Shaughnessy Number: 109301

Date out of EFGWB: MAR 7 1991

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 soil photodegradation, field soil dissipation data

Date Received: 01/03/91

EFGWB#(s): 91-0308

Total Reviewing Time (decimal days): 3.0 Days

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:

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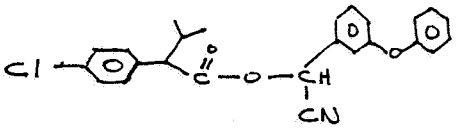
|---|---|
| chemical name: | (S)-cyano(3-phenoxyphenyl)methyl-(S)-4-chloro-α(1-methylethyl)benzeneacetate |
| common name: | Esfenvalerate |
| trade name: | Asana® |
| structure: |  |
| CAS #: | 51630-38-1 |
| Shaughnessy #: | 109301 |

2. TEST MATERIAL: n.a.

3. STUDY/ACTION TYPE:

submission of soil photodegradation and field dissipation data

4. STUDY IDENTIFICATION:

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.

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.

5. REVIEWED BY:

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

E. B. Conerly 3/6/91

6. APPROVED BY:

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

Akiva Abramovitch MAR 6 1991

7. CONCLUSIONS:

The soil photolysis study is acceptable to fulfill the data requirement on Esfenvalerate. During 30 calender days exposure to natural sunlight, the amount of Esfenvalerate which degraded was insignificant. In both light-exposed and dark control samples, more than 90% of parent Esfenvalerate was recovered unchanged at the end of the exposure period. Because values for light-exposed and dark control samples were very similar, that degradation which did occur was mostly attributable to metabolism. EFGWB notes that this result contrasts with that from the soil photolysis study on the racemic mixture.

The soil dissipation study is not acceptable to fulfill the data requirement at this time, but may become acceptable upon the receipt of valid additional information. It does provide the supplemental information that Esfenvalerate has a relatively short half-life (*applicant says 14 days; reviewer says 30 days*) and does not appear to leach into lower depths of soil. The information required includes the following:

1) The nominal applied concentration is 0.25 ppm, yet the time-zero sample contains only 0.15 ppm. This only accounts for ca. 60% of the nominal amount applied -- where is the rest? Also, at day 0, 0.02 ppm was found in the 15 - 30 inch depth, where none was found the previous day. Does the applicant have an explanation for this finding?

2) The 14-day half-life reported by the applicant was apparently calculated ignoring the day-60 data. However, the report contains no explanation or comment as to why that sample was omitted. For instance, was it known to be contaminated? The applicant must clarify. Using linear regression techniques on all data points, a $t_{\frac{1}{2}}$ of ca. 30 days results.

8. RECOMMENDATIONS:

The applicant should be notified that the soil photolysis data requirement is fulfilled for Esfenvalerate. Although the study is acceptable, the applicant must clarify the actual dosage used, since a discrepancy exists. Details are in DER 1.

The applicant should submit the additional information (noted above) which could make the terrestrial field dissipation study acceptable. Further details are given in DER 2.

The applicant should note the other data requirements outstanding on this chemical, which include anaerobic soil metabolism; accumulation in confined rotational crops; and laboratory bioaccumulation in fish. Note that results of the confined rotational crop study may indicate the need for tolerance setting (done through Dietary Exposure Branch) or for field rotational crop studies.

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 the 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 -- a new study, discussed in this review, 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 -- **NOT SATISFIED** for the S,S-isomer -- for the racemic mixture, the $t_{\frac{1}{2}}$ was similar to that during aerobic metabolism

terrestrial field dissipation -- **NOT SATISFIED** for the S,S-isomer -- a new study is discussed below which is considered supplemental at this time. A $t_{\frac{1}{2}}$ of 14 - 30 days is indicated -- $t_{\frac{1}{2}}$ of the racemic mixture 25 days in sandy loam (AZ), 34 days in clay loam (OK), 54 day 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

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: see DERs

11. COMPLETION OF ONE-LINER: information added

12. CBI APPENDIX: attached to DERs

DATA EVALUATION REVIEW 1

I. Study Type: soil photodegradation, data requirement 161-3

II. Citation:

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.

III. Reviewer:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 3
Organization: EFGWB/EFED/OPP

E.B. Conerly 3/6/91

IV. Conclusion:

This study is acceptable to fulfill the requirement for soil photolysis data on Esfenvalerate. Over a period of 30 calender days exposure to natural sunlight, an insignificant amount of Esfenvalerate has degraded, and much of that degradation appears due to metabolism. Ca. 6 % of the applied was identified in the form of two different degradates. EFGWB notes that this result contrasts with that from the soil photolysis study on the racemic mixture.

