

US EPA ARCHIVE DOCUMENT

12-15-86
RCB



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 15 1986

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Deputy

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 carrots

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 *M. L. Jones 12/11/86*
Review Section III
Toxicology Branch

THROUGH: Marcia Van Gemert, Ph.D., Head *M. Van Gemert 12.12.86*
Review Section III

and Theodore M. Farber, Ph.D., D.A.B.T., Chief
Toxicology Branch

Compound: Iprodione (Rovral, Glycophene) Tox. Chem.: 470A

Record No.: 184709 Tox. Project: 7-0187

Petitioner: Interregional Research Project No. 4

Accession No.: 265922 Petition No.: 7E3474

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12/12/86

Action Requested: Establish tolerances for Iprodione and its isomer and metabolite in or on the raw agricultural commodity carrots at 5 ppm.

Data Considered: 1 year dog study
3 generation reproduction in the rat
chronic/oncogenicity in the mouse (3/6/78)
developmental toxicity in the rabbit (12/12/85)

Data Currently Lacking on Iprodione: Data gaps were recently discussed with the PM for this chemical. Action is apparently under way to correct the deficiencies of acute dermal and sensitization and metabolism for the technical chemical; and developmental toxicity in a species other than the rat has apparently been submitted to the Agency (not yet received by Toxicology Branch).

1/4

Actions Under Way to Obtain Missing Data: See above

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 carrots at 5 ppm was analyzed in a Toxicology Branch ADI Printout (copy attached). The acceptable daily intake (ADI) 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 13.7968% for the U.S. population.

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

ADI= 0.25 mg/kg/day
MPI= 12 mg/kg/day (60 kg person)
TMRC= 0.034492 mg/kg/day (60 kg BW, 1.5 kg diet)
NOEL= 500 ppm (25 mg/kg/day)
Safety Factor= 100

Comments: Iprodione is currently under consideration by the Toxicology Branch ADI committee and the Agency-wide Rfd Committee which decides on the ADI for pesticide chemicals. The committee is considering changing the study used to set the ADI to the one year dog study which has a NOEL of 100 ppm (2.5 mg/kg/day). It is possible a safety factor of 100 will be chosen for this study, which could result in an ADI of 0.025 mg/kg/day for this chemical.

TOXICOLOGY BRANCH ADI PRINTOUT

Date: 12/09/86

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.
WHO last reviewed 1977.

RESIDUE CONTRIBUTION OF PUBLISHED TOLERANCES

DRAFT

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
1 Almonds	0.050		0.03	0.000022500
54 Eggs	0.800		2.77	0.033240000
61 Garlic	0.100		0.03	0.000045000
67 Grapes, not including raisins	60.000		0.45	0.405000000
84 Lettuce	15.000		1.31	0.294750000
90 Meat, red	0.400		10.81	0.064860000
93 Milk and dairy products	0.300		28.62	0.128790000
128 Poultry	2.000		2.94	0.088200000
134 Raisins	300.000		0.04	0.180000000
151 Stone fruits	20.000		1.25	0.375000000
203 Kidney	3.000		0.03	0.001350000
204 Kiwi fruit	10.000		0.03	0.004500000
211 Liver	3.000		0.03	0.001350000

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

%ADI
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
137 Rice	10.000	6F3443	0.55	0.082500000
223 Ginseng	4.000	6E3426	0.03	0.001800000

TMRC
0.033892 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
13.556800

RESIDUE CONTRIBUTION OF NEW (PENDING) TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
24 Carrots	5.000	7E3474	0.48	0.036000000

TMRC
0.034492 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
13.796800
