

RCB 9-19-84

Rev. 4/14/82

Toxicology Branch/HED Review

SEP 19 1984

Caswell No(s): 470A

To: Jacoby/boole

Registration No(s):

Pesticide Petition No(s): 3F 2964

Chemical(s): Rorral

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 printout

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

Section Head: [Signature] 9/19/84

Branch Chief: [Signature] 9/19/84

Y5

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:

COMMODITY

TOLERANCES (PPM)

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:

COMMODITY

TOLERANCES (PPM)

- (a) Meat and Meat By-Products
(Except Liver and Kidney)
of Cattle, Goats, Hogs,
Horses, Poultry and Sheep
- (b) Liver and Kidney of Cattle,
Goats, Hogs, Horses, Poultry
and Sheep (Except Poultry Kidney)
- (c) Fat of Cattle, Goat, Hogs,
Horses and Sheep
- (d) Poultry Fat
- (e) Eggs

0.4

3.0

0.4

2.0

0.8

under Kidney

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:

COMMODITY

TOLERANCE (PPM)

(F) Milk

0.3

0.280 +

1020

300

2

MAY 30 1984

Caswell No(s):

470A

MS. COOL PM 21

Registration No(s): NOT SUBMITTED

Pesticide Petition No(s): 3F 2964

Chemical(s): GLYPHOSPHENE

Requested Action(s): TOLERANCE AS PER ATTACHED
"SECTION F" (1 ppm poultry - other previously approved)
Recommendation: This reviewer has no objections to
granting this action.

Art(s) cleared 180.1001: Previously

ADI occupied: Existing: 10.03 Resulting: 10.62

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

As considered in setting the ADI: A 3 generation 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

Existing regulatory actions against registration: NO

R status: Not in the list

Data: None

As 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

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)
Avi Fruit (204)	10.00	0.33	0.0450
Stone Fruits (351)	20.000	1.15	0.37404
Onions (1)	0.50	0.03	0.00002
Garlic (61)	0.100	0.03	0.00005
Lettuce (84)	15.00	1.31	0.29433

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

Unpublished, 10x Approved 3G2767, 2801, 2856, 3F2964, 4H5415

CROP	Tolerance	Food Factor	mg/day (1.5kg)
(F) Meat, red (90)	0.100	10.61	0.0022
(F) Milk & Dairy Products (93)	0.020	28.62	0.0058
Grapes, not raisins (67)	60.000	0.45	0.0470
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)	0.000	0.03	0.00000
(c) Eggs (54)	0.800	2.77	0.03324
(F) Milk & Dairy Products (93)	0.280	28.62	0.12018
Raisins (134)	120.000	0.04	0.07350

MPI	THRC	% ADI
15.0000 mg/day (60kg)	1.5048 mg/day (1.5kg)	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
Liver (211)	0.000	0.03	0.00000
(d) Poultry (128)	2.000	2.94	0.08830
Eggs (54)	0.000	2.77	0.00000
Milk & Dairy Products (93)	0.000	28.62	0.00000

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

0.02% x 100

0.02% x 5

DRAFT 4



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP3F2964-Glycophene/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.

Recommendation

(A) The "Unknown^N 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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