02006HA	ORANGES-PEEL	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.100000	0.012000	PROCESSING	100.00	0.012000
02006JA	ORANGES-JUICE	15 RAW-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02006JA	ORANGES-JUICE	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02007AA	TANGELOS	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02008AA	TANGERINES	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02008JA	TANGERINE-JUICE	15 RAW-FRESH OR CANNED	exp. 4/96?	P 0.020000	0.012000	PROCESSING	100.00	0.012000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	exp. 4/96?	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
11005AA	TOMATOES-WHOLE	21 COOKED-NFS	exp. 4/96?	P 0.010000	0.010000	IMPORT TOL	100.00	0.010000
11005AA	TOMATOES-WHOLE	31 COOKED-FRESH OR CANNED	exp. 4/96?	P 0.010000	0.010000	IMPORT TOL	100.00	0.010000

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ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 05/06/94

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CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Avermectin B1	2gen repro- rat	Incr retinal folds in weanlings, decr viability & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of oncogenicity.	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 complete 07/11/86 HED reassess 06/12/87 HED reassess 03/30/89 EPA verified 04/20/89
Caswell #063AB	NOEL= 0.1200 mg/kg				
CAS No. 65195-55-3	0.00 ppm				
A.I. CODE: 122804	LEL= 0.4000 mg/kg				
CFR No. 180.449	0.00 ppm				
	ONCO: Negative- 2 species.				On IRIS.

FOOD CODE	FOOD	TOLERANCE		ANTICIPATED		RES. VALUE USED
		FOOD FORM	PET.#	RESIDUE (ppm)	AR STATISTIC TYPE	IN TAS RUN (ppm)
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	100.00	0.020000
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	8F3592	P 0.020000	100.00	0.020000
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	8F3592	P 0.020000	100.00	0.020000

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 05/06/94

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CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
Avermectin B1	2gen repro- 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- ty & lactation indices; decr pup body wt; incr of dead pups at birth. No evidence of oncogenicity.	AD1 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 complete 07/11/86 HED reassess 06/12/87 HED reassess 03/30/89 EPA verified 04/20/89 On IRIS.	
Caswell #063AB							
CAS No. 65195-55-3							
A.I. CODE: 122804							
CFR No. 180.449							
TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES			
POPULATION SUBGROUP		CURRENT TMRC*	NEW TMRC**	ARC	XRFD		
U.S. POPULATION - 48 STATES		0.000138	0.000144	1.705250	0.000106	26.50675	
U.S. POPULATION - SPRING SEASON		0.000134	0.000141	1.895750	0.000103	25.67450	
U.S. POPULATION - SUMMER SEASON		0.000135	0.000142	1.569750	0.000105	26.33575	
U.S. POPULATION - FALL SEASON		0.000140	0.000147	1.662000	0.000108	26.96175	
U.S. POPULATION - WINTER SEASON		0.000141	0.000148	1.682250	0.000108	27.04400	
NORTHEAST REGION		0.000154	0.000161	1.788000	0.000111	27.79925	
NORTH CENTRAL REGION		0.000140	0.000147	1.806750	0.000109	27.32375	
SOUTHERN REGION		0.000118	0.000124	1.389750	0.000093	23.28425	
WESTERN REGION		0.000146	0.000154	1.978750	0.000117	29.14600	
HISPANICS		0.000178	0.000185	1.632500	0.000132	33.03425	
NON-HISPANIC WHITES		0.000136	0.000143	1.813750	0.000106	26.59900	
NON-HISPANIC BLACKS		0.000127	0.000131	0.980000	0.000090	22.45725	
NON-HISPANIC OTHERS		0.000167	0.000175	2.031750	0.000118	29.58975	
NURSING INFANTS (< 1 YEAR OLD)		0.000134	0.000134	0.179250	0.000096	24.03075	
NON-NURSING INFANTS (< 1 YEAR OLD)		0.000461	0.000464	0.776500	0.000380	95.08500	
FEMALES (13+ YEARS, PREGNANT)		0.000104	0.000110	1.381750	0.000078	19.59525	
FEMALES 13+ YEARS, NURSING		0.000115	0.000122	1.767500	0.000093	23.36500	
CHILDREN (1-6 YEARS OLD)		0.000352	0.000363	2.782500	0.000257	64.24575	
CHILDREN (7-12 YEARS OLD)		0.000216	0.000225	2.329750	0.000169	42.28100	
MALES (13-19 YEARS OLD)		0.000138	0.000145	1.631500	0.000113	28.32225	
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.000115	0.000121	1.464250	0.000090	22.59350	
MALES (20 YEARS AND OLDER)		0.000090	0.000096	1.474750	0.000073	18.30525	
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.000090	0.000096	1.515000	0.000067	16.73575	

*Current TMRC does not include new or pending tolerances.

