

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

Falipet

DEC 16 1983

Chemical(s): ROYAL-(IPRODIONE, GLYCOPHENE

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

(SECTION F ATTACHED) * TOLERANCES REQUESTED

Recommendation:

This request is acceptable

GRAPES 60 PPM

FAT, MEAT BYPROD. 0.4 PPM

DUCTS OF CATTLE

GOATS, HIGGS, HORSES

SHEEP

KIDNEY & LIVER 3.0 PPM

Eggs 0.8 PPM

MILK 0.5 PPM

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

% 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

Reviewer:

[Signature]

Date:

12-11-83

DEC 15 1983

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Unpublished, Tox Approved 3G2787, 2801, 2G2856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)	<u>60.000</u>	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)	<u>0.000</u>	0.45	0.00000
Meat, red(90)	<u>0.300</u>	10.81	0.04866
Liver(211)	<u>3.000</u>	0.03	0.00135
Kidney(203)	<u>3.000</u>	0.03	0.00135
Eggs(54)	<u>0.800</u>	2.77	0.03324
Milk&Dairy Products(93)	<u>0.280</u>	28.62	0.12018

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

$$0.2048 = x\%$$

$$X = \frac{204800}{1.0708} = 19.3$$

DRAFT