US EPA ARCHIVE DOCUMENT

WELL FILE
323C

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

AUG 1 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Vinclozalin (Ronilan) on Greenhouse Grown Cucumbers and Tomatoes Imported from Spain and the Netherlands, PP#8E3688

FROM: J. Robert Tomerlin, Ph.D. J R Tomerlin 7/29/89
Tolerance Assessment System Staff
HED/SACB (H7509C)

THROUGH: Reto Engler, Ph.D.
Chief, Science Analysis and Coordination Branch
Health Effects Division (H7509C)

TO: Susan Lewis, PM 21
Herbicide-Fungicide Branch
Registration Division (H7505C)

Action Requested

A previous TAS analysis (J. R. Tomerlin memo, 4/28/89) for this petition indicated that vinclozalin exposure exceeded the reference dose for some TAS population groups. The present analysis was conducted using per cent crop treated data to calculate exposure estimates more closely approximating actual exposure.

Discussion

1. Toxicology Endpoint: The routine chronic TAS analysis used a reference dose (ADI) of 0.025 mg/kg body weight/day, based upon a NOEL of 2.5 mg/kg body weight/day and an uncertainty factor of 100 from a 6 month dog feeding study. This value has been approved by HED (5/19/86) and Agency (7/8/86) reference dose committees.

2. Residue Information: Food uses evaluated were published tolerances from 40 CFR 180.380 and the proposed uses on cucumbers and tomatoes (W. T. Chin memo, 4/27/89). Vinclozalin usage data (J. L. Faulkner memo, 7/16/89) were used to adjust tolerance residue values for stone fruits and lettuce. A summary of the residue information used in the analysis is attached as Table 1.

3. Exposure Analysis: The TAS chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall

U.S. population and 22 population subgroups. The Anticipated Residue Contribution (ARC) was calculated using per cent crop treated data. The TMRC and ARC exposure summaries for the overall U.S. population and all 22 TAS population groups are shown in Table 2. The exposure summaries for the overall U.S. population, non-nursing infants, and children aged 1 to 6 are shown in the following table.

TMRC - ARC Vinclozalin Exposure Summary

	Overall U.S. Population	Non-Nurs. Infants	Children Aged 1 - 6
TMRC			
Published Tolerances	0.014378[a] 57.5[b]	0.086940 347.8	0.028640 114.6
PP#8E3688	0.004437 17.7	0.002939 11.8	0.008526 34.1
TMRC TOTALS	0.018815 75.2	0.089789 359.5	0.037166 148.7
ARC			
Published Tolerances	0.003139 12.6	0.002952 11.8	0.007270 29.1
PP#8E3688	0.004437 17.7	0.002939 11.8	0.008526 34.1
ARC TOTALS	0.007575 30.3	0.005892 23.6	0.015796 63.2

[a]Exposure estimate in mg/kg body weight/day.
[b]Estimated exposure expressed as per cent of the ADI.

4. Comments: Incorporating vinclozalin usage data into the TAS analysis significantly reduced the exposure estimates for published uses. One may assume that the ARC exposure estimates for published tolerances more closely approximate actual exposure.

The portion of exposure attributed to the proposed tolerances on imported tomatoes and cucumbers ranges from 3 to 34 per cent of the ADI. TAS is unable to differentiate consumption of imported cucumbers and tomatoes from consumption of domestically produced tomatoes and cucumbers. Therefore, the vinclozalin tolerance was assumed to apply to all tomato products (including tomato paste,

catsup, and the like) and cucumbers consumed in the U.S. This results in an overestimate of exposure for tomatoes and cucumbers because imports from the Netherlands and Spain account for less than 1 per cent of U.S. consumption (J. L. Faulkner memo, 6/14/89). Thus, exposure to vinclozalin from imported tomatoes and cucumbers probably represents less than 1 per cent of the ADI for all TAS population groups.

