

US EPA ARCHIVE DOCUMENT

RCB 9-19-84

Rev. 4/14/82

Toxicology Branch/HED Review

SEP 19 1984

Caswell No(s):: 470A

To: Sacoby/boole

Registration No(s):: _____

Pesticide Petition No(s):: 3F 2964

Chemical(s): Rovral

Requested Action(s): Revised Section F for petition in or Grapes (as per attached section F)

Recommendation: This petition was previously approved, the requested tolerances has been entered in the computer print out

Inert(s) cleared 180.1001: YES

% of ADI occupied: Existing None Resulting: None

Resulting % increase in TMRC: None

Data considered in setting the ADI: NONE

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: Not for this action

Comments: A copy of the previously approved action is attached

Reviewer: [Signature]

Date: Sep 15 84

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Section Head: [Signature] 9/19/84

Branch Chief: [Signature] 9/19/84

SECTION F

IPRODIONE - GRAPES

Tolerance is proposed for combined residues of the fungicide Iprodione [3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboximide], its isomer [3-(1-methylethyl)-N-3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboximide], and its metabolite [3-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboximide] in or on the following raw agricultural commodity:

<u>COMMODITY</u>	<u>TOLERANCES (PPM)</u>
Grapes	60

FAT, MEAT AND MEAT BY-PRODUCTS

Tolerances are proposed for the combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide and its non-hydroxylated metabolites (expressed as Iprodione equivalents) in or on the following raw agricultural commodities:

<u>COMMODITY</u>	<u>TOLERANCES (PPM)</u>
(a) Meat and Meat By-Products (Except Liver and Kidney) of Cattle, Goats, Hogs, Horses, Poultry and Sheep	0.4
(b) Liver and Kidney of Cattle, Goats, Hogs, Horses, Poultry and Sheep (Except Poultry Kidney)	3.0 <i>+</i>
(c) Fat of Cattle, Goat, Hogs, Horses and Sheep	0.4 <i>under Kidney</i>
(d) Poultry Fat	2.0 <i>←</i>
(e) Eggs	0.8 <i>+</i>

MILK

Tolerance is proposed for the combined residues of 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide and its non-hydroxylated and hydroxylated metabolites (expressed as Iprodione equivalents) in or on the following agricultural commodity:

<u>COMMODITY</u>	<u>TOLERANCE (PPM)</u>
(F) Milk	0.3

0.280 + ✓
0.020
0.300
2

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Caswell No(s):

470A

MS. COOL PM 21

Registration No(s): NOT SUBMITTED

Pesticide Petition No(s): 3F 2964

Chemical(s): GLYPHOPHENE

Requested Action(s): TOLERANCE AS PER ATTACHED

"SECTION F" (2 ppm poultry - other previously approved)
Recommendation: This reviewer has no objections to granting this action.

Port(s) cleared 180.1001: Previously

ADFI occupied: Existing: 10,03 Resulting: 10,62

Resulting % increase in MRC: From 1.5040 to 1.5033 = 3.3%

Data considered in setting the ADI: a 3 gene rat study NOEL = 25.0 mg/kg
500 ppm - SF = 100 - ADI = 0.2500 mg/kg/day - MFL = 15.00 mg/kg/day

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

Ongoing regulatory actions against registration: NO

R status: Not in the list

Data: None

Data gaps: Not for this action. Needed data acute dermal, Toxicity 2nd species, additional mutagenicity, a one year dog feeding study is in progress

Comments: Needed data must be submitted ASAP. PM should request data from registrant (3)

[Signature]

MAY 30 1984

File last updated 5/22/84

ACCEPTABLE DAILY INTAKE DATA

RAT, Older	NOEL	S.F.	ADI	MPI
mg/kg	ppm		mg/kg/day	mg/day (60kg)
25,000	500.0	100	0.2500	15.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Miwi Fruit (204)	10.000	0.03	0.00450
Stone Fruits (351)	20.000	1.15	0.07404
Onions (1)	0.500	0.03	0.00002
Garlic (61)	0.100	0.03	0.00005
Lettuce (84)	15.000	1.31	0.29433

MPI 15.0000 mg/day (60kg) TMRC 0.6729 mg/day (1.5kg) % ADI 4.0

Unpublished, 1cx Approved 3G2767, 2801, 2856, 3F2964, 4H5415

CROP	Tolerance	Food Factor	mg/day (1.5kg)
(B) Meat, red (90)	0.100	10.61	0.001622
(F) Milk&Dairy Products (93)	0.020	28.62	0.00058
Grapes, not raisins (67)	60.000	0.45	0.00470
Raisins (134)	180.000	0.04	0.11037
Beans, dry edible (10)	2.000	0.31	0.00930
Beans, lima (11)	2.000	0.19	0.00570
Grapes, not raisins (67)	0.000	0.45	0.00000
(a) Meat, red (90)	0.300	10.61	0.004866
(b) Liver (211)	3.000	0.03	0.00135
Kidney (203)	0.400	0.03	0.00000
(c) Eggs (54)	0.500	2.77	0.03324
(F) Milk&Dairy Products (93)	0.280	28.62	0.12018
Raisins (134)	120.000	0.04	0.07350

MPI 15.0000 mg/day (60kg) TMRC 1.5048 mg/day (1.5kg) % ADI 10.03

Current Action 3F2964 [Rev Sec F]

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Grapes, not raisins (67)	0.000	0.45	0.00000
Raisins (134)	0.000	0.04	0.00000
Meat, red (90)	0.000	10.61	0.00000
(c) Kidney (203)	0.400	0.03	0.00018
(c) Liver (211)	0.000	0.03	0.00000
(c) Poultry (128)	2.000	2.94	0.08830
Eggs (54)	0.500	2.77	0.00000
Milk&Dairy Products (93)	0.000	28.62	0.00000

MPI 15.0000 mg/day (60kg) TMRC 1.5933 mg/day (1.5kg) % ADI 10.62

0.0226 x 100

0.0226

DRAFT 4



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP3F2964-Glyphophene/grapes
Company response and new Section F
Caswell # 470A

FROM: Alex Arce *[Signature]*
Toxicology Branch
Hazard Evaluation Division (TS-769)

TO: Jacoby/Cool : PM 21
Registration Division (TS-767) *[Signature] 5/30/84*

Request: fast track review.

(A) Review registrants response to request of Alex Arce, 3-19-84, further identification of "unknown Z", "residue found in chicken liver.

(b) Request for tolerance as per attached Section F.

Recomendation

(A) The "Unknown Z" residue has been identified as the molecule contain the basic nucleus of a substituted 3, 5 dichloroaniline" the amount found in liver was 2.0/2.5 ppm that is less than the requested tolerance of 3.0 ppm from report Calculation of daily diet intake for a 60 kg person

1.5 kg = Daily diet intake
60 kg = Average person weight
0.16% = Food factor for cattle liver
3.0 ppm = Tolerance proposed
0.26% = Unknown Z% detected

The total daily intake would be 0.000031 mg kg/day
$$\frac{(1.5 \times 0.0016) (3.0 \times 0.26)}{60} = 0.000031$$

b) No objections to this tolerance request

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