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

MEMORANDUM JUN - 7 1991 OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Dietary Exposure Analysis for the Section 18, Proposed Use of Avermectin B_1 on Hops (91-WA-0016)

FROM: Stephen A. Schaible Stephen A Schaible
HED/SACB (H7509C)

TO: Rebecca Cool, PM-41
Emergency Response Section
Registration Support Branch
Registration Division (H7505C)

THROUGH: James P. Kariya JKariya
Chief, Dietary Exposure Section
Health Effects Division

Action Requested

Provide an estimate of acute and chronic dietary exposure to Avermectin B_1 through its use on hops.

Discussion

1. Toxicological Endpoint: The routine chronic DRES analysis used a Reference Dose (RfD) of 0.0004 mg/kg body weight/day, based on a no observed effect level (NOEL) of 0.12 mg/kg bwt/day and an uncertainty factor of 300. The NOEL was based on a 2 generation reproduction study in rats which demonstrated an increase in retinal folds in weanlings, decreased viability and lactation indices, and a decrease in pup body weight. This value has been approved by both the HED (3/30/89) and Agency (4/20/89) reference dose committees.

The detailed acute exposure analysis was conducted using a NOEL of 0.06 mg/kg bwt/day based on a mouse teratology study.

2. Residue Information: Food uses evaluated were published tolerances from 40 CFR 180.449 (to expire 3/31/93); meat and milk residues stemming from feed items in 40 CFR 186.300; pending tolerances for apples (in acute analysis only), celery, and tomatoes (including the pending import tolerance for tomatoes in Mexico); and the proposed Section 18 use on hops. The use of avermectin on apples arising from a pending EUP and temporary tolerance (Schaible, 4/19/91) was included in the data set for the acute exposure analysis, though any acute effects arising from this use would likely be localized to Washington state (if the petition were granted, 150 acres in Washington would be

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treated with avermectin and apples would be for fresh market use only). Anticipated residues used for both the chronic and acute analyses were developed from processing studies using field trial data for citrus, citrus juice, and cottonseed, and extrapolated from animal feeding studies for milk (V.F. Boyd memo dated 6/29/89). A summary of the residue information used in these analyses is attached as Table 1.

3. Chronic Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups.

Tolerance level residues, anticipated residues, and percent crop treated data are used to calculate the Anticipated Residue Contribution (ARC). The ARC is considered the more accurate in terms of estimating dietary exposure. A summary of the TMRC, ARC, and the representation of each as a percent of the RfD for the overall U.S. population and the 22 population subgroups is attached as Table 2.

The ARC for the overall U.S. population from published and pending uses is 0.000113 mg/kg bwt/day which represents 28% of the RfD. If the proposed use of Avermectin B_1 on hops is added the ARC is raised to 0.000115 mg/kg bwt/day, or 29% of the RfD. In the subgroup exposed to the highest risk, non-nursing infants less than one year old, there was no contribution from the proposed use on hops, but the ARC from published and pending uses was 0.000386 mg/kg bwt/day, or 96% of the RfD.

4. Acute Exposure Analysis: The DRES detailed acute exposure 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 1977-78 Nationwide Food Consumption Survey and accumulates exposure to Avermectin B_1 for each commodity consumed for which a tolerance has been established. Each analysis assumes uniform distribution of Avermectin B_1 in the commodity supply.

Since the toxicological endpoint pertains to developmental toxicity, the DRES population group of interest for this analysis is women aged 13 and above, the DRES subgroup most closely approximating women of child bearing age.

The Margin of Exposure (MOE) is a measure of how close the exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test). The MOE is calculated as the ratio of the NOEL to the exposure (NOEL/exposure (ARC)). For this analysis we derived the MOE for the highest exposure. The calculated MOE for an exposure of 0.00048 mg/kg bwt/day was 125. This means that the persons most highly exposed to avermectin through their diet would receive 1/125 the dose that represents the NOEL in animals for developmental toxicity for avermectin. A plot of the distribution used in this analysis is attached as Table 3.

5. Discussion: Based on acute concerns, we do not see a problem in this proposed Section 18 Specific Exemption being granted. Generally speaking, margins of exposure greater than 100 do not cause the Agency great concern, and the MOE value of 125 was derived from the highest exposed individual(s), so the majority of the population would have an MOE even higher. In addition, the hops consumption figure used in the acute analysis is overestimated by at least a factor of six. Data submitted by B. Petersen of Tas Inc., hops growers, and brewers suggest that instead of the assumption that hops constitutes 4.2% of beer by weight (which was used to generate the original hops consumption values for both the acute and chronic analyses), the actual figure is more likely between 0.2 and 0.7%. The average consumption value used for hops in the DRES chronic exposure analysis accounts for this more recent data, but the individual consumption value used in the acute analysis does not.

