Shaughnessy Number: 109301

Date out of EFGWB: ~~JUL 27 1992~~

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

From: Akiva Abramovitch, Section Head
Environmental Fate Review Section #3
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 #: 352-515

Chemical Name: Fenvalerate

Type Product: insecticide

Product Name: Asana XL 0.66% EC

Company Name: E.I Du Pont de Nemours

Purpose: submission of additional information on soil photolysis and field dissipation, submission of fish bioaccumulation study

Date Received: 09/10/91

92-0421

Action Code: _____ EFGWB #(s): 91-0938, -0939, ~~92-0421~~ Total Review Time: _____ days

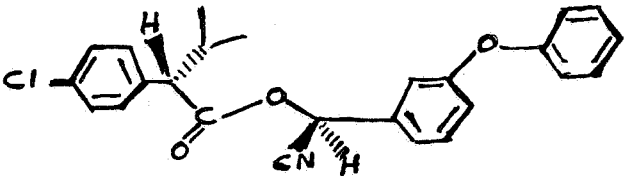
EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

161-1			162-4			164-4			166-1		
161-2			163-1			164-5			166-2		
161-3	417285-01	Y	163-2			165-1			166-3		
161-4			163-3			165-2			167-1		
162-1			164-1	417285-02	Y	165-3			167-2		
162-2			164-2			165-4	421705-01	S	201-1		
162-3			164-3			165-5			202-1		

Y = Acceptable (Study satisfied the Guideline)/Concur
P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
S = Supplemental (Study provided useful information, but Guideline was not satisfied)
N = Unacceptable (Study was rejected)/Non-Concur

1. CHEMICAL:

chemical name: (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-α(1-methylethyl)benzeneacetate
common name: Esfenvalerate
trade name: Asana®
structure:
CAS #: 51630-38-1
Shaughnessy #: 109301



2. TEST MATERIAL: n.a.

3. STUDY/ACTION TYPE: submission of fish bioaccumulation data; submission of additional information on soil photolysis and field soil dissipation

4. STUDY IDENTIFICATION:

supplemental data to Castle, S., Shepler,K., and Ruzo, L.O. Photodegradation of [^{14}] Esfenvalerate in/on Soil Surface by Natural Sunlight. performed by Pharmacology and Toxicology Research Laboratory, Richmond, CA. project ID AMR 1798-90. sponsored and submitted by E.I. Du Pont de Nemours & Co., Inc. completed 10/26/90. received 12/21/90 under MRID# 417285-01.

supplemental data to Castle, S., Shepler,K., and Ruzo, L.O. Field Soil Dissipation Studies of Esfenvalerate - a 1990 Study. dated 11/10/89. performed by Bioanalytika Laboratories, Raleigh, NC, and E.I. Du Pont de Nemours & Co. Inc., Wilmington, DE. project ID AMR-1711-90. sponsored and submitted by E.I. Du Pont de Nemours & Co., Inc. received by EPA 12/21/90 under MRID# 417285-02.

Ohsima, M. and Mikami, N. Accumulation and Metabolism of ^{14}C-Esfenvalerate in Carp (*Cyprinus carpio*). performed by Environmental Health Science Laboratory, Sumitomo Chemical Co., Hyogo, Japan. submitted by E.I. Du Pont de Nemours & Co., Inc., Wilmington, DE. received EPA 1/176/92 under MRID# 421705-01.

5. REVIEWED BY:

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

E.B. Conerly-Perks
5/6/92

6. APPROVED BY:

Typed Name: Akiva Abramovitch
Title: Section Head, Review Section 3
Organization: EFGWB/EFED/OPP

Akiva Abramovitch
JUL 23 1992

7. CONCLUSIONS:

We have noticed a contradiction between the accepted hydrolysis study and the dark control in the accepted aqueous photolysis study. The hydrolysis study indicates stability, whereas the dark control in the aqueous photolysis study yields a half-life of 13.8 days. These two sets of samples should give the same basic results, indicating either stability or a similar half-life. A reexamination of the reviews for these studies does not reveal any obvious cause for the inconsistency.

soil photolysis

The data requirement is satisfied. The additional discussion which had been requested and is included in this submission was informational only. No more data are needed.

terrestrial field dissipation

With the additional information supplied in this submission, the data requirement is satisfied. No more data are needed.

fish bioaccumulation

The study does not fulfill the requirement for fish bioaccumulation data at this time. It deviates from more typical fish bioaccumulation studies in several major ways: the test species, the method of confirmation of residue identities, and the [unavoidable] transformation which the test compound undergoes in solution.

