Shaughnessy No: 109301

EAB Log-Out Date: MAY 20 1986

Signature: [signature]

To: George LaRocca
Product Manager
Registration Division (TS-767C)

From: Emil Regelman, Chief
Review Section 3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached please find the EAB review of...

Reg./File # : 201-401

Chemical Name: FENVALERATE

Type Product: INSECTICIDE

Product Name: PYDRIN

Company Name: SHELL CHEMICAL COMPANY

Purpose : Permission to shorten 12-month root crop rotation restriction to 120 days prior to completion of confined and field crop studies

ACTION CODE: 331

EAB # (s): 6579

Date Received: 5/12/86

TAIS CODE: 65

Date Completed: 5/20/86

Total Reviewing Time: 2.0 day

Monitoring requested:

Monitoring voluntarily:

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

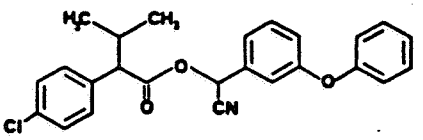
_____ Toxicology Branch

1. CHEMICAL: Common name: Fenvalerate

Chemical name: 4"-Chloro-(2'''-isopropyl)phenylaceto-2-(3'-phenoxy)phenylacetonitrile

Trade name(s): Pydrin, SD 43775 (Shell Chemical Co.); Belmark (Shell International Chemical Co); Sumicidin, Sumitly, Sumipower (Sumitomo Chemical Co.).

Structure:



Formulations: Pydrin (SD 43775) formulations 2.4 lb ai/gal EC and 4 lb ai/gal ULV concentrate (Shell Chemical Co.).

Physical/Chemical properties:

Empirical formula: $C_{25}H_{22}ClNO_3$
Molecular weight: 419.9
Physical state: Clear viscous yellow or brown liquid at 23°C; mild chemical odor.
Density: 1.17 g/ml at 23°C
Vapor pressure: 1.1×10^{-8} at 25°C
Solubility: in water, <1 mg/l at 20°C
in acetone, chloroform, cyclohexane, ethanol, and xylene, >1 g/kg
in hexane, 155 g/kg at 23°C

Stability: Stable to heat and sunlight
Stable to moisture
More stable in acid (pH 4) than alkaline solution

2. TEST MATERIAL: Stored (residue) samples from 1982 California Crop Rotation study.

3. STUDY/ACTION TYPE: Submission of residue data to shorten the 12 month crop rotation restriction to 120 days.

4. STUDY IDENTIFICATION:

(A) Lee, P.W. 1986. Characterization of the Magnitude and Chemical Nature of ^{14}C-Residues in the Root Crop (table beets) from the 30-day ^{14}C-Chlorophenyl SD-43775 Rotational Crop Study (RIR-22-005-86); Accession No. 262599.

Test Material Generated During this Study.

(B) Lee, P.W., S.M. Sterns, and W.R. Powell. 1982. A 30- and 120-day Rotation Crop Study Using ^{14}C-SD 43775 following a Single Soil Treatment at a Dosage Rate of 2 lbs. ai/acre. RIR-22-004-82; Acc. No. 248812.

5. REVIEWED BY:

John H. Jordan, Ph.D.
Microbiologist
EAB/HED/OPP

Signature: John H. Jordan

Date: 5/20/86

6. APPROVED BY:

Emil Regelman,
Supervisory Chemist
Review Section #3,
EAB/HED/OPP

Signature:

Date: MAY 20 1986

7. CONCLUSIONS:

Summary

The registrant is required to (a) further characterize the terminal portion of the beet residue and (b) to complete a ^{14}C study of the alcohol moiety. A field crop rotation study must also be conducted according to 165-2, by analyzing for the degradates found in the confined study; however, if residue(s) of toxicological concern to the Agency are found in the confined study, the registrant may prefer to propose tolerances.

The 0.15 ppm average ^{14}C beet root degradate residues calculated from non-lyophilized (wet weight) samples (Table 2, RIR-22-0050-86) is a significant residue. Higher degradate residue levels may have been present, initially, in the stored samples, because there is no storage stability data for degradates. Storage stability data for the parent compound indicate approximately 90% stability for 2 years; the samples were stored for 4 years.

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Characterization of the terminal residue is incomplete. For example, after acid hydrolysis of the mature root sample, 19.3% of the radioactivity is identified only as water soluble, and 21.6% as unextractable. The water soluble and unextractable components must be subjected to a more intense acid or base hydrolysis, and/or to enzyme hydrolysis, to release more of the radioactive components. Because hydrolysis seems to be an important pathway, it is also necessary to determine the fate of the alcohol moiety. A second study using ^{14}C alcohol-labelled fenvalerate is required.

The registrant has tentatively identified about 40% of the ^{14}C degradate(s) residues, but approximately 80-90% of the radioactivity must be identified/quantified. It may not be possible to identify all of the radioactivity, but all major degradates (10% or above) must be identified. The registrant must demonstrate that no (single) degradate, that comprises a significant portion of the residue, remains unidentified.

Further characterization of the terminal residue, and analyses showing the fate of the ^{14}C labelled alcohol moiety should identify the degradates to be studied in the field.

8. RECOMMENDATION:

Shortening of the crop rotation restriction to 120 days cannot be considered until the requirements in the Summary (Section 7) are completed.

9. BACKGROUND:

A. Introduction

There is a 12-month crop rotation restriction against planting root crops except those on the label; sugar beets and table beets are not on the label. Raw data from a California study, B in Section 4 , showed 2.44 ppm total ^{14}C residue from lyophilized 1982 beet samples. Wet weight calculations using the same beet sample data resulted in 0.30 ppm total ^{14}C residues. Non-lyophilized wet-weight beet root sample residues averaged 0.15 ppm.

EAB action #6283 (3/26/86) required the registrant to conduct confined and field crop rotation studies with sugar and table beets. The registrant responded with residue analyses from 1982 samples generated from a confined ^{14}C study, B, in Section 4; the analytical results are documented in study A, Section 4.

B. Directions for Use

Fenvalerate is a contact insecticide for use on a variety of field, vegetable, and orchard crops, ornamentals, forests, terrestrial noncrop sites, and domestic and commercial indoor and outdoor sites. Application rates range from 0.05 to 0.75 lb ai/A. The maximum application rate is 2-lb. ai/Acre/year. Fenvalerate may be formulated with petroleum distillates. Single active ingredient formulations consist of 2.4 lb ai/gal EC, 8.6% impregnated materials, and 0.01% RTU. Fenvalerate is generally surface applied by ground equipment or aircraft. The 2.4 lb ai/gal EC is a restricted use pesticide and applicators must be certified or under the direct supervision of applicators certified to apply fenvalerate. Fenvalerate is highly toxic to bees.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

See Conclusions, Section 7.

11. COMPLETION OF ONE-LINER

One liner has not been initiated to date.

12. CBI APPENDIX:

No CBI included except study (A), referenced in Section 4.