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

RCP
~~Quick~~
~~Nelson~~
File petition

SEP 30 1980

MEMORANDUM

OFFICE OF TOXIC SUBSTANCES

SUBJECT: PP#0E2380; Ronilan; vinclozolin in or on Kiwi fruit at 10 ppm.
CASWELL#323C Accession#099483

WHO 8/25/80

FROM: William Dykstra
Toxicology Branch, HED (TS-769)

TO: Henry Jacoby (21)
Registration Division (TS-767)
and
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Recommendations:

1) The proposed tolerance can be toxicologically supported.

Section F - Petition requests that a tolerance be established for residues of the fungicide, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety, in or on the raw agricultural commodity Kiwi fruit at 10 ppm.

Review:

1) No new toxicity data submitted.

2) Previously reviewed toxicity data.

a) Memo of 4/17/78 from R. Gessert in PP#8G2068.

°Studies conducted with Formulation: Ronilan

°Rat Acute Oral LD50 > 16,000 mg/kg (both sexes)
°Rabbit Acute Dermal LD50 > 2000 mg/kg (both sexes)
°Rat Acute Inhalation LC50 > 1.7 mg/L for 4 hours

°Studies conducted with Technical

°Rat Acute Oral LD50 > 10,000 mg/kg (both sexes)
°Rat Acute Dermal LD50 > 2500 mg/kg (both sexes)
°90-Day Rat Feeding: NOEL = 450 ppm
°90-Day Dog Feeding: NOEL = 300 ppm
°Mouse Teratology: negative at 600 ppm
°3-Generation Rat Reproduction: NOEL = 1458 ppm
°Dominant Lethal Assay in Mice: negative at 2000 mg/kg for five days.
°Chronic Feeding/Oncogenic in Rats for 130 Weeks: oncogenic potential: negative; NOEL = 486 ppm
°Chronic Feeding/Oncogenic in Mice for 26 Months: oncogenic potential: negative; NOEL = 1458 ppm
°Metabolism: reported oral dosing in rats.

The 90-day dog study was conducted at 100, 300, 1000 and 2000 ppm.

At 1000 ppm (the LEL), an increase in thrombocytes occurred in the hematograms of female dogs. Differential blood counts showed Jolly Bodies. Histological investigations disclosed hepatic cholestasis.

The 6-month dog study will utilize a 1000 fold safety factor to calculate the ADI. Permanent tolernces (9F2205, strawberries, OE2338, Kiwi fruit) utilize 14.26% of PADI.

The temporary tolerances and EUP for stone fruit and lettuce ends in February, 1981.

Given these considerations, although the PADI is exceeded, the proposed tolerance can be toxicologically supported.

TS-769:TOX/HED:th:LCHITLIK:8-21-80

No CFR number Ronilan 8/21/80

File last updated 8/21/80

ACCEPTABLE DAILY INTAKE DATA

Dog mg/kg	NOEL ppm	S.F.	PADI mg/kg/day	MPI mg/day/60kg
7.500	300.00	2000	0.0038	0.2250

Unpublished, Tox Approved 9G2204, 9F2205

CROP	Tolerance	Food Factor	mg/day/1.5kg
Apricots(3)	25.000	0.11	0.04216
Peaches(114)	25.000	0.90	0.33725
Lettuce(84)	10.000	1.31	0.19622
Cherries(30)	5.000	0.10	0.00766
Nectarines(100)	2.500	0.03	0.00113
Plums, inc prunes(125)	1.000	0.13	0.00199
Strawberries(152)	10.000	0.18	0.02759

MPI	TMRC	% ADI
0.2250 mg/day/60kg	0.6140 mg/day/1.5kg	272.89

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Current Action 0E2338

CROP	Tolerance	Food Factor	mg/day/1.5kg
Kiwi Fruit(204)	10.000	0.03	0.00450

MPI	TMRC	% ADI
0.2250 mg/day/60kg	0.6185 mg/day/1.5kg	274.89

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