

US EPA ARCHIVE DOCUMENT

Toxicology Branch/ILDI Review

WATSON FILE

OCT 10 1985

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

849 A 060101

To: Henry Jacoby, PM No 21

Registration No(s):: 618-75 (Mertect 340-F)

Pesticide Petition No(s):: 5 G 32.58 + 618-EUP-RR

Chemical(s): Thiabendazole 2-(4-thiazolid)  
benzimidazole

Requested Action(s): Mertect, Sharp and Dolime requests a temporary tolerance for the use of Thiabendazole fungicide to treat Aspergillus spp. and Penicillium spp. on stored corn grain at 20 ppm.

Recommendation: Toxicology Branch has sufficient toxicity data in support for the safety to this residue level on corn grain, but defer to RCB regarding secondary residues on meat, fat and meat by products resulting from this use.

Inert(s) cleared 180.1001: Yes

% of ADI occupied: Existing: 46.92 Resulting: 51.92

Resulting % 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/NO)

Existing regulatory actions against registration: None

RPAR status: None

New Data: None

Data gaps: Sensitization study.

Comments: The established 0.4 ppm milk tolerance will be adequate to cover TBZ residues from proposed use (RCB, Sung Cheng, 9/10/85).

Reviewer: Carol Rodriguez

Date: 10/4/85 OCT 10 1985

Section Head: Jane C Harris 10/4/85

Branch Chief: [Signature] 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~~ <sup>LEL</sup> = 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 Fla.  
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

10/4/85

File last updated 2/21/85

ACCEPTABLE DAILY INTAKE DATA

**DRAFT**

ADI/ORDER VALUE	S.F.	ADI	ADI
mg/kg		mg/kg/day	mg/day (60kg)
10.000 200.00	100	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	0.03	0.00005
Pigs( 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
Beans( 34)	0.100	2.77	0.00416
Poultry(124)	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	T.R.F.C.	ADI
0.0000 mg/day (60kg)	1.0002 mg/day (1.5kg)	24.44

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Unpublished, for approval 112542, 212003, 22736, 312042, 312003, 112775

CROP	tolerance	food factor	mg/day (1.5kg)
Grapes, not raisins( 67)	10.000	0.45	0.06745
Wheat(170)	2.000	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(133)	0.500	2.67	0.02156
Potatoes(127)	7.000	0.43	0.00950
Beans, dry edible( 10)	0.100	0.01	0.00047

ADI	T.R.F.C.	ADI
0.0000 mg/day (60kg)	2.0101 mg/day (1.5kg)	46.22

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Printed on 10/4/85

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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