In the chronic exposure analysis, the proposed use of avermectin on hops contributes only a minimal amount to the ARC, and the ARC does not exceed the RfD for any of the subgroups. Thus it would appear that the chronic risk from this proposed use of avermectin on hops is minimal.

Attachments

cc: DES, CBTS, Tox 1 and 2, Caswell # 063AB

TABLE 1

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 06/05/91 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.	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 oncogenicity.	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 complete 07/11/86. HED reassess 06/12/87. HED reassess 03/30/89. EPA verified 04/20/89. 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)
02001AA	CITRUS CITRON	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002AA	GRAPEFRUIT-UNSP	00 NOT SPECIFIED	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002AB	GRAPEFRUIT-PULP	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002AB	GRAPEFRUIT-PULP	21 COOKED-NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02002JA	GRAPEFRUIT-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02002JA	GRAPEFRUIT-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02003AA	KUMQUATS	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AA	LEMONS-UNSPEC	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AA	LEMONS-UNSPEC	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AB	LEMONS-PULP	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004AB	LEMONS-PULP	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004HA	LEMONS-PEEL	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004HA	LEMONS-PEEL	21 COOKED-NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004JA	LEMONS-JUICE	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02004JA	LEMONS-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02004JA	LEMONS-JUICE	21 COOKED-NFS	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02004JA	LEMONS-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02005AA	LIMES-UNSPEC	00 NOT SPECIFIED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02005AB	LIMES-PULP	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02005HA	LIMES-PEEL	21 COOKED-NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02005JA	LIMES-JUICE	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02005JA	LIMES-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02005JA	LIMES-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02006AA	ORANGES-UNSPEC	00 NOT SPECIFIED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02006AB	ORANGES-PULP	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006AB	ORANGES-PULP	21 COOKED-NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006HA	ORANGES-PEEL	21 COOKED-NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006HA	ORANGES-PEEL	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006HA	ORANGES-PEEL	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02006JA	ORANGES-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02006JA	ORANGES-JUICE	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
02007AA	TANGELOS	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02008AA	TANGERINES	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.012000	PROCESSING	100.00	0.012000
02008JA	TANGERINE-JUICE	15 RAW-FRESH OR CANNED	8F3592	P 0.020000	0.006000C	PROCESSING	100.00	0.006000
08020AA	HOPS	21 COOKED-NFS	91WA001	N 0.400000	0.400000		100.00	0.400000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	9F3703	A 0.010000	0.010000		100.00	0.010000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	1E3943	A 0.010000	0.010000	IMPORT TOL	100.00	0.010000
11005AA	TOMATOES-WHOLE	21 COOKED-NFS	9F3703	A 0.010000	0.010000		100.00	0.010000
11005AA	TOMATOES-WHOLE	21 COOKED-NFS	1E3943	A 0.010000	0.010000	IMPORT TOL	100.00	0.010000
11005AA	TOMATOES-WHOLE	31 COOKED-FRESH OR CANNED	9F3703	A 0.010000	0.010000		100.00	0.010000

