US EPA ARCHIVE DOCUMENT

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 93PA0001. Section 18 Exemption for Vinclozolin on Snap Beans. DRES Dietary Exposure/Risk Estimates.

FROM: Richard Griffin
Chemistry Branch I / Tolerance Support
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4/7/93

THROUGH: Debra Edwards, Chief
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4/8/93

TO: Libby Pemberton, PM 41
Emergency Response and Minor Uses Section
Registration Support Branch
Registration Division

Toxicological endpoints for risk assessment:

Chronic:

o RfD: The Agency approved (1986) reference dose is 0.025 mg/kg/day, based on the NOEL (2.5 mg/kg/day) of a six-month dog feeding study and an uncertainty factor of 100.

Acute:

DRES one-day consumption/exposure estimates for U.S. females (13+ years) are compared to an endpoint of 15.0 mg/kg/day (based on the NOEL of a rat developmental toxicity study) to provide "acute" risk (margin of exposure) estimates.

Residue:

Exposure estimates are based on the published food tolerances of 40 CFR 180.380/185.1850 and the following "not expected to exceed" or enforcement levels for 93PA0001.

3.00 ppm...succulent snap beans
0.06 ppm...milk
0.10 ppm...cattle fat
0.06 ppm...cattle muscle
0.75 ppm...cattle liver
0.22 ppm...cattle kidney (W.R. Cook memo, 3/2/93)

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

Current tolerances are summarized in Table 1.

Please note this assessment includes tolerances for the import of cucumbers and tomatoes (inexplicably omitted in previous HED dietary risk assessments). DRES default concentration factors for processed tomato products are used in this assessment based on a chemistry review for peppers/tomatoes (memo of C. Deyrup, 3/16/87) which reported residue concentration in a fractionation study.

There are no anticipated residue estimates.

Percent crop treated:

Chronic exposure estimates for stone fruits and lettuce have been factored by percent use data. All other commodities are assessed at 100 percent.

Chronic exposure/risk estimates:

Published uses: Tolerance x 100% use (TMRC)

	mg/kg/day	% RfD
Average U.S. population:	0.018814	75
Non-nursing infants:	0.089879	360
Children (1-6 yrs):	0.037164	150

Published uses: Tolerance x (limited) percent use data (ARC)

Average U.S. population:	0.007571	30
Non-nursing infants:	0.005891	24
Children (1-6):	0.015794	63

93PA0001: Enforcement level x 100 percent use:

Average U.S. population:	0.001357	5
NN infants:	0.006494	26
Children:	0.003107	12

Acute exposure/risk:

The following "acute" exposure estimates are based on tolerances and the above not expected to exceed levels associated with the section 18 use.

MOE = NOEL (15 mg/kg) / exposure estimate (mg/kg)

- Estimated percent days that relevant population group (women) are exposed to Vinclozolin, based on all commodities: 100.

- Average MOE: 912.

Acute risk cont.

- Estimated maximum one-day exposure: 0.21 mg/kg/day (MOE 71).
- Estimated percent women with an MOE < 100: 1.
- Estimated maximum one-day exposure, based <u>only</u> on beans/cattle residues: > 0.015 mg/kg/day (MOE 1,000).

cc: 18 file
RF
R Griffin

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: 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. 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	
14011AA	ONIONS-DRY-BULB (CIPOLLINI)	3F2934			1.0000	
14011DA	ONIONS-DEHYDRATED OR DRIED	3F2934			1.0000	
43058AA	WINE AND SHERRY	1E2457			6.0000	