Shaughnessy No.: 109301

Date Out of EAB: AUG 26 1986

Signature:

To: George LaRocca
Product Manager #15
Registration Division (TS-767)

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

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 : Remove 12-month beet-crop rotation restriction ; Characterize/Identify terminal crop rotation residues and complete field crop rotation study

Action Code(s): 301

EAB #(s) : 6774

Date Received: 8/15/86

TAIS Code: 65

Date Completed: 8/25/86

Total Reviewing Time: 2.0 days

Deferrals to:

____ Ecological Effects Branch

____ Residue Chemistry Branch

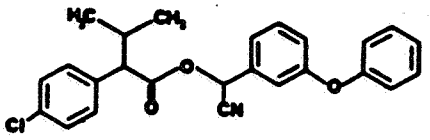
____ Toxicology Branch

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:

Emperical 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} mmHg at 25°C
Solubility: in water, <1 mg/l at 20°C
in acetone, chloroform, cyclohexane, ethanol, and xylene, >1 kg/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: Terminal residues in samples frozen in 1982

3. STUDY/ACTION TYPE: Submission to satisfy data requirement--identification of terminal residues

4. STUDY IDENTIFICATION:

(A) Nobuyoshi M. et al.,1985. The Metabolism of Fenvalerate in Plants: The Conjugation of the Acid Moiety. Pestic. Sci. 1985. 16: 46-58.

(B) Nobuyoshi M. et al.,1984. New conjugated Metabolites of 3-Phenoxybenzoic Acid in Plants. Pestic. Sci. 1984. 15: 531-542.

(C) Fan,H.Y.1977.Residue studies in rotation crops in ^{14}C-SD 43775-treated soils. Acc. No. 096386 ; TIR-22-113-77.[Previously Submitted]

(D) Fan H.Y. et al., 1980. A 30, 60, and 120-day rotation crop study using carbon-14 labeled chlorophenyl and phenoxyphenyl-SD 43775. Shell Chemical Co., Acc. No. 242588; TIR-22-004-80.[Previously Submitted]

(E) 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/Ac. RIR-22-004-82; Acc. No. 248812. [Previously Submitted]

(F) Skelsey, J.J. 1983. Residue data for SD 43775 in table beets grown in soil which had previously received ten applications of SD 43775. a California study. Acc. No. 261050; RIR-24-142-83.[Previously Submitted]

(G) 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. Acc. No. 262599; RIR-22-005-86.[Previously Submitted]

5. REVIEWED BY:

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

Signature: John H. Jordan
Date: August 25, 1986

6. APPROVED BY:

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

Signature: Paul J. Mastrobone for
Date: August 26, 1986

7. CONCLUSIONS:

Summary

EAB action # 6579 (5/20/86) required specific terminal beet residue identification and field crop rotation residue uptake data. However, the registrant's submittal contains no new data addressing terminal residue identification or field crop rotation residue uptake.

1. The 40% (0.06 ppm) residue characterized as water soluble and bound must be identified. Suggested techniques are acid/base/enzymatic hydrolysis.
2. The remaining 60% (0.09 ppm) residue must be characterized and identified as completely as possible.
3. If <80% (0.12 ppm) of the total radioactivity is identified, the registrant must show that the activity of any single unidentified component is <10%.
4. A field crop rotation study with beets in California is required in conjunction with the confined study.

Characterization of the terminal residue is not as complete as the Agency requires; for example, in the mature root, 19.3%(0.029 ppm)of the activity is water soluble, after acid hydrolysis, and 21.6%(0.032 ppm)is unextractable. About 40%(0.06 ppm)of the ^{14}C terminal residue has been characterized. Subjecting of the water soluble and unextractable portions to enzymatic hydrolysis or more severe acid/base hydrolysis may result in release of more radioactivity. Normally 80% - 90%(0.12 - 0.135 ppm)of the radioactivity must be identified. This may be impossible,however, it should be possible to demonstrate that the residue is a mixture of components, none of which comprises a significant (>10%) portion of the residue. Conjugates must also be identified.

The two studies submitted, A,B (Section 4) show metabolites in excised leaves of plants other than beets. Unfortunately, major metabolites vary with the plant variety and, therefore, only beet (plant) data will be of value in the characterization of the major beet metabolite residues. In addition to the rotation crop residue issue, the metabolite storage stability is also unknown. Parent storage stability data show 90% stability for 2 years.

In study G only the chlorophenyl moiety was labeled; however, data in previous studies C,D,E,F,(Section 4)indicate that the alcohol moiety did not result in detectable residues.

The ppm parent equivalent regulation, quoted by the registrant in their July 25, 1986 submission(from EPA RCB guidelines, page 9), is an RCB tolerance guideline -- not an EAB crop rotation uptake regulation. EAB requires characterization of residue fractions less than 0.1 ppm. It may be more convenient for the registrant to obtain a tolerance than to produce data to remove the 12-month crop rotation restriction. If further data confirm the suspicion that detectable fenvalerate metabolites are present in beet roots, tolerances for inadvertent residues will be required.

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8. RECOMMENDATIONS:

In action # 6579, EAB recommended further identification of the terminal beet residue and completion of a field crop rotation uptake study. Alternatively the registrant may prefer to apply for a tolerance.

9. BACKGROUND:

A. Introduction

EAB action #6579 (5/20/86) required the registrant to further characterize the terminal residue, to perform studies on the alcohol moiety, and to conduct a field crop rotation study. However, data were presented from studies C,D,E,F (Section 4) which show no detectible residues from the alcohol moiety. Therefore, only terminal residue characterization and field crop rotation remain to be satisfied.

B. Directions for Use

Fenvalerate is a contact insecticide for use on a variety of field, vegetable, and orchard crops, ornamentals, forests, terrestrial non-crop 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/Ac/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 and Recommendations, Sections 7 and 8

11. COMPLETION OF ONE-LINER:

One-liner has not been completed to date

12. CBI APPENDIX:

No CBI included except the hard copy in the original package

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