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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Vinclozolin (Ronilan) on Greenhouse-grown Tomatoes Imported from Spain and the Netherlands, 8E3688

FROM: J. Robert Tomerlin, Ph.D. 4/28/89
Tolerance Assessment System Staff
HED/SACB (H7509C)

THROUGH: R. Bruce Jaeger 4/28/89
Head, Special Analysis and Outreach Section
HED/SACB (H7509C)

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

Action Requested

Provide an estimate of dietary exposure resulting from the proposed use of vinclozolin on imported greenhouse-grown cucumbers and tomatoes.

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 tolerances on cucumbers and tomatoes (W. T. Chin memo, 4/27/89). 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 estimated TMRC for the overall U.S. population was calculated as 0.018815 mg/kg body weight/day, which represents 75% of the ADI. The two most highly exposed TAS subgroups, nursing and non-nursing infants, had TMRCs of 0.044215 mg/kg body weight/day (177% of the ADI) and

0.089879 mg/kg body weight/day (360% of the ADI), respectively. A complete TMRC summary is shown in Table 2.

Since there are other pending actions in the data file, the "DIFFERENCE..." column in Table 2 gives the increase in exposure, in terms of the per cent of the ADI, resulting from the proposed tolerances on cucumbers and tomatoes.

4. Comments: The bulk of the exposure for the three TAS subgroups discussed comes from published tolerances. The actual exposure is likely lower than what is estimated in this analysis because we used tolerance level residues and assume that 100 per cent of the crops were treated. An exposure estimate closer to actual exposure could be calculated if anticipated residue and per cent crop treated data were available for stone fruits, particularly peaches. Peaches account for over 20% of the ADI for the overall U.S. population, over 130% of the ADI for nursing infants, and over 200% of the ADI for non-nursing infants.

The exposure resulting from the proposed tolerances on imported greenhouse-grown cucumbers and tomatoes is also overestimated, because all tomatoes consumed were assumed to have been treated with vinclozolin, regardless of country of origin or type of production.

Attachments

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

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 323C DATE: 04/27/89 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 SF -->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 NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED	
01006AA	RASPBERRIES	3F2934			10.0000	
01014AA	GRAPES-FRESH	1E2457			6.0000	
01014DA	GRAPES-RAISINS	7H5529			30.0000	H
01014JA	GRAPES-JUICE	1E2457			6.0000	
01016AA	STRAWBERRIES	9F2205			10.0000	
05001AA	APRICOTS-FRESH	2F2650			25.0000	
05001DA	APRICOTS-DRIED	2F2650			25.0000	
05002AA	CHERRIES-FRESH	2F2650			25.0000	
05002DA	CHERRIES-DRIED	2F2650			25.0000	
05002JA	CHERRIES-JUICE	2F2650			25.0000	
05003AA	NECTARINES	2F2650			25.0000	
05004AA	PEACHES-FRESH	2F2650			25.0000	
05004DA	PEACHES-DRIED	2F2650			25.0000	
05005AA	PLUMS(DAMSONS)-FRESH	2F2650			25.0000	
05005DA	PLUMS-PRUNES(DRIED)	5H5462			75.0000	H
05005JA	PLUMS/PRUNE-JUICE	5H5462			75.0000	H
06018AA	KIWI	0E2380			10.0000	
10010AA	CUCUMBERS	8E3688	1.0000			
11003AA	PEPPERS,SWEET,GARDEN	4E2998			3.0000	
11005AA	TOMATOES-WHOLE	8E3688	3.0000			
11005JA	TOMATOES-JUICE	8E3688	3.0000			
11005RA	TOMATOES-PUREE	8E3688	3.0000			
11005TA	TOMATOES-PASTE	8E3688	3.0000			
11005UA	TOMATOES-CATSUP	8E3688	3.0000			
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	8E3620			5.0000	
13013AA	LETTUCE-LEAFY VARIETIES	3F2934			10.0000	
13020AA	LETTUCE-UNSPECIFIED	2F2595			10.0000	
13045AA	LETTUCE-HEAD VARIETIES	2F2595			10.0000	
14007AA	GARLIC	3F2934			1.0000	
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	3F2934			1.0000	
14011DA	ONIONS-DEHYDRATED OR DRIED	3F2934			1.0000	
43058AA	WINE AND SHERRY	1E2457			6.0000	

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Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 04/27/89 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 SF -->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		
U.S. POPULATION - SPRING SEASON	0.014570	0.018774	75.095844	16.815804		
U.S. POPULATION - SUMMER SEASON	0.019597	0.024233	96.933640	18.545160		
U.S. POPULATION - FALL SEASON	0.011811	0.016255	65.021036	17.775296		
U.S. POPULATION - WINTER SEASON	0.011549	0.016012	64.048696	17.851196		
NORTHEAST REGION	0.015894	0.020461	81.844336	18.269612		
NORTH CENTRAL REGION	0.014456	0.019121	76.482044	18.659552		
SOUTHERN REGION	0.010556	0.014529	58.115240	15.890680		
WESTERN REGION	0.018858	0.023588	94.350000	18.917620		
HISPANICS	0.016187	0.021376	85.505376	20.758492		
NON-HISPANIC WHITES	0.015065	0.019671	78.685984	18.424440		
NON-HISPANIC BLACKS	0.009284	0.012333	49.333812	12.198116		
NON-HISPANIC OTHERS	0.012645	0.016505	66.019136	15.440612		
NURSING INFANTS (< 1 YEAR OLD)	0.043414	0.044215	176.860764	3.203156		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.086940	0.089879	359.516964	11.757980		
FEMALES (13+ YEARS, PREGNANT)	0.012391	0.016333	65.330468	15.767148		
FEMALES 13+ YEARS, NURSING	0.014154	0.018208	72.833748	16.219728		
CHILDREN (1-6 YEARS OLD)	0.028640	0.037166	148.663276	34.104012		
CHILDREN (7-12 YEARS OLD)	0.017718	0.024599	98.397964	27.524328		
MALES (13-19 YEARS OLD)	0.008719	0.013617	54.467636	19.593352		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.009298	0.013381	53.522968	16.330116		
MALES (20 YEARS AND OLDER)	0.010252	0.013796	55.183332	14.174668		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.012353	0.015752	63.009352	13.597012		

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