

Toxicology Branch/ILHD Review

CARTWELL FILE

OCT 10 1985

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEW
EPA SERIES 361

849 A 060101

To: Henry Jacoby, PM No 21Registration No(s): 618-75 (Mertect 340-F)Pesticide Petition No(s): 5 G 32.58 & 618-EUP-RRChemical(s): Thiabendazole 2-(4-thiazolyl)
benzimidazoleRequested Action(s): Mertect, Sharp and Dohme requests a temporary tolerance
for the use of Thiabendazole fungicide to treat Aspergillus spp. and
Recommendation: Penicillium spp. on stored corn grain at 20 ppm.Toxicology Branch has sufficient toxicity data in support for the safety
to this residue level on corn grain, but defer to RCB regarding secondary
Inert(s) cleared 180.1001: Yes (residues in meat, fat and meat by products
resulting from this use)% of ADI occupied: Existing: 46.92 Resulting: 51.92Resulting % increase in TMRC: 10.7%Data considered in setting the ADI: Please, see attached summary of toxicity
data considered in setting this action. Refer to the enclosed ADI printout.Attached (?): ADI printout: (YES/NO); TOX "one-liner": YES/NO; DER: YES/NOExisting regulatory actions against registration: NoneRPAR status: NoneNew Data: NoneData gaps: Sensitization studyComments: The established 0.4 ppm milk tolerance will
be adequate to cover TBZ residues from proposed
use (RCB, Lung Cheng, 9/10/85).Reviewer: Carlos RodriguezDate: 10/4/85 OCT 10 1985Section Head: Jan C Harris 10/4/85Branch Chief: John W. 10/5/85

Toxicity Data Considered in Setting This Action:

- Acute oral LD50 (male rat) = 3.97 g/kg
(95% Conf. = 2.92 - 2.40 g/kg)
- Acute oral LD50 (female rat) = 3.54 g/kg
(95% Conf. = 2.14 - 5.85 g/kg)
- Acute oral LD50 (mouse) = 3.8 g/kg
- 2-Year rat feeding: Systemic NOEL = 10 mg/kg/day.
Systemic LEL = 40 mg/kg (growth depression)
Oncogenic potential - negative at 160
mg/kg/day (highest dose tested)
Dose levels tested: 10, 40 and 160 mg/kg/day.
- 2-Year dog feeding: Systemic NOEL = 50 mg/kg/day;
Systemic LEL = 125 mg/kg/day (decreased
body weight).
Dose levels tested: 20, 50 and 125 mg/kg/day.
- Lifetime oncogenic (mouse feeding) - Oncogenic NOEL >
5,330 ppm or 800 mg/kg/day (highest
level tested)
Systemic NOEL = 600 ppm or 100 mg/kg/day
Systemic ~~NOEL~~ ^{LEL} = 2000 ppm or 300 mg/kg/day -
lower weight gain. ✓
Dose levels tested 660 ppm (100 mg/kg/day),
2000 ppm (300 mg/kg/day), 5,330 ppm
(800 mg/kg/day).
- Rat Teratology: Teratogenic NOEL > 80 mg/kg/day (given
by gavage, single dose tested)
Maternal NOEL - < 80 mg/kg (only dose tested)
- lower mean implantation sites.
- Rabbit teratology: Teratogenic NOEL > 800 mg/kg/day.
(highest dose tested).
Dose levels tested: 100, 200, 400 and
800 mg/kg/day.
Maternal NOEL: 100 mg/kg
LOEL: 200 mg/kg - weight loss.
- 3-Generation reproduction (rat) - Reproductive NOEL =
20 mg/kg, reproductive LOEL = 40 mg/kg -
decreased viability index of F1a.
Dose levels tested: 20, 40 and 80 mg/kg.
- Mutagenicity Studies:
 1. Microbial (S. typhimurium) negative for induced
revertants.
 2. Microbial (E. coli) negative for induced revertants.
 3. Host-mediated - negative
 4. In vivo Bone marrow - negative for chromosomal
damage.
 5. Primary Bacterial DNA damage/repair - negative.

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6. In vitro cytogenetics - negative - no increase in chromosome breakage in human embryonic fibroblast cultures.

- Metabolism, absorption, distribution and excretion in man, dog, rat, sheep, goat, cattle and swine:

Rapidly metabolized in man. Radioactive agent in animal species in many respects were similar to those found in man. Tissues from laboratory animals were virtually free of radioactivity.

CFR 185.242

imidacloprid

10/1/85

file last updated 2/21/85

ACCEPTABLE DAILY INTAKE DATA

DRAFT

ADI, oral	ADI	ADI
mg/kg	mg/kg/day	mg/day (60kg)
10.000	0.1000	6.0000

Published Tolerances

CROP	tolerance	food factor	mg/day (1.5kg)
Apples(2)	10.000	2.53	0.37950
Citrus Fruits(33)	10.000	3.81	0.57179
Pears(116)	10.000	0.26	0.03832
Bananas(7)	0.400	1.42	0.00852
Squash(191)	1.000	0.11	0.00165
Sugar, cane&beet(154)	0.250	3.64	0.01364
Milk&Dairy Products(93)	0.100	28.62	0.4292
Sweet Potatoes(157)	0.020	0.40	0.00012
Soybeans (oil)(140)	0.100	0.52	0.00156
Cattle(26)	0.100	7.18	0.01078
Goats(62)	0.100	0.63	0.00005
Hogs(39)	0.100	3.43	0.00515
Horses(208)	0.100	0.03	0.00005
Sheep(145)	0.100	0.19	0.00029
Rice(137)	3.000	0.55	0.02483
Carrots(24)	10.000	0.48	0.07205
EGS(34)	0.100	2.77	0.00416
Poultry(126)	0.100	2.74	0.00441
Papayas(109)	5.000	0.03	0.00225
Avocados(6)	10.000	0.03	0.00450
Mangoes(86)	10.000	0.03	0.00450
Potatoes(127)	3.000	0.43	0.24426
Wheat(170)	0.200	10.36	0.03109

ADI	TRFC	ADI
0.0000 mg/day (60kg)	1.0002 mg/day (1.5kg)	24.44

Unpublished, for approval 112542, 112603, 112736, 312812, 312803, 112775

CROP	tolerance	food factor	mg/day (1.5kg)
Grapes, not raisins(67)	10.000	0.45	0.06745
Wheat(170)	0.200	10.36	0.43524
Milk&Dairy Products(93)	0.100	28.62	0.12577
Cantaloupe(23)	12.000	0.02	0.09382
Strawberries(152)	5.000	0.10	0.1500
Potatoes(153)	5.000	2.67	0.02156
Potatoes(127)	7.000	0.43	0.00950
Beans, dry edible(16)	0.100	0.51	0.00547

ADI	TRFC	ADI
0.0000 mg/day (60kg)	2.0151 mg/day (1.5kg)	46.42

Printed on 10/1/85

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CROP tolerance food factor mg/day (1.5kg)
corn, grain(60) 0.0000 0.0000

FE1 1000 1000
0.0000 mg/day(60kg) 0.1101 mg/day(1.5kg) 51.92

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Chemical:	1H-Benzimidazole, 2-(4-thiazolyl)-
PC Code:	060101
HED File Code	13000 Tox Reviews
Memo Date:	10/10/85
File ID:	00000000
Accession Number:	412-03-0116

HED Records Reference Center
06/30/2003