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

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

DATE: 05/06/94

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000099	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	24.802	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000003	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	0.767	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000102	MG/KG/DAY
THE NEW ARC WILL OCCUPY	25.569	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000004	MG/KG/DAY
THIS ARC WILL OCCUPY	0.938	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000106	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	26.507	% OF THE ADI.

processed tomatoes

*celery,
strawberries*

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000377	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	94.309	% 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:	0.347	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000379	MG/KG/DAY
THE NEW ARC WILL OCCUPY	94.656	% 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	0.429	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000380	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	95.085	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000246	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	61.463	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000006	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	1.485	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000252	MG/KG/DAY
THE NEW ARC WILL OCCUPY	62.948	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000005	MG/KG/DAY
THIS ARC WILL OCCUPY	1.298	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000257	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	64.246	% OF THE ADI.

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***** 15:44 Friday, April 29, 1994 *****
DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION
*****
*NAME: AVERMECTIN
*SMELL NO: 063AB CFR NO: CFR A 00000.0012 SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.
*CAS NO: 65195-55-3 SHAUGHNESSY NO: 122804 B 000100 Reproductn Rat Systemic
*STATUS CODES: C

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*****STATUS CODES:*****
**RDV INFO: The LD value used in this analysis is 0.0006 MG/KG of BODY WEIGHT/DAY
**FILE INFO: No Tolerance Data Are Used--Without User Modifications.
*****AR DATA: No User Modifications*****
*****: FOOD FORM CONTRIBUTION*****
*****: TO EXPOSURE*****
*****LISTING OF RELEVANT FOODS & FOOD SUBS, ORDERED BY MENU CATEGORY. MENU PATTERN = I*****
*****CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER:OIL)*****

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POPULATION = FEMALES(13+ YRS)

[illegible]

MENU CATEGORY 1: MEATS

Product Description	Weight (kg)	Price (USD)
53001BA BEEF-NEAT BYPRODUCTS		
21 COOKED-NFS	6.02	0.0200
26 COOKED-FRESH-PICKLED, CORNED, OR CURED	0.63	0.0200
53001BB BEEF(ORGAN MEATS)-OTHER		
21 COOKED-NFS	5.98	0.0200
51 COOKED-CANNED	0.17	0.0200
53001DA BEEF-DRIED		
21 COOKED-NFS	0.24	0.0200
53001FA BEEF(BONELESS)-FAT (BEEF TALLOW)		
10 RAW-FRESH OR NFS	27.96	0.0200
21 COOKED-NFS	84.16	0.0200
22 COOKED-FRESH-BAKED	48.78	0.0200
23 COOKED-FRESH-BOILED	10.06	0.0200
24 COOKED-FRESH-BROILED	18.16	0.0200
25 COOKED-FRESH-FRIED	36.86	0.0200
53001KA BEEF(ORGAN MEATS)-KIDNEY		
21 COOKED-NFS	0.02	0.0200
53001LA BEEF(ORGAN MEATS)-LIVER		
25 COOKED-FRESH-FRIED	1.11	0.0200
31 COOKED-FRESH OR CANNED	0.00	0.0200
53001MA BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)		
10 RAW-FRESH OR NFS	0.00	0.0200
21 COOKED-NFS	50.09	0.0200
22 COOKED-FRESH-BAKED	4.41	0.0200
23 COOKED-FRESH-BOILED	7.99	0.0200

MENU CATEGORY 4: MILK: NON-FAT SOLIDS

[illegible]

MENU CATEGORY 5: MILK: FAT SOLIDS

50000FA MILK-FAT SOLIDS

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***** 15:44 Friday, April 29, 1994 *****
DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION
*****
*NAME: AVERMECTIN
*CASWELL NO: 063A8
*CAS NO: 65195-55-3 SHAUGHNESSY NO: 122804 B
*STATUS CODES: C
*****
STUDY NOEL RDV SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO.
000000.0012 A 000000.0012 000100 Reproductn Rat Systemic
*****

