

12-7-78

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 7, 1978

SUBJECT: Pesticide Petition 8F2117, EPA Reg. No: 352-372 & 352-371 to establish a tolerance for residues of oxamyl in/on corn grain, fodder and forage of 0.1 p.p.m.

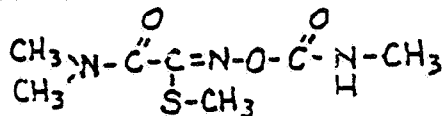
FROM: John E. Preston, Ph.D. Toxicology Branch 001719

TO: Richard Green Product Specialist (#12)

Petitioner: E.I. DuPont de Nemours & Company
Wilmington, DE.

Background data

Chemically, Oxamyl is Methyl N', N'- dimethyl-N-[(methyl carbamoyl) oxy]-l-thiooxamimidate with the structure:



Caswell No. 625A

It is an insecticide, nematocide and acetylcholinesterase inhibitor. Two formulations of oxamyl are available: Vydate G, a granular product with 10% active ingredient (a.i.) and Vydate L, a water soluble liquid containing 24% of the active ingredient, Oxamyl.

Related Petitioner: 6F1696, 6F1695, 3G1349, 3G1316, 7F1907, 7F1909, 7F1937 & 6F1811.

Recommendation

No toxicological data were submitted with this petition. However, data previously submitted in support of petitions #3G1316 & 3G1349 were incorporated by reference.

These data were reviewed and the acceptable daily intake (ADI) and theoretical maximal residue contribution (TMRC) of residues of Oxamyl on corn grain were calculated (attached).

The petition to establish a tolerance for residues of Oxamyl in/on corn grain, fodder & forage of 0.1 p.p.m. is toxicologically supported.

Summary of Toxicity Data

I Acute Studies

Acute Oral LD 50 in rats, CR-CD, male. 5 rats/dose level, 3 dose levels: 50, 30 & 15 mg/kg. Vydate L formulation with 26% a.i. (oxamyl)

Results
 LD 50 = 37 (27-51) mg/kg
 of a.i.
 Core Minimum Data
 Source: 352-GTR (371/372)
 A #'s 8910, 03100

I Acute Studies (cont.)

Acute Dermal LD 50 in rabbit.
6 male rabbits/dose level.
4 dose levels: 1000, 750, 500
& 250 mg/kg. Vydate L formula-
tion with 26% a.i.

Primary Skin Irritation, in
guinea pigs, albino. 10 males/
dose level. 2 dose levels:
0.05 ml of a 50% and a 100%
solution of test solution, namely
Vydate L with 26% of a.i. (Oxamyl)

Primary Skin, Sensitization in
guinea pigs. Dose was: 0.1 ml
of 1% solution of a.i. per sacral
intradermal injection, giving 4
inj. over a 3 wk. period. After
2 week rest, challenge doses of
0.05 ml of 50% and 100% Vydate L
were given topically,
(26% oxamyl)

Primary Eye Irritation in rabbit,
albino. 6 rabbits/dose using 0.1
ml of Vydate L formulation to right
eye. (Vydate L with 26% Oxamyl)

Acute Aerosol Inhalation Study in
rats, Sprague Dawley albino. 5 M
& 5 F per dose level. 4 dose levels
13.7, 9, 5.5 & 2.1 g/l. Test
material identified only as H7648-03
or MR-1617 (probable Vydate L
formulation) One hour exposure at
each dose level.

001719

Results

LD 50 = 740 ± 150 mg/kg of a.i.

Core Minimum Data
Source: 352-371/372
A # 08910, 03100

Not a skin irritant.

Supplementary- dose was too low.

Source: 352-371/2
A #08910, 03100

Results

Not a skin sensitizer

Classification:
Supplementary, dose too low, dose
administ. ered ~~a~~ weekly rather than
tri-weekly intervals.
Source: 352-371/2
A # 08910, 03100

Negative as eye irritant.

Classification: Core Minimum Data
Source: 352-371/2
A #08910,

LD 50 = 4.5 mg/l

Signs/symptoms: excitation, lacri-
mation, rhinitis, tremors, prostration.
Classification: Invalid test; material
not identified, study by I.B.T. Labs.

