

Shaughnessy Number: 109301

Date out of EFGWB: APR 11 1990

To: George LaRocca/Adam Hayward
Product Manager 15
Registration Division (H7505C)

From: Emil Regelman, Supervisory Chemist
Environmental Fate Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Thru: Hank Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, please find the EFGWB review of...

Reg./File #: 352-485, 352-515

Chemical Name: Fenvalerate

Type Product: insecticide

Product Name: Asana XL 0.66% EC

Company Name: E.I DuPont de Nemours

Purpose: label and tolerance petition amendment

Date Received: 1/05/90

Action Code: 331

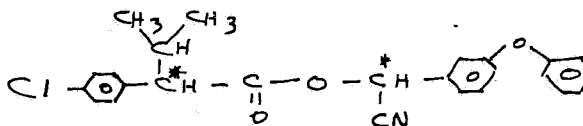
EFGWB#(s): 90-0270, 90-0269

Total Reviewing Time (decimal days): 1.0

Deferrals to: Ecological Effects Branch, EFED
Science Integration and Policy Staff, EFED
Non-Dietary Exposure Branch, HED
Dietary Exposure Branch, HED
Toxicology Branch

1. CHEMICAL:

chemical name: (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro- α -(1-methylethyl)benzeneacetate
common name: fenvalerate
trade name: pydrin
structure:



CAS #: 51630-38-1
Shaughnessy #: 109301

2. TEST MATERIAL: n.a.

3. STUDY/ACTION TYPE:

label amendment and tolerance petition amendment -- use of active isomer instead of racemic mixture, reduction of application rate, reduction of proposed tolerance on celery (90-0270) and brussels sprouts (90-0271).

4. STUDY IDENTIFICATION: n.a.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E.B. Conerly 4/6/90

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 2
Organization: EFGWB/EFED/OPP

E. Regelman
APR 11 1990

7. CONCLUSIONS:

- 1) There are no environmental fate data in the submission.
- 2) There is no basis in available data for EFGWB to object to these requests.

8. RECOMMENDATIONS:

- 1) Subject to concerns identified by Tox and/or Dietary Exposure Branch, EFGWB has no objections to granting of this amendment.
- 2) The applicant should, with all due speed, submit acceptable hydrolysis and fish bioaccumulation studies.
- 3) The applicant should submit a report of the field dissipation study which a previous review (JMJ 2/4/86) indicated would be performed, since EFGWB does not have this information on file. Its acceptance is not guaranteed.
- 4) With those exceptions, no further data are required by EFGWB at this time.

9. BACKGROUND:

The old product was to be applied to brussels sprouts as follows:

total = a maximum of 1.6 lb/A/yr S,S-isomer equivalent = 0.4 lb

The pure active isomer is to be applied as follows:

total = a maximum of 0.4 lb/A/yr S,S-isomer equivalent = 0.4 lb

[The applicant says that this is approximately three fold reduction in total amount of fenvalerate applied. This reviewer would call it fourfold.] The total amount of material applied is clearly decreased by several fold, and the amount of active ingredient remains the same. Therefore, the environmental effects must be the same or less. Incidentally, the new product is slightly more concentrated (at 0.66 lb/gallon of the S,S-isomer) than the old product, which contained 2.4 lb/gallon of fenvalerate including 0.6 lb/gallon S,S-isomer.

The old product was to be applied to carrots as follows:

total = a maximum of 2.0 lb/A/yr S,S-isomer equivalent = 0.5 lb

The pure active isomer is to be applied as follows:

total = a maximum of 0.5 lb/A/yr S,S-isomer equivalent = 0.5 lb

The total amount of material applied is clearly decreased by several fold, and the amount of active ingredient remains the same. Therefore, the environmental effects must be the same or less.

