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TXR-393

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

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4/17/81

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg.#707-145; Goal 25W Herbicide; Oxyfluorfen; 707-EUP-OT; PP#1G2492; Oxyfluorfen in or on Onions at 0.05 ppm
CASWELL#188AAA Accession#099985

FROM: William Dykstra, Toxicologist WBD 4/17/81
Toxicology Branch, HED (TS-769)

TO: Richard Mountfort (23)
Registration Division (TS-767)
and
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

Recommendations:

1. The EUP and temporary tolerance of 0.05 ppm in/on onions can be toxicologically supported.

Section F:

Proposed temporary tolerance:

The registrant requests that a temporary tolerance be established for residues of goal herbicide, 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl) benzene and metabolites containing the diphenyl linkage.

onions ..... 0.05 ppm

EUP Program

State	Goal 25-W (lbs a.i.)	Acres
Michigan	31.25	100
New York	31.25	100

1 of 6

000393

Detailed of Goal 25-W/Onion Weed Control Evaluation Program

Total active for program = 62.5 (250 lb prod)

Size of entire program = 200 acres

Size of test sites = 5 acres each

Maximum number per state = 20

Number of states involved = 2

Timing of Application = May/June/July

Type of Application = postemergence to onions and weeds

Dosage rate = A single application of 0.25 lb. active per acre
or up to 3 applications of 1/8 lb active per acre.

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Composition of Goal 25-W

Ingredient	Percent Weight
[redacted]	35.2
a) active ingredient [redacted]	
[redacted]	100.0

Inerts cleared under 180.1001.

Review:

A. Toxicity Studies presented with this petition

1. Acute Oral LD_{50} of Goal 25-W (Rohm and Haas Report#79R-56; 6/21/79)

One group of 10M Charles River CD rats were gavaged with a 20% (w/v) aqueous dispersion of the test substance at 5.0 gm/kg. Observation was for 14 days.

Results: No deaths, LD_{50} > 5.0 gm/kg (males)

Toxic Signs: Brown stained anogenital area in 4/10 male rats

Body Weight: Survivors gained weight

Necropsy: No visible lesions or gross changes observed

Toxicity Category IV: Caution

Classification: Core-Minimum Data

a) Females not tested.

2. Acute Dermal LD_{50} of Goal 25-W (Rohm and Haas Report#79R-56; 6/21/79)

One group of 6 male NZW rabbits (one-half of the rabbits were further abraded) received 5.0 gm/kg of test material on the skin under an impervious cuff for 25 hours. Observations for 14 days.

Results: No deaths, LD_{50} > 5.0 gm/kg (males)

Toxic Signs: Diarrhea, scant tray droppings, brown stained anogenital area

Skin Irritation: Very slight erythema, no edema

Body Weight: Survivors gained weight

Necropsy: 4/6 animals had no visible lesions or gross changes; 1/6 animals had pale kidneys; 1/6 animals had a pale liver; 1/6 animals had very bloated large intestines.

Toxicity Category III: Caution

Classification: Core-Minimum Data

a) Females not tested.

3. Primary Skin Irritation in Rabbits (Rohm and Haas Report#79R-56; 6/21/79)

0.5 gm of test material was applied to intact and abraded skin sites on the fur clipped trunks of 6 NZW rabbits under impervious cuff for 24 hours. Observation and scoring at 24, 72 hr. and 7 days.

Results: No irritation; P.I. = 0

Toxicity Category IV: Caution

Classification: Core-Minimum Data

4. Primary Eye Irritation in Rabbits (Rohm and Haas Report#79R-56; 6/21/79)

0.1 gm of test material was introduced into the conjunctival sac of one eye of each of nine NZW rabbits with the untreated eye serving as control. The treated eyes of three rabbits were washed with water approximately 20-30 seconds after dosing.

Observations at 4, 24 hours, 2, 3, 4 and 7 days.

Results: Washed Eyes: No irritation in 3/3 eyes

Unwashed Eyes: Corneal opacity in 5/6 eyes reversible by 72 hours. Iritis in 5/6 eyes reversible by 72 hours; conjunctivitis in 6/6 eyes reversible by 72 hours.