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* ***** *  
**RDV INFO: The LD value used in this analysis is 0.0006 MG/KG of BODY WEIGHT/DAY  
***FILE INFO: No Tolerance Data Are Used--without User Modifications.  
***** AR DATA: No User Modifications*  
*****  
***** LISTING OF RELEVANT FOODS & FOOD FORMS, ORDERED BY MENU CATEGORY. MENU PATTERN = I  
***** CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER-OIL)  
***** : FOOD FORM CONTRIBUTION  
***** : TO EXPOSURE
```

POPULATION = FEMALES(13+ YRS)									
FOOD CODE	FOOD AND FOOD FORM DESCRIPTION	NUMBER OF CONSUMER DAYS AS PERCENT OF POTENTIAL PERSON DAYS	TOLERANCE DATA		AR DATA		DAILY MAXIMUM RESIDUE (EXCL. AR)	DAILY ANTICIPATED RESIDUE (INCL. AR)	
			VALUE	TYPE	VALUE	REF.			
10	RAW-FRESH OR NFS	77.74	:	:	0.0050	:	0.009728	0.009728	
21	COOKED-NFS	88.74	:	:	0.0050	:	0.002802	0.002802	
51	COOKED-CANNED	3.00	:	:	0.0050	:	0.001219	0.001219	

MENU CATEGORY 6: GRAINS(EXCL. RICE), SOYBEANS, VEG. OILS					
270030A	COTTONSEED-OIL				
18	PROCESSED OIL	96.90	0.0050		0.000086
27003WA	COTTONSEED-MEAL				
18	PROCESSED OIL	0.90	0.0050		0.000031

MENU CATEGORY 8: TOMATOES					
11005XA	TOMATOES-WHOLE				
10	RAW- FRESH OR NFS	28.57		0.0100 C	0.009831
21	COOKED-NFS	11.19		0.0100 C	0.012531
31	COOKED- FRESH OR CANNED	6.61		0.0100 C	0.004379

Item	Unit	Weight	Price	Unit Price
10 RAW-FRESH OR NFS		0.07	0.0100 C	0.02896
21 COOKED-NFS		2.01	0.0100 C	0.031764
11005RA TOMATOES-PUREE				
10 RAW-FRESH OR NFS		0.05	0.0100 C	0.001494
21 COOKED-NFS		5.85	0.0100 C	0.011838
31 COOKED-FRESH OR CANNED		2.82	0.0100 C	0.003188
32 COOKED-FRESH OR CANNED		2.30	0.0100 C	0.004830

[illegible]

MENU CATEGORY 9: OTHER VEGETABLES, INCL. BRASSICA			
13002AA	CELERY		
10	RAW- FRESH OR NFS	22.60	0.0500
21	COOKED-NFS	5.07	0.0500
13016AA	FENNEL		

MENU CATEGORY 10: FRUITS

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION
 ***** 15:44 Friday, April 29, 1994 16 *****
 *NAME: AVERMECTIN *CASWELL NO: 063AB *CFR NO: CFR *STUDY NOEL *SF *STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *
 *CAS NO: 65195-55-3 SHAUGHNESSY NO: 122804 B *RDV NOEL 000100 Reprductn Rat Systemic
 *STATUS CODES: *RDV INFO: The LD value used in this analysis is 0.0006 MG/KG of BODY WEIGHT/DAY
 FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications
 LISTING OF RELEVANT FOODS & FOOD FORMS, ORDERED BY MENU CATEGORY. MENU PATTERN = I : FOOD FORM CONTRIBUTION
 CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER:OIL) : TO EXPOSURE
 : (UG/KG BODY WT PER DAY)

POPULATION = FEMALES(13+ YRS)

FOOD CODE	FOOD AND FOOD FORM DESCRIPTION	NUMBER OF CONSUMER : DAYS AS PERCENT OF : POTENTIAL PERSON DAYS	TOLERANCE DATA		AR DATA	DAILY MAXIMUM RESIDUE (EXCL. AR)	DAILY ANTICIPATED RESIDUE (INCL. AR)
			VALUE	TYPE			
01016AA	STRAWBERRIES						
	10 RAW-FRESH OR NFS	2.04	0.0200			0.021589	
	21 COOKED-NFS	10.57	0.0200			0.000792	
	70 RAW-FROZEN	0.88	0.0200			0.010676	
02001AA	CITRUS CITRON	0.21	0.0200			0.001522	
02002AA	22 COOKED-FRESH-BAKED	0.00	0.0030 C			0.000000	
	00 NOT SPECIFIED (NO CONSUMPTION)						
02002AB	GRAPEFRUIT-PULP	3.59	0.0030 C			0.007795	
	10 RAW-FRESH OR NFS	0.01	0.0030 C			0.003264	
02002JA	GRAPEFRUIT-JUICE	2.78	0.0100 C			0.035675	
	15 RAW-FRESH OR CANNED	0.09	0.0100 C			0.019342	
02003AA	KUMQUATS	0.00	0.0200			0.012836	
	10 RAW-FRESH OR NFS						
02004AA	LEMONS-UNSPECIFIED	0.82	0.0200			0.005316	
	10 RAW-FRESH OR NFS	0.20	0.0200			0.000543	