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.	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 oncogenicity.	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 complete 07/11/86. HED reassess 06/12/87. HED reassess 03/30/89. EPA verified 04/20/89. 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)
11005AA	TOMATOES-WHOLE	31 COOKED-FRESH OR CANNED	1E3943	A 0.010000	0.010000	IMPORT TOL	100.00	0.010000
11005JA	TOMATOES-JUICE	10 RAW-FRESH OR NFS	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005JA	TOMATOES-JUICE	10 RAW-FRESH OR NFS	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005JA	TOMATOES-JUICE	21 COOKED-NFS	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005JA	TOMATOES-JUICE	21 COOKED-NFS	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005RA	TOMATOES-PUREE	10 RAW-FRESH OR NFS	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005RA	TOMATOES-PUREE	10 RAW-FRESH OR NFS	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005RA	TOMATOES-PUREE	21 COOKED-NFS	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005RA	TOMATOES-PUREE	21 COOKED-NFS	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005RA	TOMATOES-PUREE	31 COOKED-FRESH OR CANNED	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005RA	TOMATOES-PUREE	31 COOKED-FRESH OR CANNED	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005RA	TOMATOES-PUREE	32 COOKED-FRESH OR CANNED-BAKED	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005RA	TOMATOES-PUREE	32 COOKED-FRESH OR CANNED-BAKED	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005RA	TOMATOES-PUREE	51 COOKED-CANNED	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005RA	TOMATOES-PUREE	51 COOKED-CANNED	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005TA	TOMATOES-PASTE	21 COOKED-NFS	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005TA	TOMATOES-PASTE	21 COOKED-NFS	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005TA	TOMATOES-PASTE	22 COOKED-FRESH-BAKED	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005TA	TOMATOES-PASTE	22 COOKED-FRESH-BAKED	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005TA	TOMATOES-PASTE	31 COOKED-FRESH OR CANNED	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005TA	TOMATOES-PASTE	31 COOKED-FRESH OR CANNED	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
11005UA	TOMATOES-CATSUP	21 COOKED-NFS	9F3703	A 0.010000	0.010000C		100.00	0.010000
11005UA	TOMATOES-CATSUP	21 COOKED-NFS	1E3943	A 0.010000	0.010000C	IMPORT TOL	100.00	0.010000
13002AA	CELERY	10 RAW-FRESH OR NFS	8F3649	A 0.050000	0.050000		100.00	0.050000
13002AA	CELERY	21 COOKED-NFS	8F3649	A 0.050000	0.050000		100.00	0.050000
27003OA	COTTONSEED-OIL	18 PROCESSED OIL	6G3320	P 0.005000	0.001000	FLD TRIALS	100.00	0.001000
27003WA	COTTONSEED-MEAL	18 PROCESSED OIL	6G3320	P 0.005000	0.001000	FLD TRIALS	100.00	0.001000
50000DB	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	8F3592	P 0.005000	0.005000		100.00	0.005000
50000DB	MILK-NON-FAT SOL	21 COOKED-NFS	8F3592	P 0.005000	0.005000		100.00	0.005000
50000DB	MILK-NON-FAT SOL	51 COOKED-CANNED	8F3592	P 0.005000	0.005000		100.00	0.005000
50000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	8F3592	P 0.005000	0.005000		100.00	0.005000
50000FA	MILK-FAT SOLIDS	21 COOKED-NFS	8F3592	P 0.005000	0.005000		100.00	0.005000
50000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	8F3592	P 0.005000	0.005000		100.00	0.005000
50000SA	MILK SUG (LACT)	21 COOKED-NFS	8F3592	P 0.005000	0.005000		100.00	0.005000
50000SA	MILK SUG (LACT)	51 COOKED-CANNED	8F3592	P 0.005000	0.005000		100.00	0.005000
53001BA	BEEF-MEAT BYP	21 COOKED-NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001BA	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001BB	BEEF-OTH ORGAN	21 COOKED-NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001BB	BEEF-OTH ORGAN	51 COOKED-CANNED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001DA	BEEF-DRIED	21 COOKED-NFS	8F3592	P 0.020000	0.020000		100.00	0.020000

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 063AB

DATE: 06/05/91

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FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001FA	BEEF-FAT	21 COOKED-NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001KA	BEEF-KIDNEY	21 COOKED-NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001MA	BEEF-LEAN	21 COOKED-NFS	8F3592	P 0.020000	0.020000		100.00	0.020000
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	8F3592	P 0.020000	0.020000		100.00	0.020000
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	8F3592	P 0.020000	0.020000		100.00	0.020000