It may become acceptable if the following conditions are met:

a) if it can be demonstrated that the TLC method used for confirmation is adequate in this case.

b) if satisfactory comparison can be made between carp and bluegill.

It does provide the supplemental information that Esfenvalerate bioaccumulates significantly in carp, and will depurate readily once exposure is halted. EFGWB notes that depuration is only 70 - 80% complete at the end of 14 days.

8. RECOMMENDATIONS:

1) The applicant should provide, if possible, an explanation for the inconsistent results between the hydrolysis and aqueous photolysis studies.

2) The applicant must provide a comparison between bioaccumulation studies done on the two species of fish, carp vs. bluegill. At minimum, this must demonstrate that bioaccumulation and depuration patterns in the two fish are highly similar. Also, the adequacy of the TLC method must be demonstrated.

9. BACKGROUND:

The status of environmental fate data requirements to support registration of the S,S-isomer for use on terrestrial food crops is given below (taken from Dynamac reviews of 3/18/86 and 3/9/88 except as noted).

CHEMICAL PROCESSES -- can be satisfied by data on the racemic mixture

hydrolysis -- satisfied -- MRID# 409993-03 reviewed for the Phase IV project (EBC, 3/20/91) indicates stability at pH 5, 7,and 9

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

leaching/adsorption/desorption -- satisfied by data on the racemic mixture -- 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

PROCESSES WITH A BIOLOGICAL COMPONENT -- must be tested with the S,S-isomer

soil photodegradation -- satisfied for the S,S-isomer -- the study indicates stability to photodegradation on soil. In an unacceptable study previously reviewed, the half-life of [racemic] phenoxyphenyl labelled compound was 14-28 days on sandy loam soil.

aerobic soil metabolism -- satisfied for the racemic mixture and the S,S-isomer -- in a silt loam soil the isolated S,S-isomer degrades with a $t_{\frac{1}{2}}$ of 75 days. When followed as part of the racemic mixture this same isomer has a $t_{\frac{1}{2}}$ of 95 days under otherwise similar conditions.

anaerobic soil metabolism -- RESERVED for the S,S-isomer -- for the racemic mixture, the $t_{\frac{1}{2}}$ was similar to that during aerobic metabolism. The available data from the two aerobic metabolism studies and the anaerobic metabolism study are consistent in suggesting that metabolism will not be a major mode of degradation. Although this study would normally be required for the S,S-isomer, EFGWB will reserve the requirement at this time.

terrestrial field dissipation -- satisfied for the S,S-isomer -- discussed below. A first $t_{\frac{1}{2}}$ of 14 days is indicated -- $t_{\frac{1}{2}}$ of the racemic mixture 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 -- NOT SATISFIED for the S,S-isomer -- residue from the racemic mixture detected at levels to 0.061 ppm.

field accumulation in rotational crops -- NOT SATISFIED for the S,S-isomer -- no residues from the racemic mixture (lod 0.01 ppm)

fish bioaccumulation -- NOT SATISFIED for either the racemic mixture or the S,S-isomer, but may be upgraded by additional information. The additional information must provide a comparison between carp and blugill patterns of accumulation and depuration.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: see also DER

photodegradation on soil -- In the current submission, the applicant has clarified the dosage rate, which was 35.5 ppm. The original comment was merely a request for clarification and did not identify a deficiency.

field soil dissipation -- In the current submission, the applicant has clarified certain discrepancies in the data. The major deficiency was an omission of the final data point without an explanation. The explanation was provided. The study may now be considered fully acceptable, and fulfills the data requirement.

11. COMPLETION OF ONE-LINER: information added

12. CBI APPENDIX: attached, also informational material

FENVALERATE Sh # 109301

Page_____ is not included in this copy.

Pages 6 through 23 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

X FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.