



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

Rec'd Team 16
4/6/81

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

APR 3 1981

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DATE:

SUBJECT: PP#1F2451, 3125-GGE-322, -323, -324 - This petition requests a permanent tolerance for 1-Methylethyl 2- [ethoxy (1-methylethyl) amino] phosphinothioyl] oxy] benzolate (Oftanol) and its cholinesterase inhibiting metabolites be established at 1.0 PPM in or on dry bulb onions. CASWELL#447AB

FROM: Charles Frick, Toxicologist *C. Frick*
Toxicology Branch (TS-769) *4/2/81*

JDC
4/2/81

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

THRU: Chris Chaisson, Acting Chief
Toxicology Branch (TS-769)

Petitioner: Mobay Chemical Corp.

Recommendation:

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

The NEL for this compound is 1.0 PPM based on 2-year rat feeding study cholinesterase inhibition effects. The safety factor utilized is 10x. For complete information regarding the NEL, ADI, MPI and TMRC, see computer printout at end of review.

Formulations: Amaze 20% Granular
Amaze 15% Granular
Amaze 5% 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# 862025)

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

Toxicology Data Base - This compound has no outstanding data gaps.

Two-year Feeding Study (Dog)

NEL=2 PPM

Chronic Feeding (108 weeks) and Oncogenic Study in Mice

Negative oncogenic response NEL = Not Determined

Two-Year Feeding and Oncogenic Study in the Rat

Negative oncogenic response

NEL = 1.0 PPM

Three Generation Reproduction Study (RAT)

NEL=1.0 PPM

Acute Neurotoxicity Studies (Hen)

No indication of Neurotoxicity

Teratology Study (Rat)

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

Dominant Lethal Test in the Male Mouse

Negative

Teratology Study (Rabbit)

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

Ames Test

Negative for mutation

TS-769:CFrick:th:TOX/HED:4-2-81:#1

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NO CFS NUMBER

Oftanol

3/27/31

file last updated 3/27/61

ACCEPTABLE DAILY INTAKE DATA

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

Unpublished, Fox Approved PP# 3F2090

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Corn, all types(38)	0.100	2.51	0.00377
Meat, inc poultry(39)	0.100	13.65	0.02077
Milk&Dairy Products(93)	0.020	28.62	0.00858
Eggs(54)	0.020	2.77	0.0083

RPI	THRC	% ADI
0.3000 mg/day(60kg)	0.0340 mg/day(1.5kg)	11.32

Current Action PP# 1F2451

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Onion(dry bulb)(106)	1.000	0.72	0.1073

RPI	THRC	% ADI
0.3000 mg/day(60kg)	0.0447 mg/day(1.5kg)	14.89

$0.0447 - 0.0340 = 0.0107$
 $\% \text{ increase in THRC} = 31.4706\%$
 $\% \text{ increase in THRC due to this use} = 31.4706\%$
 $\% \text{ increase in ADI} = 4.89\%$

CFR.180.387

File last updated 1/20/84

ACCEPTABLE DAILY INTAKE DATA

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

Published 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	13.35	0.02077
Milk & Dairy Products (93)	0.020	28.02	0.00858
Eggs (54)	0.020	2.77	0.00083

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

Unpublished, Tox Approved 1F2411, 3F2917

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Onion (dry bulb) (106)	1.000	0.72	0.01073
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	THRC	% ADI
0.3000 mg/day (60kg)	0.0489 mg/day (1.5kg)	16.30

Current Action Section 18 [84-OR-02]

CROP	Tolerance	Food Factor	mg/day (1.5kg)
Onion (dry bulb) (106)	0.000	0.72	0.00000

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

DRAFT