

US EPA ARCHIVE DOCUMENT



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

APR 10 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Fenoxycarb - Request for Quarantine Exemption
Under Section 18 for One-Time Use of Logic® (EPA
Registration No. 35977-4) Against Fire Ants - EPA
ID No. 87-AZ-03 - TB Project No. 7-0311

Tox. Chem. No. 652C

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DVO 2 Apr 87

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Marcia van Gemert 4/12/87
W. J. ...

and

Theodore Farber, Ph.D., Chief
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Recommendation:

TB approves the subject section 18 request for the
spring season of 1987: one-time aerial application of Logic®
(1% fenoxycarb) for control of fire ants.

The Arizona Commission of Agriculture and Horticulture
has requested a section 18 Quarantine Exemption for use of
Logic®, a 1% fenoxycarb (ai) formulation [redacted]
[redacted] to control fire ants. The pesticide

INERT INGREDIENT INFORMATION IS NOT INCLUDED

would be applied by a one-time aerial application at a rate of 0.015 lb/ai/A to sites as follows:

Citrus	650 acres
Pasture and rangeland	120 acres
Dairy feed lots	60 acres

RCB has stated (memorandum of February 6, 1987) that available data do not show a difference between plant and animal metabolism. RCB states, furthermore, that maximum residues likely to be found as a result of the proposed use are < 0.05 ppm in citrus (and citrus processed commodities) and < 0.1 ppm in milk.

Fenoxycarb residues are not likely to be found in animal products as a result of the proposed use, according to RCB.

By memorandum of August 20, 1985, TB approved registration of Logic® 1% Fire Ant Bait for use on nonagricultural turf (including residential sites). By memorandums of June 14 and July 22, 1985, TB approved an amendment of EUP 35977-EUP-2 to include treatment of pasture and rangeland with 1% fenoxycarb formulation (50.25 lb; 3350 acres) for a 1-year period. For this latter approval TB required data as follows:

1. All uses: Acute, irritation, and sensitization studies (6 studies total, performed on formulation).
2. Food uses (performed on technical material):
 - a. 90-day oral toxicity, rodent, and nonrodent;
 - b. Teratogenicity; and
 - c. Mutagenicity battery:
 - (1) Gene mutation,
 - (2) Chromosome aberration, and
 - (3) Primary DNA damage.

All of the above studies, or equivalent studies, were accepted by TB as a satisfactory EUP data base for application of fenoxycarb to residential sites and pasture/rangeland. Aerial application was not approved at that time.

Data Results Applicable to the Subject Request:

1. Acute studies show results in Toxicity Categories III and IV (technical and 0.6%/10.3% formulations).

2. Subchronic studies

NOEL

- | | |
|---|---|
| a. 6-Month Oral - dog
(Hoffmann-LaRoche
No. B-104-927; 1983) | 150 mg/kg/day |
| b. 1-Year Interim Report,
rat feeding study
(Hazleton, Europe
No. 4342-161/123;
1985; adequate for
90-day study) | 200 ppm = 10.0
mg/kg/day |
| c. 90-Day Feeding - mouse
(Hoffmann-LaRoche
No. B-104-802; 1983) | 100 mg/kg/day |
| d. 21-Day Dermal - rat
(Hazleton Labs, Ltd.,
No. 4552-161/157; 1985) | 200 mg/kg/day |
|
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| 3. Teratogenicity | |
| a. Rat
(Hoffmann-LaRoche
No. B-104-875; 1983) | 150 mg/kg/day
(embryotoxicity;
not teratogenic) |
| b. Rabbit
(Hoffmann-LaRoche
No. B-104-700; 1984) | Neither terata
nor embryotoxicity
at 300 mg/kg/day
(HDT) |
|
 | |
| 4. Mutagenicity battery:
Negative in all tests
(all 3 mutagenicity
categories) | |
|
 | |
| 5. Cholinesterase (housefly)
Inhibition: No inhibition
by fenoxycarb (a carba-
mate) at highest <u>in vitro</u>
concentration tested
(2.5×10^{-4} M) | |

Residue Contributions:

An estimated TMRC for the requested one-time use would be 0.00033 mg/kg/day for the U.S. population (memorandum, D.S. Saunders, RCB, March 27, 1987). The most exposed subgroup would be nonnursing infants, having an estimated TMRC of 0.00156 mg/kg/day.

PADI Calculation:

Based on a NOEL of 10.0 mg/kg/day (interim report, rat feeding study) the PADI for fenoxycarb is as follows:

$$\text{PADI} = \frac{10.0}{1000} = 0.01 \text{ mg/kg/day}$$

Conclusion:

Thus the estimated TMRC for the general population is 3.3% of the PADI, while for nonnursing infants it is 15.6% of the PADI.

TB approves the subject (section 18) request for the spring season of 1987: one-time use of Logic® by aerial application. For the proposed one-time use, aerial application is permitted, in view of the low acute inhalation toxicity of fenoxycarb: Toxicity Category III for a 0.6% formulation.

The label Precautionary Statements are satisfactory.