02004AB	22 COOKED-FRESH-BAKED	0.05	0.0200			0.009633	
	10 RAW-FRESH OR NFS	0.34	0.0200			0.000502	
02004HA	LEMONS-PEEL	0.24	0.1000			0.016412	
	31 COOKED-FRESH OR CANNED	0.97	0.1000			0.000248	
02004JA	LEMONS-JUICE	5.51	0.0200			0.003851	
	10 RAW-FRESH OR NFS	0.95	0.0200			0.018390	
	15 RAW-FRESH OR CANNED	14.21	0.0200			0.001945	
	21 COOKED-NFS	2.40	0.0200			0.007854	
02005AA	31 COOKED-FRESH OR CANNED	0.00	0.0200			0.000000	
	00 NOT SPECIFIED (NO CONSUMPTION)						
02005AB	LIMES-UNSPECIFIED	0.03	0.0200			0.010292	
	10 RAW-FRESH OR NFS						
02005HA	LIMES-PEEL	0.00	0.1000			0.000142	
	10 RAW-FRESH OR NFS						
02005JA	LIMES-JUICE	0.31	0.0200			0.037568	
	15 RAW-FRESH OR NFS	0.07	0.0200			0.029731	
	31 COOKED-FRESH OR CANNED	0.05	0.0200			0.006736	
02006AA	ORANGES-UNSPECIFIED						

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION

 *NAME: AVERMECTIN
 *CASWELL NO: 063AB
 *CAS NO: 65195-55-3
 *STATUS CODES:

*RDV INFO: The LD value used in this analysis is 0.0006 MG/KG of BODY WEIGHT/DAY
 *FILE INFO: No Tolerance Data Are Used--Without User Modifications.
 LISTING OF RELEVANT FOODS & FOOD FORMS, ORDERED BY MENU CATEGORY. MENU PATTERN = 1
 CHEMICAL IS ASSUMED TO BE UNIFORMLY DISTRIBUTED (WATER:OIL)

POPULATION = FEMALES(13+ YRS)

FOOD CODE	FOOD AND FOOD FORM DESCRIPTION	NUMBER OF CONSUMER DAYS AS PERCENT OF POTENTIAL PERSON DAYS	VALUE (PPM)	SORC (PPM) TYPE	AR DATA VALUE (PPM) REF.	DAILY MAXIMUM RESIDUE (EXCL. AR)	DAILY ANTICIPATED RESIDUE (INCL. AR)
02006AB	00 NOT SPECIFIED (NO CONSUMPTION)	0.00			0.0030 C		0.000000
	10 RAW-FRESH OR NFS	5.10			0.0030 C		0.006772
	21 COOKED-NFS	0.36			0.0030 C		0.000367
02006HA	00 NOT SPECIFIED (NO CONSUMPTION)	0.10			0.0700 C		0.000371
	22 COOKED-FRESH-BAKED	1.33			0.0700 C		0.000275
	31 COOKED-FRESH OR CANNED	0.34			0.0700 C		0.000684
02006JA	00 NOT SPECIFIED (NO CONSUMPTION)	22.81			0.0100 C		0.033739
	15 RAW-FRESH OR CANNED	1.12			0.0100 C		0.006696
	31 COOKED-FRESH OR CANNED						
02007AA	00 NOT SPECIFIED (NO CONSUMPTION)	0.12			0.0200		0.036027
	10 RAW-FRESH OR NFS						
02008AA	00 NOT SPECIFIED (NO CONSUMPTION)	0.50			0.0200		0.026851
	10 RAW-FRESH OR NFS						
02008JA	00 NOT SPECIFIED (NO CONSUMPTION)	0.01			0.0200		0.046919
	15 RAW-FRESH OR CANNED						

DETAILED ACUTE ANALYSIS INCLUDING AR/S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 15:44 Friday, April 29, 1994 23

 *NAME: AVERMECTIN
 *CASWELL NO: 063AB
 *CAS NO: 65195-55-3 SHAUGHNESSY NO: 122804 B
 *STATUS CODES:
 *RDV INFO: The LD value used in this analysis is 0.0006 MG/KG of BODY WEIGHT/DAY
 *FILE INFO: No Tolerance Data Are Used--Without User Modifications.

 STUDY RDV NOEL SF STUDY TYPE SPECIES EFF. LEV. CORE GRADE DOC. NO. *
 A 00000.0012 000100 Reproductn Rat Systemic *
 AR DATA: No User Modifications*

FEMALES(13+ YRS)

ESTIMATES BASED ON TOLERANCES:		ESTIMATED % OF POTENTIAL		MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ANTICIPATED RESIDUES:		PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV	
TOLERANCES:		0.00	0.000000	0.00	
ANTICIPATED RESIDUES:		99.73	0.000068	11.36	
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 1.8 2 3 4 5 10 15 20
100	13	1	0	0	0 0 0 0 0 0 0 0 0 0 0 0

$$\begin{aligned}
 \text{exposure} &= 0.6 * 0.0006 \text{ mg/kg/day} \\
 &= 0.00036 \text{ mg/kg/day}
 \end{aligned}$$

$$\begin{aligned}
 \text{MOE} &= \frac{\text{NOEL}}{\text{exposure}} \\
 &= \frac{0.06}{0.00036} \\
 &= 167
 \end{aligned}$$

15