

DEC 1 1983

Caswell No(s):

12-14-83

470A RCB ①

CFR-180.399

To: H. Jacoby PM 8/

Registration No(s): 359-685

Pesticide Petition No(s): 3F 2840

Chemical(s): ROVRAL-(IPRODIONE, GLYCOPHENE)

RECEIVED
DEC 16 1983

Requested Action(s): REVISED SECTION "F" - REVISE

LABEL CHANGES - LIMIT USE TO HEAD LETTUCE

(SECTION F ATTACHED)

Recommendation:

ONLY

This request is acceptable

Inert(s) cleared 180.1001: YES (PREVIOUSLY, STA. OF INERT NOT

% of ADI occupied: Existing: 7.14 Resulting: 8.19 SUBMITTED

Resulting % increase in TMRC: From 1.0708 To 1.2278 mg/day/15kg = 14.66%

Data considered in setting the ADI: A 3 generation reproduction study-rat

NAEL = 500PPM, SE = 100, ADI = 0.2506 mg/kg/d, MPI = 15.0 mg/d/100kg

Attached (?): ADI printout: YES/NO; TOX "one-liner": YES/NO; DER: YES/NO

Existing regulatory actions against registration: NONE

RPAR status: NOT IN THE LIST

New Data: NONE

Data gaps: ACUTE DERMAL; TERATOLOGY, SECOND SPECIE;
ADDITIONAL MUTAGENICITY TEST, AS PER SECTION "F" OF
FIFRA GUIDELINES, 1 YEAR DOG STUDY THAT IS IN PROGRESS

Comments: Petitioner must submit data gaps

Reviewer: [Signature]

Date:

Dec 11-83

DEC 14 1983

Section Head: [Signature] 12/14/83

Pl. L. L. L. 12/14/83

File last updated 11/18/83

ACCEPTABLE DAILY INTAKE DATA

RAT, Older NOEL	S.F.	ADI	MPI
mg/kg	ppm	mg/kg/day	mg/day (60kg)
25.000	500.00	100	0.2500
			15.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Kiwi Fruit (204)	10.000	0.03	0.00450
Stone Fruits (151)	20.000	1.25	0.37404
Almonds (1)	0.050	0.03	0.00002

MPI	TMRC	% ADI
15.0000 mg/day (60kg)	0.3786 mg/day (1.5kg)	2.52

Unpublished, Tox Approved 3G2787, 2801, 2G2856

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Meat, red (90)	0.100	10.81	0.01622
Milk & Dairy Products (93)	0.020	28.62	0.00858
Grapes, not raisins (67)	60.000	0.45	0.40470
Raisins (134)	180.000	0.04	0.11037
Lettuce (84)	7.000	1.31	0.13735
Beans, dry edible (10)	2.000	0.31	0.00930
Beans, lima (11)	2.000	0.19	0.00570

MPI	TMRC	% ADI
15.0000 mg/day (60kg)	1.0708 mg/day (1.5kg)	7.14

Current Action 3F2840 [Rev Sec E]

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Lettuce (84)	8.000	1.31	0.15697

MPI	TMRC	% ADI
15.0000 mg/day (60kg)	1.2278 mg/day (1.5kg)	8.19

.1570 — x% increased

$$X \frac{.1570 \times 100}{1.0708} = \frac{15.70000}{1.0708} = 14.66\%$$

DRAFT