Data requirements for the racemic mixture have been fulfilled except for the following:

HYDROLYSIS -- An acceptable hydrolysis study is required. Apparently in error, the hydrolysis data requirement was previously declared fulfilled, and the EFGWB one-liner states that fenvalerate is stable to hydrolysis. Examination of file material shows:

- 1) There is no review of an acceptable hydrolysis study in EFGWB files.
- 2) Based on results of two unacceptable hydrolysis studies and the dark control of an acceptable aqueous photolysis study, fenvalerate is subject to hydrolysis, not stable.
- 3) The error seems to have occurred when EFGWB summarized the reviews referenced below.

FISH BIOACCUMULATION -- an acceptable study on fish bioaccumulation is also required.

The applicant wishes to use data developed in studies on the racemic mixture (25% each of four isomers) to support registration of the S,S-isomer, now isolated in a relatively pure form. *Per the product manager, DuPont will discontinue marketing the racemic mixture.* Based on the aerobic soil metabolism study described below, the S,S-isomer does not persist any longer when isolated than when it is present as a part of a racemic mixture. The status of data requirements, taken from Dynamac reviews of 3/18/86 and 3/9/88, is given below. Studies were apparently performed using the racemic mixture unless otherwise stated.

hydrolysis -- NOT SATISFIED, although previous EFGWB summaries stated otherwise -- two reviewed studies were not acceptable. The review of one study says that fenvalerate is stable up to 93.5 hours, and then states that the study is not acceptable because it was discontinued too soon. EFGWB did not incorporate the second statement in its summary. A second study at elevated temperature was not acceptable for several reasons -- organic solvent in the mixture, incorrect pH.

photolysis in water -- satisfied -- half-life of 6 days at pH 5 vs a dark control with (hydrolytic) half-life of 13.8 days

soil photodegradation -- satisfied -- half-life of phenoxyphenyl labelled compound was 14-28 days on sandy loam soil; more than 50% of

chlorophenyl material was undegraded after 28 days -- under natural light, 53% was undegraded, and under artificial light, 60% was undegraded.

aerobic soil metabolism -- satisfied -- THE S,S-ISOMER WAS TESTED -- half-lives of 65 days to more than 1 year in a variety of soils -- A study was submitted and accepted (JMJ 2/4/86) which demonstrates that in a silt loam soil the isolated S,S-isomer degrades with a half-life of 75 days. When followed as part of the racemic mixture, this same isomer has a half-life of 95 days under otherwise similar conditions. The same review mentions a field dissipation study to be performed using the single isomer.

anaerobic soil metabolism -- satisfied -- rates similar to aerobic metabolism

leaching/adsorption/desorption -- satisfied for aged and unaged *via column leaching studies* -- immobile in sand, sandy loam, loam, and silt loam; 88% was found in the top 3 cm after leaching with 20 cm of water

terrestrial field dissipation -- declared satisfied based on 1979 studies; there is no review on file of a field dissipation study which was supposed to have begun in 1986 to test the S,S-isomer -- in the 1979 studies, half-lives of 25 days in sandy loam (AZ), 34 days in clay loam (OK), 54 days in silt loam (LA), and 54 days in sandy loam (AL)

confined accumulation in rotational crops -- satisfied, residue detected at levels up to 0.061 ppm

field accumulation in rotational crops -- no residues detected (lod 0.01 ppm)

fish bioaccumulation -- NOT SATISFIED -- maximum BCF in edible tissue of rainbow trout ca 400x when exposed in a static system

Fenvalerate is susceptible to degradation via a number of pathways (see summary below). Fenvalerate and its degradation products did not show mobility when tested with a variety of soils. The combination of lability and lack of mobility indicate that fenvalerate is not likely to contaminate ground-water.

hydrolysis ("semi-valid" data) --	t 1/2	13.8 days pH 5
aqueous photolysis --	t 1/2	6 days pH 5
soil photolysis --	t 1/2	14 - 28 days in sandy loam
aerobic soil metabolism --	t 1/2	65 - 365 days
anaerobic soil metabolism --	t 1/2	similar to aerobic
terrestrial field dissipation --	t 1/2	25 - 54 days

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: n.a.

11. COMPLETION OF ONE-LINER: no information added

12. CBI APPENDIX: n.a.