Rev. 4/14/82 Toxicology Branch/HED Review

RCB DEC 1 1983

~~NOV 30 1983~~

Caswell No(s).: 470 A CFR No 180.399

To: H. Jacoby

Registration No(s).: 359-685

Pesticide Petition No(s).: 3 F 2964

Chemical(s): Rovral Iprodione

Requested Action(s): Application for amended registration and petition for tolerance - Grapes - add grapes to the present label. (Refer to attached Sec F

* For other requested tolerances in milk, meat, eggs, kidney liver & raisins,

Recommendation: This request is acceptable

Inert(s) cleared 180.1001: Yes , previously . Note : This request did not include the statement of ingredients (INERT)

% of ADI occupied: Existing: 7.14 Resulting: 9.22

Resulting % increase in TMRC: From 1.070% to 1.3836 mg/kg/in 1.5 kg = 29.21 %

Data considered in setting the ADI: A three generation reproduction study -rat NOEL= 500 ppm (25 mg/kg ; S. F.= 100 ; A D I = 0.25 mg/kg/day; MP I=15mg/ in a 60 kg pers

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

Existing regulatory actions against registration: None

RPAR status: Is not in the R P A R list

New Data: None

Data gaps: Acute dermal L D 50 , A second teratology study and other required mutagenicity tests as per previously requested

1 year dog chronic, in progress

Comments: Fulfillment of the data gaps has been previously requested, Before granting other tolerances for this chemical the data gaps must be submitted as per previously request of pertaining studies .

* Adding & modifying

Reviewer: [signature] Date: Nov 1983

Section Head: William M Burtle 11/23/83 SIGNATURE [signature] 11/30/83

CFR 180.399 Iprodione /18/83

File last upaated 11/13/83

ACCEPTABLE DAILY INTAKE DATA

RAT,Older NOEL mg/kg	ppm	S.F.	ADI mg/kg/day	MPI 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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Unpublisned,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

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Current Action 3F2964

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Grapes, not raisins(67)	0.000	0.45	0.00000
Raisins(134)	120.000	0.04	0.07358
Milk&Dairy Products(93)	0.280	28.62	0.12018
Eggs(54)	0.800	2.77	0.03324
Meat,inc poultry(89)	0.400	13.85	0.08309
Kidney(203)	3.000	0.03	0.00135
Liver(211)	3.000	0.03	0.00135

MPI	TMRC	% ADI
15.0000 mg/day(60kg)	1.3836 mg/day(1.5kg)	9.22

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DRAFT

$1.0708 \times 100 = 0,3128 - X$

$X = \frac{31.2800}{1.0708}$

$X = 29.21$

29.2

10708 | 312800.
21416
98640
96372
2268.0

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SECTION F

Rhône-Poulenc Inc. proposes permanent tolerances for combined residues of the fungicide Iprodione {3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide}, its isomer {3-(1-methylethyl)-N-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide}, and its metabolite {3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboxamide} in or on the following:

	ppm
Grapes	60
Raisins	300
Raisin Waste	1000
Dried Grape Pomace	225

Rhône-Poulenc Inc. proposes permanent tolerances for combined secondary residues of Iprodione, its des-isopropyl metabolite and its hydroxylated metabolite, 1-(3,5-dichloro-4-hydroxyphenyl)-biuret in or on the raw agricultural commodities as follows:

r.a.c.	ppm
Milk	0.3

Rhône-Poulenc Inc. proposes permanent tolerances for combined secondary residues of Iprodione and its des-isopropyl metabolite in or on raw agricultural commodities, as follows:

r.a.c.	ppm
Kidney and Liver	3.0
Meat, Fat and Meat By-Products of cattle, goats, hogs, horses, poultry and sheep	0.4
Eggs	0.8