Attachments

cc: TAS (Tomerlin, SACB), DEB, Caswell #323C, Anderson (TOX-HAFS)

Table 1

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 323C DATE: 07/28/89 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Vinclozolin (Ronilan) Caswell #323C CAS No. 50471-44-8 A.I. CODE: 113201 CFR No. 180.380	6mo feeding- dog NOEL= 2.5000 mg/kg 100.00 ppm LEL= 7.5000 mg/kg 300.00 ppm ONCO: Class E (HED WOTE).	Increased absolute and relative adrenal weights. Histo changes seen in adrenal at higher doses. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.025000	No data gaps.	HED complete 05/19/86. EPA verified 07/08/86. WHO last reviewed 1988; temp. ADI established. 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)
01006AA	RASPBERRIES	10 RAW-FRESH OR NFS	3F2934	P 10.00000	10.000000		100.00	10.000000
01006AA	RASPBERRIES	15 RAW-FRESH OR CANNED	3F2934	P 10.00000	10.000000		100.00	10.000000
01006AA	RASPBERRIES	31 COOKED-FRESH OR CANNED	3F2934	P 10.00000	10.000000		100.00	10.000000
01006AA	RASPBERRIES	62 COOKED-FRESH OR FROZEN-BAKED	3F2934	P 10.00000	10.000000		100.00	10.000000
01006AA	RASPBERRIES	70 RAW-FROZEN	3F2934	P 10.00000	10.000000		100.00	10.000000
01014AA	GRAPES-FRESH	10 RAW-FRESH OR NFS	1E2457	P 6.000000	6.000000		100.00	6.000000
01014AA	GRAPES-FRESH	21 COOKED-NFS	1E2457	P 6.000000	6.000000		100.00	6.000000
01014AA	GRAPES-FRESH	31 COOKED-FRESH OR CANNED	1E2457	P 6.000000	6.000000		100.00	6.000000
01014DA	GRAPES-RAISINS	10 RAW-FRESH OR NFS	7H5529	P 30.00000	30.000000C		100.00	30.000000
01014DA	GRAPES-RAISINS	21 COOKED-NFS	7H5529	P 30.00000	30.000000C		100.00	30.000000
01014DA	GRAPES-RAISINS	22 COOKED-FRESH-BAKED	7H5529	P 30.00000	30.000000C		100.00	30.000000
01014JA	GRAPES-JUICE	10 RAW-FRESH OR NFS	1E2457	P 6.000000	6.000000		100.00	6.000000
01014JA	GRAPES-JUICE	15 RAW-FRESH OR CANNED	1E2457	P 6.000000	6.000000		100.00	6.000000
01014JA	GRAPES-JUICE	21 COOKED-NFS	1E2457	P 6.000000	6.000000		100.00	6.000000
01016AA	STRAWBERRIES	10 RAW-FRESH OR NFS	9F2205	P 10.00000	10.000000		100.00	10.000000
01016AA	STRAWBERRIES	21 COOKED-NFS	9F2205	P 10.00000	10.000000		100.00	10.000000
01016AA	STRAWBERRIES	70 RAW-FROZEN	9F2205	P 10.00000	10.000000		100.00	10.000000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	2F2650	P 25.00000	25.000000		1.00	0.250000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	2F2650	P 25.00000	25.000000		1.00	0.250000
05002AA	CHERRIES-FRESH	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	2F2650	P 25.00000	25.000000		1.00	0.250000
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	2F2650	P 25.00000	25.000000		1.00	0.250000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED	2F2650	P 25.00000	25.000000		1.00	0.250000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	2F2650	P 25.00000	25.000000		1.00	0.250000
05002JA	CHERRIES-JUICE	21 COOKED-NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05004AA	PEACHES-FRESH	21 COOKED-NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	2F2650	P 25.00000	25.000000		1.00	0.250000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	2F2650	P 25.00000	25.000000		1.00	0.250000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05004DA	PEACHES-DRIED	21 COOKED-NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05005AA	PLUMS-FRESH	10 RAW-FRESH OR NFS	2F2650	P 25.00000	25.000000		1.00	0.250000
05005AA	PLUMS-FRESH	31 COOKED-FRESH OR CANNED	2F2650	P 25.00000	25.000000		1.00	0.250000
05005DA	PLUMS-PRUNES	10 RAW-FRESH OR NFS	5H5462	P 75.00000	75.000000C		1.00	0.750000
05005DA	PLUMS-PRUNES	21 COOKED-NFS	5H5462	P 75.00000	75.000000C		1.00	0.750000

Table 1, continued

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 323C DATE: 07/28/89 PAGE: 2