Toxicity Category III: Warning

Classification: Core-Minimum Data

5. Acute Inhalation Toxicity of Goal WP-25 (TD 79-52) Dust to Rats (Rohm and Haas Report#79R-68; 10/22/79)

One group of 10M + 10F rats were exposed for four hours to a gravimetric concentration of 0.65 mg/L. Observation for 14 days.

Results: No deaths, LC_{50} > .65 mg/L

Toxic Signs: Eye squint, dyspnea, excessive salivation, lacrimation, decreased startle response.

Body Weight: Survivors gained weight

Necropsy: Red spotted or red cervical lymph nodes, scattered brown spots, pinpoint brown foci, diffuse brown areas and scattered red spots on the lungs, spotted thymus, distended bladder, and nephrosis.

Toxicity Category II: Warning

Classification: Core-Minimum Data

B. Previously Submitted Toxicity Data

°Rat Oral LD_{50} > 5.0 gm/kg (tech)
°Rat Cytogenetic: negative
°Ames Assay: positive
°Rat Teratology: negative at 1000 mg/kg; NOEL = 100 mg/kg
°3-Generation Rat Reproduction: NOEL = 10 ppm
°2-Year Rat Feeding: NOEL = 40 ppm
°20-Month Mouse Feeding: NOEL = 2 ppm
°2-Year Dog Feeding: NOEL not established; LEL = 100 ppm

C. Toxicology Studies Requested in Oxyfluorfen Position Document

°Mouse Oncogenicity Study
°Rat Oncogenicity Study
°Rabbit Teratology with postnatal evaluation study
°6-Month (or longer) Dog Feeding Study
°Mutagenicity (multi-test evidence)

D. Oxyfluorfen is an RPAR Chemical

E. Tolerances established under 40 CFR 180.381

F. Calculation of the ADI

The ADI is based on the systemic NOEL of 2 ppm (0.3 mg/kg/day) in the chronic mouse feeding study. This is the most sensitive species for which chronic data are available. A 100 fold safety factor was used to calculate the ADI.

$$\text{ADI} = 0.3 \text{ mg/kg/day} \times \frac{1}{100} = 0.003 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 0.18 mg/day

G. Published tolerances utilize 19.57% of the ADI. Unpublished, TOX approved tolerances utilize the ADI to 22.15%. The current action utilizes 0.34% of the ADI. All tolerances utilize 22.49% of the ADI. (Computer printout attached).

Conclusions and Recommendations:

The EUP program and temporary tolerance can be toxicologically supported.

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5

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[illegible] T[illegible]

[illegible]	[illegible]	[illegible]	[illegible]	TPI
[illegible]	[illegible]	[illegible]	mg/kg/day	mg/day (60kg)
[illegible]	[illegible]	[illegible]	[illegible]	0.1[illegible]

[illegible]

[illegible]	Tolerance	Food Factor	mg/day(1.5kg)
[illegible]([illegible])	[illegible]	[illegible].77	[illegible]
[illegible]dairy [illegible]([illegible])	[illegible]	[illegible]	0.[illegible]2146
[illegible]([illegible])	[illegible]	7.[illegible]	[illegible]
[illegible]([illegible])	[illegible]	[illegible].03	0.[illegible]
Eggs([illegible])	[illegible]	3.43	0.00258
[illegible]([illegible])	[illegible]	0.03	0.00092
Poultry(12)	[illegible]	2.[illegible]4	0.00221
[illegible]([illegible])	[illegible]	0.19	0.00015
Onions(1)	[illegible]	0.03	0.00062
Other fruits(1[illegible])	[illegible]	1.25	0.00094
Grapes, inc raisins([illegible]6)	[illegible]	0.49	0.00037

TPI	TMRC	% ADI
0.1[illegible] mg/day(60kg)	0.0352 mg/day(1.5kg)	19.57

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Unpublished,Tox Approved 8 2028,9H5193,8F2058,9H5230

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Cottonseed (41)	0.2[illegible]	0.15	0.00045
Soybeans(14[illegible])	0.25[illegible]	0.92	0.00344
Corn,grain(68)	0.050	1.00	0.00075

TPI	TMRC	% ADI
0.1800 mg/day(60kg)	0.0399 mg/day(1.5kg)	22.15

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Current Action PP# 1G2492

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Onions(105)	0.[illegible]50	0.03	0.00062

TPI	TMRC	% ADI
0.1800 mg/day(60kg)	0.0405 mg/day(1.5kg)	22.49

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6