9-10-86 RCB

Cook

File petition

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

SEP 10 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: IR-4 Proposal to establish tolerances for Iprodione and its isomer and metabolite(s) in or on ginseng

TO: Hoyt Jamerson, PM 43
Emergency Response and Minor Use Section
Registration Support and Emergency Response Branch
Registration Division (TS-767)

FROM: Margaret L. Jones
Review Section III
Toxicology Branch, HED
(TS-769)

M. L. Jones 9/9/86

THROUGH: Marcia Van Gemert, Ph.D., Head
Review Section III

M Van Gemert 9.9.86

and Theodore M. Farber, Ph.D, Chief
Toxicology Branch

W Farber 9.9.86

Compound: Iprodione; Rovral; Glycophene Tox. Chem. No: 470A

Record No: 176364, 176366 Tox. Project No: 2136

Petitioner: Interregional Research Project No. 4

Accession No: 263586, 263748 Petition No: 6E3426, 6H5504

Action Requested: Establish tolerances for Iprodione and its isomer and metabolite in or on the raw agricultural commodity ginseng at 2 ppm and in or on the commodity ginseng at 4 ppm.

Data Considered:

Reproduction in the rat (undated)
Chronic/oncogenicity in the mouse (3/6/78)
Subchronic dog (undated)
Developmental toxicity in the rabbit (12/12/85)

Data Currently Lacking on Iprodione: Toxicology data requirements were published in the Federal Register (Vol.49 No.207, 10/24/84, pp. 42892-42893). According to these requirements, the following data for the technical chemical are lacking:

Acute dermal LD_{50}

1/4

Dermal sensitization
Developmental toxicity in a species other than the rabbit
General metabolism

Actions Under Way to Obtain Missing Data: No known action is presently under way to obtain these data.

Published Tolerances for Iprodione: Tolerances exist for Iprodione in or on raw agricultural commodities as published in 40 CFR 180.399, 21 CFR 193.251, and 21 CFR 561.263.

Effect of Proposed Tolerance on Acceptable Daily Intake (ADI): The present request for tolerances of Iprodione in or on ginseng at 4 ppm was analyzed in a Toxicology Branch ADI Printout (copy attached). The acceptable daily intake is based on the three generation reproduction study in rats with a no observed effects level of 500 ppm (25 mg/kg/day). The cumulative percent of the ADI used from the existing and proposed actions is 13.0068 for the U.S. population.

Acceptable Daily Intake, Maximum Permissible Intake, and Theoretical Maximum Residue Contribution:

ADI = 0.25 mg/kg/day
MPI = 15 mg/kg/day (60 kg person)
TMRC = 0.033 mg/kg/day
NOEL = 500 ppm (25 mg/kg/day)
Safety Factor = 100

Recommendation: Toxicology Branch recommends approval of the proposed tolerance for Iprodione in or on ginseng at 4 ppm. We again recommend taking steps to obtain the currently lacking toxicity data on Iprodione

TOXICOLOGY BRANCH ADI PRINTOUT Date: 09/08/86

Glycophene (Iprodione) ADI = 0.250000 mg/kg/day
Caswell #470A NOEL = 0.0000 mg/kg Safety Factor = 100
CFR No. 180.399 LEL = 0.0000 mg/kg
Status: ADI NOT VERIFIED BY TOX ADI COMMITTEE OR AGENCY RFD COMMITTEE.

DRAFT

RESIDUE CONTRIBUTION OF PUBLISHED TOLERANCES

	CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
1	Almonds	0.050		0.03	0.000023
54	Eggs	0.800		2.77	0.033240
61	Garlic	0.100		0.03	0.000045
67	Grapes, not including raisins	60.000		0.45	0.405000
84	Lettuce	15.000		1.31	0.294750
90	Meat, red	0.400		10.81	0.064860
93	Milk and dairy products	0.300		28.62	0.128790
128	Poultry	2.000		2.94	0.088200
134	Raisins	300.000		0.04	0.180000
151	Stone fruits	20.000		1.25	0.375000
203	Kidney	3.000		0.03	0.001350
204	Kiwi fruit	10.000		0.03	0.004500
211	Liver	3.000		0.03	0.001350

TMRC %ADI
0.026285 mg/kg/day (60kg BW, 1.5kg diet) 10.514050

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

	CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
1	Almonds	0.250	5F3241	0.03	0.000112500
10	Beans, dry edible	4.000	4F3150	0.31	0.018600000
11	Beans, lima	2.000	4F3150	0.19	0.005700000
12	Beans, snap	2.000	4F3150	0.98	0.029400000
17	Boysenberries	15.000	4F3129	0.03	0.006750000
18	Blueberries	15.000	5E3214	0.03	0.006750000
19	Broccoli	25.000	6F3305	0.10	0.037500000
48	Currants	15.000	5E3214	0.03	0.006750000
90	Meat, red	0.200	4F3129	10.81	0.032430000
93	Milk and dairy products	0.400	4F3129	28.62	0.171720000
105	Onions	0.500	4F3111	0.83	0.006225000
115	Peanuts	0.100	4G3037	0.36	0.000540000
115	Peanuts	0.400	4F3129	0.36	0.002160000
127	Potatoes	0.500	6F3366	5.43	0.040725000

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
135 Raspberries	15.000	5E3214	0.03	0.006750000

TMRC
0.032487 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
12.994800

RESIDUE CONTRIBUTION OF NEW (PENDING) TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
223 Ginseng	4.000	6E3426	0.03	0.001800000

TMRC
0.032517 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
13.006800