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Vinclozolin (Ronilan) Caswell #323C CAS No. 50471-44-8 A.I. CODE: 113201 CFR No. 180.380	6mo feeding- dog NOEL= 2.5000 mg/kg 100.00 ppm LEL= 7.5000 mg/kg 300.00 ppm ONCO: Class E (HED WOTE).	Increased absolute and relative adrenal weights. Histo changes seen in adrenal at higher doses. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.025000	No data gaps.	HED complete 05/19/86. EPA verified 07/08/86. WHO last reviewed 1988; temp. ADI established. 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)
05005DA	PLUMS-PRUNES	31 COOKED-FRESH OR CANNED	5H5462	P 75.00000	75.000000C		1.00	0.750000
05005JA	PRUNE-JUICE	10 RAW-FRESH OR NFS	5H5462	P 75.00000	75.000000C		1.00	0.750000
05005JA	PRUNE-JUICE	62 COOKED-FRESH OR FROZEN-BAKED	5H5462	P 75.00000	75.000000C		1.00	0.750000
06018AA	KIWI	10 RAW-FRESH OR NFS	0E2380	P 10.00000	10.000000		100.00	10.000000
10010AA	CUCUMBERS	10 RAW-FRESH OR NFS	8E3688	A 1.000000	1.000000		100.00	1.000000
10010AA	CUCUMBERS	11 RAW-FRESH-PICKLED,CORNED,OR CURED	8E3688	A 1.000000	1.000000		100.00	1.000000
10010AA	CUCUMBERS	21 COOKED-NFS	8E3688	A 1.000000	1.000000		100.00	1.000000
11003AA	PEPPERS,SWEET	10 RAW-FRESH OR NFS	4E2998	P 3.000000	3.000000		100.00	3.000000
11003AA	PEPPERS,SWEET	21 COOKED-NFS	4E2998	P 3.000000	3.000000		100.00	3.000000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
11005AA	TOMATOES-WHOLE	21 COOKED-NFS	AE3688	A 3.000000	3.000000		100.00	3.000000
11005AA	TOMATOES-WHOLE	31 COOKED-FRESH OR CANNED	8E3688	A 3.000000	3.000000		100.00	3.000000
11005JA	TOMATOES-JUICE	10 RAW-FRESH OR NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
11005JA	TOMATOES-JUICE	21 COOKED-NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
11005RA	TOMATOES-PUREE	10 RAW-FRESH OR NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
11005RA	TOMATOES-PUREE	21 COOKED-NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
11005RA	TOMATOES-PUREE	31 COOKED-FRESH OR CANNED	8E3688	A 3.000000	3.000000		100.00	3.000000
11005RA	TOMATOES-PUREE	32 COOKED-FRESH OR CANNED-BAKED	8E3688	A 3.000000	3.000000		100.00	3.000000
11005RA	TOMATOES-PUREE	51 COOKED-CANNED	8E3688	A 3.000000	3.000000		100.00	3.000000
11005TA	TOMATOES-PASTE	21 COOKED-NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
11005TA	TOMATOES-PASTE	22 COOKED-FRESH-BAKED	8E3688	A 3.000000	3.000000		100.00	3.000000
11005TA	TOMATOES-PASTE	31 COOKED-FRESH OR CANNED	8E3688	A 3.000000	3.000000		100.00	3.000000
11005UA	TOMATOES-CATSUP	21 COOKED-NFS	8E3688	A 3.000000	3.000000		100.00	3.000000
13003AA	CHICORY	10 RAW-FRESH OR NFS	8E3620	P 5.000000	5.000000		100.00	5.000000
13013AA	LETTUCE-LEAFY	10 RAW-FRESH OR NFS	3F2934	P 10.00000	10.000000		25.00	2.500000
13020AA	LETTUCE-UNSPEC	10 RAW-FRESH OR NFS	2F2595	P 10.00000	10.000000		25.00	2.500000
13045AA	LETTUCE-HEAD	10 RAW-FRESH OR NFS	2F2595	P 10.00000	10.000000		25.00	2.500000
13045AA	LETTUCE-HEAD	21 COOKED-NFS	2F2595	P 10.00000	10.000000		25.00	2.500000
14007AA	GARLIC	10 RAW-FRESH OR NFS	3F2934	P 1.000000	1.000000		100.00	1.000000
14007AA	GARLIC	21 COOKED-NFS	3F2934	P 1.000000	1.000000		100.00	1.000000
14007AA	GARLIC	32 COOKED-FRESH OR CANNED-BAKED	3F2934	P 1.000000	1.000000		100.00	1.000000
14011AA	ONIONS-DRY-BULB	10 RAW-FRESH OR NFS	3F2934	P 1.000000	1.000000		100.00	1.000000
14011AA	ONIONS-DRY-BULB	21 COOKED-NFS	3F2934	P 1.000000	1.000000		100.00	1.000000
14011AA	ONIONS-DRY-BULB	22 COOKED-FRESH-BAKED	3F2934	P 1.000000	1.000000		100.00	1.000000
14011AA	ONIONS-DRY-BULB	31 COOKED-FRESH OR CANNED	3F2934	P 1.000000	1.000000		100.00	1.000000
14011DA	ONIONS-DRIED	12 RAW-FRESH-DRIED	3F2934	P 1.000000	1.000000		100.00	1.000000
43058AA	WINE AND SHERRY	10 RAW-FRESH OR NFS	1E2457	P 6.000000	6.000000		100.00	6.000000
43058AA	WINE AND SHERRY	21 COOKED-NFS	1E2457	P 6.000000	6.000000		100.00	6.000000

