US EPA ARCHIVE DOCUMENT

3-16-88

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

MAR 16 1988

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 Request for the Use of Vinclozolin on Snap Beans - TAS Dietary Exposure Analysis. 88-OR-07 / 88-WA-04.

FROM: Susan L. Stanton
Tolerance Assessment Program
HED/RCB (TS-769C)

Susan L. Stanton 3/16/88

THRU: Karl Arne, Ph.D.
Branch Senior Scientist
HED/RCB (TS-769C)

TO: Eugene Asbury
Emergency Response and Minor Use Section
Registration Division (TS-767C)

Action Requested

Provide a dietary exposure analysis in conjunction with the requested Section 18 Exemption for applications of the fungicide vinclozolin to snap beans.

Discussion

1. A routine chronic analysis was conducted using a Reference Dose (ADI) of 0.025 ppm based on a NOEL of 2.5 mg/kg/day from a 6-month dog feeding study with a safety factor of 100. This value has been verified by the TOX Branch and Agency reference dose committees.

2. The food uses evaluated were those published in 40 CFR 180.380 and 21 CFR 193.137, as well as other pending tolerances (raspberries, leaf lettuce, and dry bulb onions) and the proposed use on snap beans. Table 1 provides a complete listing of residue information.

3. The TAS routine chronic analysis calculates the Theoretical Maximum Residue Contribution (TMRC) for the U.S. population and each of 22 population subgroups (see Table 2) and compares this exposure estimate to the reference dose (ADI in this case). The results of the present analysis are summarized below:

	Published Tolerances	Sec. 18 (Snap Beans)	Other (3F2934)	Total Exposure
U.S. Population	0.014194[a] (56.8%)[b]	0.000400 (1.6%)	0.000181 (0.7%)	0.014775 (59.1%)
Non-nursing Infants	0.086899 (347.6%)	0.001640 (6.6%)	0.000041 (0.2%)	0.088580 (354.3%)
Children 1-6 yrs.	0.028401 (113.6%)	0.000687 (2.7%)	0.000238 (1.0%)	0.029326 (117.3%)

[a]TMRC expressed as mg/kg body weight/day.
[b]Exposure (TMRC) as a percent of the ADI.

4. This analysis uses tolerance level residues with an assumption of 100% crop treated, a conservative approach that likely overestimates exposure significantly.

cc: TAS File
Reading File
circ.
TOX (Rathman)
Vinclozolin SF
PMSD

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 323C

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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	6m feeding- dog NOEL= 2.5000 mg/kg 100.00 ppm LEL= 7.5000 mg/kg 300.00 ppm ONCO: Class E (TOX WOTE).	Increased absolute and relative adrenal weights. Histo changes seen in adrenal at higher doses. No evidence of oncogenicity in rats or mice.	ADI 100 OPP RfD= 0.025000 EPA RfD= 0.025000 WHO RfD 0.040000 Type: TADI	No data gaps.	TOX complete 5/19/86. ORD verified 7/8/86. WHO last reviewed 1986; temp. ADI established. On IRIS.

FOOD CODE	FOOD NAME		PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED	
01006AA	RASPBERRIES		3F2934		10.0000		
01014AA	GRAPES-FRESH	EXPIRES 5/13/88	1E2457			6.0000	
01014DA	GRAPES-RAISINS	EXPIRES 5/13/88	7H5529			30.0000	H
01014JA	GRAPES-JUICE	EXPIRES 5/13/88	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	
11003AA	PEPPERS,SWEET,GARDEN		4E2998			3.0000	
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		
15003AA	BEANS-SUCCULENT-GREEN		88OR07	2.0000			
43058AA	WINE AND SHERRY	EXPIRES 5/13/88	1E2457			6.0000	

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 03/16/88

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	6m feeding- dog NOEL= 2.5000 mg/kg 100.00 ppm LEL= 7.5000 mg/kg 300.00 ppm ONCO: Class E (TOX WOTE).	Increased absolute and relative adrenal weights. Histo changes seen in adrenal at higher doses. No evidence of oncogenicity in rats or mice.	ADI 100 OPP RfD= 0.025000 EPA RfD= 0.025000 WHO RfD 0.040000 Type: TADI	No data gaps.	TOX complete 5/19/86. ORD verified 7/8/86. WHO last reviewed 1986; 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	0.014194	0.014775	59.099984	2.323940		
U.S. POPULATION - SPRING SEASON	0.014359	0.014953	59.812432	2.376340		
U.S. POPULATION - SUMMER SEASON	0.019410	0.020018	80.070220	2.431256		
U.S. POPULATION - FALL SEASON	0.011644	0.012217	48.866076	2.289896		
U.S. POPULATION - WINTER SEASON	0.011378	0.011928	47.711356	2.198248		
NORTHEAST REGION	0.015686	0.016196	64.784840	2.040008		
NORTH CENTRAL REGION	0.014262	0.014851	59.405736	2.356848		
SOUTHERN REGION	0.010425	0.011060	44.240144	2.541456		
WESTERN REGION	0.018627	0.019197	76.789484	2.281508		
HISPANICS	0.016012	0.016461	65.843620	1.794168		
NON-HISPANIC WHITES	0.014867	0.015454	61.817568	2.349108		
NON-HISPANIC BLACKS	0.009185	0.009778	39.112368	2.373260		
NON-HISPANICS OTHER	0.012468	0.013133	52.533500	2.662664		
NURSING INFANTS (<1 YEAR OLD)	0.043337	0.044038	176.153260	2.806108		
NON-NURSING INFANTS (<1 YEAR OLD)	0.086899	0.088580	354.319224	6.722784		
FEMALES (13+ YEARS, PREGNANT)	0.012231	0.012604	50.417696	1.495460		
FEMALES 13+ YEARS, NURSING	0.013807	0.014493	57.973584	2.745252		
CHILDREN (1-6 YEARS OLD)	0.028401	0.029326	117.304040	3.698556		
CHILDREN (7-12 YEARS OLD)	0.017497	0.018284	73.136804	3.149756		
MALES (13-19 YEARS OLD)	0.008551	0.009080	36.318608	2.115056		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.009136	0.009616	38.464544	1.919672		
MALES (20 YEARS AND OLDER)	0.010088	0.010562	42.249580	1.896528		
FEMALES (20 YEARS AND OLDER)	0.012167	0.012675	50.700940	2.031276		

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