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 06/05/91 PAGE: 1

CHEMICAL INFORMATION	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.	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 oncogenicity.	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 complete 07/11/86. HED reassess 06/12/87. HED reassess 03/30/89. EPA verified 04/20/89. On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000133	0.000153	38.285000	5.130250	0.000115	28.70175
U.S. POPULATION - SPRING SEASON	0.000129	0.000149	37.251250	5.022750	0.000111	27.62675
U.S. POPULATION - SUMMER SEASON	0.000129	0.000152	37.978750	5.784250	0.000116	28.91350
U.S. POPULATION - FALL SEASON	0.000136	0.000155	38.852000	4.804500	0.000116	29.08900
U.S. POPULATION - WINTER SEASON	0.000137	0.000156	39.064250	4.913500	0.000117	29.18025
NORTHEAST REGION	0.000148	0.000171	42.676250	5.561250	0.000121	30.23925
NORTH CENTRAL REGION	0.000135	0.000156	38.883750	5.063500	0.000118	29.45000
SOUTHERN REGION	0.000114	0.000131	32.842000	4.461500	0.000101	25.20950
WESTERN REGION	0.000140	0.000164	40.929750	5.810500	0.000126	31.59550
HISPANICS	0.000172	0.000196	48.895750	5.993750	0.000143	35.73600
NON-HISPANIC WHITES	0.000131	0.000152	38.014750	5.345250	0.000116	28.87575
NON-HISPANIC BLACKS	0.000123	0.000137	34.205500	3.353000	0.000096	23.95075
NON-HISPANIC OTHERS	0.000162	0.000182	45.475750	4.975750	0.000126	31.40200
NURSING INFANTS (< 1 YEAR OLD)	0.000132	0.000136	34.064500	1.061000	0.000098	24.53075
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000456	0.000469	117.361500	3.253250	0.000386	96.42900
FEMALES (13+ YEARS, PREGNANT)	0.000100	0.000116	29.098500	4.119250	0.000085	21.26875
FEMALES 13+ YEARS, NURSING	0.000110	0.000130	32.504750	5.076250	0.000102	25.38225
CHILDREN (1-6 YEARS OLD)	0.000344	0.000375	93.865250	7.972750	0.000270	67.43550
CHILDREN (7-12 YEARS OLD)	0.000210	0.000235	58.861250	6.422750	0.000179	44.80925
MALES (13-19 YEARS OLD)	0.000133	0.000153	38.274000	4.923000	0.000122	30.40650
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000111	0.000128	31.913500	4.239750	0.000097	24.29325
MALES (20 YEARS AND OLDER)	0.000085	0.000106	26.447500	5.078750	0.000084	20.87975
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000086	0.000103	25.796000	4.388500	0.000074	18.48075

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

TOLERANCE ASSESSMENT SUMMARY FOR Avermectin B1 DATE: 06/05/91
USING ANTICIPATED RESIDUES
CASWELL #063AB

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000094	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	23.572	% 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:	0.374	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000096	MG/KG/DAY
THE NEW ARC WILL OCCUPY	23.946	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000019	MG/KG/DAY
THIS ARC WILL OCCUPY	4.756	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000115	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	28.702	% OF THE ADI.

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000373	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	93.176	% OF THE ADI.
NO NEW ANTICIPATED RESIDUES ARE IN THE FILE.		
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000013	MG/KG/DAY
THIS ARC WILL OCCUPY	3.254	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000386	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	96.429	% OF THE ADI.

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

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.000238	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	59.463	% 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:	0.002	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.000238	MG/KG/DAY
THE NEW ARC WILL OCCUPY	59.465	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000032	MG/KG/DAY
THIS ARC WILL OCCUPY	7.971	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.000270	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	67.436	% OF THE ADI.

TABLE 3

DETAILED ACUTE ANALYSIS INCLUDING AR'S: ALL STATISTICS BASED ON USERS' DAILY CONSUMPTION 10:55 WEDNESDAY, JUNE 5, 1991 22

*NAME: AVERMECTIN

	STUDY	RDV	NOEL	SF	STUDY TYPE	SPECIES	EFF. LEV.	CORE GRADE	DOC. NO.
*CASWELL NO: 063AB CFR NO: CFR .	A	00000.0012		000100	Reprodctn	Rat	Systemic		*
*CAS NO: 65195-55-3 SHAUGHNESSY NO: 122804	B								*
*STATUS CODES:	C								*

*RDV INFO: The LD value used in this analysis is .0006 MG/KG of BODY WEIGHT/DAY *

FILE INFO: No Tolerance Data Are Used--Without User Modifications. AR DATA: No User Modifications

FEMALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	99.75	0.000086	14.33

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
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	23	3	1	0	0	0	0	0	0	0	0	0	0	0	0	0

MALES(13+ YRS)

	ESTIMATED % OF POTENTIAL	MEAN DAILY RESIDUE CONTRIBUTION PER USER-DAY	
ESTIMATES BASED ON	PERSON DAYS THAT ARE USER-DAYS	MG/KG BODY WEIGHT/DAY	AS PERCENT OF RDV
TOLERANCES:	0.00	0.000000	0.00
ANTICIPATED RESIDUES:	99.88	0.000111	18.49

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
TOLERANCES:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ANTICIPATED RESIDUES:	100	32	8	3	1	1	0	0	0	0	0	0	0	0	0	0	0

exposure = .8 x .0006 =

$MOE = \frac{NOEL}{exp} = \frac{.06}{.00048} =$