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 07/28/89 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Vinclozolin (Ronilan) Caswell #323C CAS No. 50471-44-8 A.I. CODE: 113201 CFR No. 180.380	6mo feeding- dog NOEL= 2.5000 mg/kg 100.00 ppm LEL= 7.5000 mg/kg 300.00 ppm ONCO: Class E (HED WOTE).	Increased absolute and relative adrenal weights. Histo changes seen in adrenal at higher doses. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.025000	No data gaps.	HED complete 05/19/86. EPA verified 07/08/86. WHO last reviewed 1988; temp. ADI established. 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	0.014378	0.018815	75.258160	17.745160	0.007575	30.30060
U.S. POPULATION - SPRING SEASON	0.014570	0.018774	75.095844	16.815804	0.007545	30.18059
U.S. POPULATION - SUMMER SEASON	0.019597	0.024233	96.933640	18.545160	0.007768	31.07071
U.S. POPULATION - FALL SEASON	0.011811	0.016255	65.021036	17.775296	0.007485	29.94012
U.S. POPULATION - WINTER SEASON	0.011549	0.016012	64.048696	17.851196	0.007504	30.01404
NORTHEAST REGION	0.015894	0.020461	81.844336	18.269612	0.008297	33.18906
NORTH CENTRAL REGION	0.014456	0.019121	76.482044	18.659552	0.007753	31.01141
SOUTHERN REGION	0.010556	0.014529	58.115240	15.890680	0.006070	24.28002
WESTERN REGION	0.018858	0.023588	94.350000	18.917620	0.008954	35.81624
HISPANICS	0.016187	0.021376	85.505376	20.758492	0.007812	31.24962
NON-HISPANIC WHITES	0.015065	0.019671	78.685984	18.424440	0.008011	32.04344
NON-HISPANIC BLACKS	0.009284	0.012333	49.333812	12.198116	0.004779	19.11408
NON-HISPANIC OTHERS	0.012645	0.016505	66.019136	15.440612	0.006443	25.77296
NURSING INFANTS (< 1 YEAR OLD)	0.043414	0.044215	176.860764	3.203156	0.001637	6.54830
NON-NURSING INFANTS (< 1 YEAR OLD)	0.086940	0.089879	359.516964	11.757980	0.005892	23.56708
FEMALES (13+ YEARS, PREGNANT)	0.012391	0.016333	65.330468	15.767148	0.006458	25.83022
FEMALES 13+ YEARS, NURSING	0.014154	0.018208	72.833748	16.219728	0.007891	31.56517
CHILDREN (1-6 YEARS OLD)	0.028640	0.037166	148.663276	34.104012	0.015796	63.18360
CHILDREN (7-12 YEARS OLD)	0.017718	0.024599	98.397964	27.524328	0.010696	42.78378
MALES (13-19 YEARS OLD)	0.008719	0.013617	54.467636	19.593352	0.006872	27.48689
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.009298	0.013381	53.522968	16.330116	0.006144	24.57448
MALES (20 YEARS AND OLDER)	0.010252	0.013796	55.183332	14.174668	0.006031	24.12340
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.012353	0.015752	63.009352	13.597012	0.006216	24.86397

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