Source: 352-371/2
A #'s 08910, 03100

2

II Subchronic

Subchronic Feeding study in dogs, 13 weeks. Beagle dogs. No data on no. dogs/dose level. Three dose levels: 150, 100 & 50 p.p.m. Oxamyl, IND 1410.

Subchronic Feeding study in Rats- 90-day. No data on species, or no. of rats/dose level. 3 dose levels: 500, 100 & 50 p.p.m. (note 500 was reduced to 150 p.p.m. after 4 days.) Oxamyl, IND 1410.

III Chronic Studies

Chronic Feeding in Rats- 24 months. CHR-CD albino rats, 36 M & 36 F/dose level. 3 dose levels: 150, 100 & 50 p.p.m. (Administered in corn oil mixed with feed) Test material, a wettable powder with 95% technical Oxamyl, IND-1410.

Reproduction Study in Rats- 1 Generation. CHR-CD albino rats. 16 F (& 3 M) per dose level. 3 dose levels: 150, 100 & 50 p.p.m. Males & Females were taken from same dose group in main (24 month) feeding study after 12 weeks.

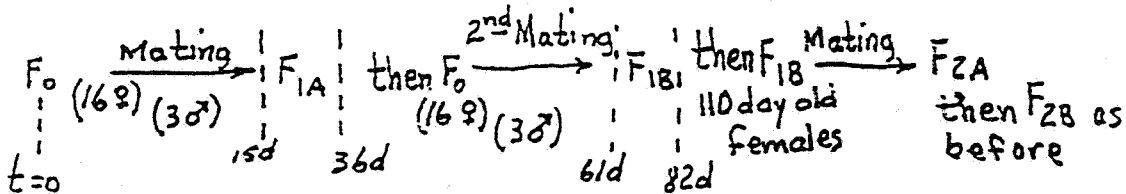
Results

No significant differences, test vs control dogs. A summary report Classification: Invalid, inadequate data to classify study. Source: PP #3G1316 A #092248 Introduction (p.1).

NOEL = 50 p.p.m. At or above 100 p.p.m. there was dec. wgt. gain but no other clinical, gross or histopath. changes. Classification: Invalid- a summary study with insufficient data for evaluation. Source: PP #3G1316 A #092248 (Introduction, P.1)

NOEL = 50 p.p.m. based on wgt. gain, food intake, hematol., urinalysis, ChE activity, gross & histopathology. Classification: Core Minimum Data. Source: PP #3G1316, A #092248, 11/29/72

NOEL = 50 p.p.m. based on all parameters studied, weight gain to fertility index. Classification: Core Minimum Data Source: PP #3G1316 A #092248, 11/29/72.



Oxamyl technical as wet. pc.

3

001719

-4-

Chronic Feeding Study dogs- 2 years.
Beagle, male and female, 1-2 years of
age. 4 M & 4 F/dose level. 3 dose
levels: 150, 100 & 50 p.p.m.
Oxamyl, technical-as a 95% oxamyl
wetttable powder.

NOEL = 100 p.p.m. based on B.wgt.
food intake, hematology, urinalysis,
biochem., mortality or pathology
except some evidence of liver effect
at 150 p.p.m.
Classification: Core Minimum
Source: PP #3G1316
A #092248, 11/29/72.

Teratogenicity Study in Rats. (IL 5-71)

R. Schmidt, D.V.M. in his memo of 11/6/72 to Drew M. Baker, Chief
Petitions Control Branch, Pesticides Tolerances Division, reviewed
a Teratogenic study in rats (5-71) in which he concluded that there
was no effect on embryonal development at the 4 dose levels used:
300, 150, 100 & 50 p.p.m.

Note: All the above studies were carried out by the Haskell Laboratory
for Toxicology and Industrial Medicine (HL) at the E.I. DuPont DeNemours
& Company Newark, Delaware except the Acute Inhalation Toxicity Study which
was done by Industrial Bio Test Laboratories (IBT) and should therefore be
validated.

RD initial R. Gessert
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4