

US EPA ARCHIVE DOCUMENT

DEC 14 1983

Caswell No(s):

470A

RCB

To: H. Jacoby PM 21

CFR-180.399

Registration No(s): 359-685

Pesticide Petition No(s): 4H5415

COOK RECEIVED  
F. Lepelstein  
DEC 16 1983

Chemical(s): ROYAL - (IPRODIONE, GLYCOPHENE

Requested Action(s): REVIEW PETITION FOR FOOD & FEED ADDITIVE TOLERANCES (SECTION "F" ATTACHED

Recommendation: This request is acceptable

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

of ADI occupied: Existing: 7.14 Resulting: 7.63

Resulting % increase in TMRC: From 1.0708 to 11444 = 0.0736 mg/day/1.5kg = 6.78%

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

NOEL = 500PPM, SF = 100, ADI = 0.2506 mg/kg/d, MPl = 15.0 mg/d/60kg

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

Existing regulatory actions against registration: NONE

PAR 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: Data gaps must be submitted

Reviewer: [Signature] 12-17-83

Date: DEC 14 1983 12-11-83  
[Signature] 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

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Unpublished, Tox Approved 3G2787, 2801, 2G2856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	0.00358
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

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Current Action 4H5415

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Raisins (134)	120.000	0.04	0.07358

MPI	TMRC	% ADI
15.0000 mg/day (60kg)	1.1444 mg/day (1.5kg)	7.63

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0.0736 = X%

$$X = \frac{0.0736 \times 100}{1.0708} = \frac{7.3600}{1.0708} = 6.78\%$$

DRAFT