



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

WELL FILE
323C

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. *Reto Engler*
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

	<u>Overall U.S. Population</u>	<u>Non-Nurs. Infants</u>	<u>Children Aged 1 - 6</u>
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

^aExposure estimate in mg/kg body weight/day.

^bEstimated 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,

Vinclozalin Dietary Exposure Analysis, page 3

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

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ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 323C

CHEMICAL			STUDY TYPE		EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS	
FOOD CODE	FOOD	FOOD FORM	PET. #	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)				
Vinclozolin (Ronilan)		6mo feeding- dog		Increased absolute and relative adrenal weights.	ADI	UF	-->100	No data gaps.		HED complete 05/19/86.		
Caswell #323C		NOEL= 2.5000 mg/kg			OPP RfD= 0.025000					EPA verified 07/08/86.		
CAS No. 50471-44-8		100.00 ppm		Histo changes seen in adrenal at higher doses.	EPA RfD= 0.025000					WHO last reviewed 1988;		
A.I. CODE: 113201		LEL= 7.5000 mg/kg								temp. ADI established.		
CFR No. 180.380		300.00 ppm		No evidence of oncogeni-								
		ONCO: Class E (HED NOTE).		city in rats or mice.						On IRIS.		
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Table 1, continued

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Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 07/28/89

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CHEMICAL INFORMATION		STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
Vinclozolin (Ronilan)	6mo feeding- dog	Increased absolute and relative adrenal weights.	ADI	UF -->100	No data gaps.	HED complete 05/19/86.		
Caswell #323C	NOEL= 2.5000 mg/kg	Histo changes seen in adrenal at higher doses.	OPP RfD= 0.025000			EPA verified 07/08/86.		
CAS No. 50471-44-8	100.00 ppm	No evidence of oncogeni-	EPA RfD= 0.025000			WHO last reviewed 1988;		
A.I. CODE: 113201	LEI= 7.5000 mg/kg	city in rats or mice.				temp. ADI established.		
CFR No. 180.380	300.00 ppm					On IRIS.		
ONCO: Class E (HED WOTE).								
TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES				
CURRENT TMRC*		NEW TMRC**		ARC	%RFD			
POPULATION SUBGROUP								
U.S. POPULATION - 48 STATES		0.014378	0.018815	75.258160	0.007575	30.30060		
U.S. POPULATION - SPRING SEASON		0.014570	0.018774	75.095844	0.007545	30.18059		
U.S. POPULATION - SUMMER SEASON		0.019597	0.024233	96.933640	0.007768	31.07071		
U.S. POPULATION - FALL SEASON		0.011811	0.016255	65.021036	0.007485	29.94012		
U.S. POPULATION - WINTER SEASON		0.011549	0.016012	64.048696	0.007504	30.01404		
NORTHEAST REGION		0.015894	0.020461	81.844336	0.008297	33.18906		
NORTH CENTRAL REGION		0.014456	0.019121	76.482044	0.007753	31.01141		
SOUTHERN REGION		0.010556	0.014529	58.115240	0.006070	24.28002		
WESTERN REGION		0.018858	0.023588	94.350000	0.008954	35.81624		
HISPANICS		0.016187	0.021376	85.505376	0.007812	31.24962		
NON-HISPANIC WHITES		0.015065	0.019671	78.685984	0.008011	32.04344		
NON-HISPANIC BLACKS		0.009284	0.012333	49.333812	0.004779	19.11408		
NON-HISPANIC OTHERS		0.012645	0.016505	66.019136	0.006443	25.77296		
NURSING INFANTS (< 1 YEAR OLD)		0.043414	0.044215	176.860764	0.001637	6.54830		
NON-NURSING INFANTS (< 1 YEAR OLD)		0.086940	0.089879	359.516964	0.005892	23.56708		
FEMALES (13+ YEARS, PREGNANT)		0.012391	0.016333	65.330468	0.006458	25.83022		
FEMALES 13+ YEARS, NURSING		0.014154	0.018208	72.833748	0.007891	31.56517		
CHILDREN (1-6 YEARS OLD)		0.028640	0.037166	148.663276	0.015796	63.18360		
CHILDREN (7-12 YEARS OLD)		0.017718	0.024599	98.397964	0.010696	42.78378		
MALES (13-19 YEARS OLD)		0.008719	0.013617	54.467636	0.006872	27.48689		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)		0.009298	0.013381	53.522968	0.006144	24.57448		
MALES (20 YEARS AND OLDER)		0.010252	0.013796	55.183332	0.006031	24.12340		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)		0.012353	0.015752	63.009352	0.006216	24.86397		

*Current TMRC does not include new or pending tolerances.

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