

US EPA ARCHIVE DOCUMENT

DEC 15 1983

Caswell No(s):

470A

RCB ②

12-15-83

To: H. Jacoby PM 21

CFR-180.399

Registration No(s): 359-685

Cook

RECEIVED

Pesticide Petition No(s): 3F2964

Fallop

DEC 16 1983

Chemical(s): ROYRAL - (IPRODIONE, GLYCOPHENE

Requested Action(s): APPLICATION FOR AMENDED REGISTRATION - PROPOSING TO ADD GRAPES TO PRESENT LABEL

(SECTION F ATTACHED) * TOLERANCES REQUESTED

GRAPES	60 PPM
FAT, MEAT BYPROD	0.4 PPM
DUCTS OF CATTLE	
GOATS, HIGGS, HORSES	
SHEEP	
KIDNEY & LIVER	3.0 PPM
ECS	0.8 PPM
MILK	0.5 PPM

Recommendation: This request is acceptable

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

% of ADI occupied: Existing: 7.14 Resulting: 8.50

Resulting % increase in TMRC: From 1.0708 To 1.2756 = mg/day / 15 Kg = 19.3 %

Data considered in setting the ADI: A 3 generation reproduction study - rat NOEL = 500PPM, SF = 100, ADI = 0.2506 mg/Kg/d, MPI = 15.0 mg/d/60Kg

Attached (?): ADI printout: YES/✓; TOX "one-liner": YES/✓; 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

DEC 15 1983

Reviewer: [Signature]

Date: 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

Unpublished, Tox Approved 3G2787, 2801, 2G2856

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Meat, red(90)	0.100	10.81	0.1622
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 3F2964

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Grapes, not raisins(67)	0.000	0.45	0.00000
Meat, red(90)	0.300	10.81	0.04866
Liver(211)	3.000	0.03	0.00135
Kidney(203)	3.000	0.03	0.00135
Eggs(54)	0.800	2.77	0.03324
Milk&Dairy Products(93)	0.280	28.62	0.12018

MPI	TMRC	% ADI
15.0000 mg/day (60kg)	1.2756 mg/day(1.5kg)	8.50

0.2048 = x%

X = $\frac{2.04800}{1.0708} = 19.3$

DRAFT