US EPA ARCHIVE DOCUMENT

RCB

447 AB

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

MEMORANDUM

JUL 28 1983

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Mr. Miller, PM#16
Registration Division (TS-767)

THRU: William L. Burnam, Chief
Toxicology Branch/HED (TS-769)

SUBJECT: PP#3F2917 - Petition for tolerance of Oftanol (AMAZE) 1-Methyethyl 2-[[ethoxy[1-methylethyl)amino] phosphinothioyl] oxy] benzoate and its cholinesterase inhibiting metabolites on brussels sprouts, cabbage, cauliflower, and broccoli.

Petitioner: Mobay Chemical Corp.
Kansas City, Missouri

Action Requested:

TOLERANCE PROPOSAL

CROP	INTERVAL BETWEEN LAST APPLICATION AND HARVEST	PROPOSED TOLERANCE (PPM)
Broccoli	30	0.3
Brussels sprouts	45	0.3
Cabbage	30	0.3
Cauliflower	45	0.3

Recommendation:

Toxicology Branch cannot envision any overt hazard associated with the implementation of this action request.

Formulation to be used: Amaze 20% Granular
Amaze 15% Granular
Amaze 6 Emulsifiable

The data requirements for the above formulations have been satisfied (PP#8F2090).

All inerts in the formulations are cleared under Section 180.1001 (RCB review of PP#8F2025).

With the exception of mutagenic potential, this compound has no outstanding data gaps.

Nothing in the chemical file would indicate any pending regulatory actions against the registration of this pesticide.

The NOEL for this compound is 1.0 ppm based on a 2-year rat feeding study. The safety factor, based on cholinesterase inhibition is 10x. The current published and unpublished tolerances have established a TMRC of 0.0447 mg/day (1.5 kg), utilizing 14.89% of the ADI. The establishing of the requested tolerances will result in a TMRC of 0.0489 mg/day (1.5 kg) or an increase of 8.9% and utilize 16.30% of the ADI.

A detailed review of the following studies can be found in PP#8F2090 Charles Frick review 11/15/79.

Toxicology Data Base:

Two-Year Feeding Study (Dog)

NOEL = 2 ppm

Chronic Feeding (108-Weeks) and Oncogenicity Study in Mice

Negative oncogenic response - NOEL = Not Determined

Two-Year Feeding and Oncogenic Study in the Rat

Negative oncogenic response.
NOEL = 1.0 ppm

Three Generation Reproduction Study (Rat)

NOEL = 1.0 ppm

Acute Neurotoxicity Studies (Hen)

No indication of Neurotoxicity.

Teratology Study (Rat)

No effects noted at highest level tested (3 mg/kg/day).

Dominant Lethal Test in the Male Mouse

Negative

Teratology Study (Rabbit)

No Teratogenic effect noted at highest level tested (5 mg/kg/day)

Ames Test

Negative for mutation.

C. Frick 7/22/83 7/26/83

Charles Frick,
Toxicology Branch/HED (TS-769)

TS-769:th:TOX/HED:CFrick:7-18-83:card #5

File last updated 5/3/83

ACCEPTABLE DAILY INTAKE DATA

RAT,Older NOEL mg/kg	NOEL ppm	S.F.	ADI mg/kg/day	MPI mg/day(60kg.)
0.050	1.00	10	0.0050	0.3000

Publisned Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Corn,all types(38)	0.100	2.51	0.00377
Meat,inc poultry(89)	0.100	13.85	0.02077
Milk&Dairy Products(93)	0.020	28.62	0.00858
Eggs(54)	0.020	2.77	0.00083

MPI	TMRC	% ADI
0.3000 mg/day(60kg)	0.0340 mg/day(1.5kg)	11.32

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Unpublisned,Tox Approved 1F2451

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Onion(dry bulb)(106)	1.000	0.72	0.01073

MPI	TMRC	% ADI
0.3000 mg/day(60kg)	0.0447 mg/day(1.5kg)	14.89

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Current Action 3F2917

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Broccoli(19)	0.300	0.10	0.00046
Brussel Sprouts(20)	0.300	0.03	0.00014
Cabbage,sauerkraut(22)	0.300	0.74	0.00331
Cauliflower(27)	0.300	0.07	0.00032

MPI	TMRC	% ADI
0.3000 mg/day(60kg)	0.0489 mg/day(1.5kg)	16.30

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.0489
.0447
.0042

.00047 $\sqrt{.0042}$ = 8.9% increase TMRC

DRAFT