V. Materials and Methods:

test compound -- [$^{14}$C]-chlorophenyl-Esfenvalerate, radiopurity >99%, spec. act. 2780 µCi/mmol, 66.3 µCi/mg; isomeric purity > 98% as determined by chiral phase HPLC.

stock solution -- 1.07 mg [$^{14}$C]Esfenvalerate ($1.572 \times 10^8$ dpm) and 2.6 mg of unlabelled Esfenvalerate in 6.7 ml acetonitrile

soil -- Hanford sandy loam, stored at field moisture in the dark until use, passed through a 2-mm sieve to remove debris prior to use. Slurries of soil (3.1 gm soil and 3 ml distilled water) were formed *in situ* in the bottoms of Petri dishes and allowed to air dry. Aliquots (372 µl) of distilled water were added to each soil plate just prior to chemical application to achieve 75% of field capacity.

test application -- 200 µl stock solution was added to each dish as evenly as possible in a circular pattern. This was equivalent to 0.5 lb/A or 35.5[2] µg/gm, ca. 10 x the maximum single application rate on the label.

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[2] This reviewer's calculations indicate the following:

stock solution -- 2.67 mg/6.7 ml = 0.3985 mg/ml
200 µl added to soil -- (0.3985 mg/ml) x (0.2 ml)
= 0.0797 mg
0.0797 mg added to 3.1 gm soil -- (0.0797 mg/3.1 gm)
= 0.0257 mg/g
= 25.7 µg/gm

exposure protocol -- The dishes were subjected to natural sunlight photolysis on the Hanford sandy loam soil surface at an application rate of 0.5 lb/A) equivalent to approximately 10 x maximum single application label use rate. Dark control samples were also examined. Ethylene glycol and 10% NaOH were used in separate traps to capture volatile organics and $CO_2$ respectively. Sunlight intensities and soil temperatures within soil chambers were monitored continuously throughout the 30-day period. The exposure phase of this study was conducted on the roof of PTRL's facility, Richmond Ca from August 28 to September 27, 1990. The average temperature during the course of the study was 24.2 $^0$C, maintained by a circulating temperature controlled jacket.

sampling protocol -- samples were taken at 0, 2, 4, 7, 14, 21, and 30 days.

sample treatment -- soil samples were extracted with methanol and analyzed by LSC and HPLC. Some samples were also analyzed by 2-dimensional TLC. Trapping solution was analyzed for total radioactivity by LSC.

analyses

HPLC -- in a water/acetonitrile system (conditions attached) -- recoveries of radioactivity averaged 93.8 $\pm$ 4% -- detection by LSC

TLC -- detection by radiographic scanner

system 1: carbon tetrachloride/ether (3:1) -- $r_f$ for Esfenvalerate = 0.69

system 2: toluene/ether (3:1) -- $r_f$ for Esfenvalerate = 0.85

LSC

VI. Study Author's Results and/or Conclusions:

Under test conditions, there was no significant photolytic degradation of Esfenvalerate. Approximately 90% of the initially applied [$^{14}$C]-Esfenvalerate was recovered [unchanged] from both the light exposed and dark control samples, at the termination of the 30-day exposure period. Meaningful degradation rate or half-life data could not be estimated. $^{14}CO_2$ or radioactive volatile components were not observed. Significant degradation products accounting for greater than 3% of the applied radioactivity were not detected in this study. Material balance was greater than 94%.

VII. Reviewer's Comments:

1) The applicant is correct that these data do not lend themselves to calculation of a half-life. Linear regression of the data (concentration of Esfenvalerate against time) yields correlation coefficients less than 0.5 and slopes less than 1% for both dark and irradiated samples, indicating that no time trend can be established.

2) The applicant is correct that little change takes place in Esfenvalerate concentration over the 30 days of the study. Esfenvalerate is not highly photodegradable on soil.

3) This reviewer's calculations (see preceding page) indicate that the application rate <u>using the applicant's own figures</u> was ca. 26 ppm. This value is also in good agreement with the stated 0.5 lb/A to which it is compared. Nevertheless, the analytical results indicate that 35.5 ppm may have been applied. The applicant must clarify.

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4) The dark controls could be viewed as a metabolism study of sorts, and the further interpretation could be made that the data indicate that little aerobic soil metabolic activity occurs under these conditions. This would be in contrast to the moderate but definite soil metabolism activity reported in other studies.

VIII. CBI Information Addendum: attached

FENVALERATE Sh # 109301

Page_____ is not included in this copy.

Pages 8 through 32 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.