



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. *K. Arne*
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:

	<u>Published Tolerances</u>	<u>Sec. 18 (Snap Beans)</u>	<u>Other (3F2934)</u>	<u>Total Exposure</u>
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%)

^aTMRC expressed as mg/kg body weight/day.

^bExposure (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

DATE: 03/16/88

PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES		DATA GAPS/COMMENTS	STATUS
			ADI	100		
Vinclozolin (Ronilan)	6m feeding- dog	Increased absolute and relative adrenal weights.	OPP RfD= 0.025000		No data gaps.	TOX complete 5/19/86.
Caswell #323C	NOEL= 2.5000 mg/kg	Histo changes seen in adrenal at higher doses.	EPA RfD= 0.025000			ORD verified 7/8/86.
CAS No. 50471-44-8	LEL= 7.5000 mg/kg	No evidence of oncogenicity in rats or mice.	WHO RfD 0.040000			WHO last reviewed 1986; temp. ADI established.
A.I. CODE: 113201	300.00 ppm		Type: TADI			On IRIS.
CFR No. 180.380	ONCO: Class E (TOX NOTE)					

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM)	
			PENDING	PUBLISHED
01006AA	RASPBERRIES	3F2934		
01014AA	GRAPES-FRESH	1E2457	10.0000	
01014DA	GRAPES-RAISINS	7H5529		6.0000 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(DAWSONS)-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		
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	880R07	2.0000	
43058AA	WINE AND SHERRY	1E2457		6.0000

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 03/16/88

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS		REFERENCE DOSES		DATA GAPS/COMMENTS		STATUS
		6m feeding- dog	Increased absolute and relative adrenal weights. Histo changes seen in adrenal at higher doses. No evidence of oncogenicity in rats or mice.	ADI	100	No data gaps.		
Vinclozolin (Ronilan)	NOEL=	2.5000 mg/kg		OPP RFD=	0.025000			TOX complete 5/19/86.
Caswell #323C	100.00 ppm			EPA RFD=	0.025000			ORD verified 7/8/86.
CAS No. 50471-44-8	LEL=	7.5000 mg/kg						WHO last reviewed 1986;
A.I. CODE: 113201		300.00 ppm		WHO RFD	0.040000			temp. ADI established.
CFR No. 180.380	ONCO: Class E (TOX NOTE)			Type: TADI				On IRIS.

TOTAL TMRC (MG/KG BODY WEIGHT/DAY)

POPULATION SUBGROUP	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.