UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EFGWB # 91-0206
Case 816169
Shaughnessy # 109301
DP BARCODE D158759

3-15-91

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of Phase IV Package for Fenvalerate

TO: Amy Rispin, Chief, Science Analysis and Coordination Staff
Environmental Fate and Effects Division (H7507C)

FROM: E. Brinson Conerly, Chemist, Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C) E.B. Conerly 3/15/91

THRU: Akiva Abramovitch, Section Head, Chemical Review Section 3
Environmental Fate and Effects Division (H7507C) Akiva Abramovitch

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

The Phase IV review package for (Es)fenvalerate (Shaughnessy # 109301, case 816169, Barcode D158759) was provided to EFGWB on 12/03/90. The material called Fenvalerate is a racemic mixture. Esfenvalerate is the isolated S,S-isomer, and is the only form currently being marketed. The LUIS report was received 2/3/91, and did not specify isomeric composition. Upon review of the entire package, it was determined that:

1) According to the LUIS report, the uses are terrestrial food/feed, terrestrial non-food, forestry, residential outdoor, indoor food, indoor non-food, indoor medical, and indoor residential uses.

Data status listed below refers to **Esfenvalerate**.

Data requirements for terrestrial food use are as follows:
hydrolysis -- satisfied -- a previously unreviewed study (MRID 409993-03, DER attached) provides acceptable data
photolysis in water -- satisfied
photolysis on soil -- satisfied -- EBC 3/7/91 (MRID# 417285-01)
aerobic soil metabolism -- satisfied
anaerobic soil metabolism -- **NOT** satisfied
leaching/adsorption/desorption -- satisfied
terrestrial field dissipation -- **partially** satisfied -- additional information needed -- EBC 3/7/91 (MRID# 417285-01)
confined rotational crop accumulation -- **NOT** satisfied
field rotational crop accumulation -- reserved pending results of confined accumulation study
fish bioaccumulation -- **NOT** satisfied

(continued on next page)

The forestry use adds the following requirements:

anaerobic aquatic metabolism -- **NOT** satisfied
forestry field dissipation -- **NOT** satisfied
accumulation in aquatic non-target organisms -- reserved, may be imposed if toxicity and other considerations indicate

2) The chemical identity information has been submitted. It should be referred to Product Chemistry for review.

3) The package contains summaries of hydrolysis (previously unreviewed study, DER attached), aerobic soil metabolism, leaching/adsorption/desorption, and field dissipation studies.

4) The EFGWB files contain the following relevent material:

a) Dynamac review 3/18/86 -- rejection of hydrolysis study, acceptance of leaching/adsorption/desorption study

b) Dynamac review 3/9/88 -- acceptance of aqueous photolysis study

c) EBC 3/7/91 (MRID# 417285-01) -- acceptance of photolysis on soil study, partial acceptance of field dissipation study

d) JMJ review 2/4/86 -- acceptance of aerobic soil metabolism study on S,S-isomer

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR (ES)FENVALERATE (CASE # 816169/2280), Pg.1

Chemical Code : 109301 Reviewer: E.B. Conerly Pesticide Type : Insecticide
Date: Uses:

	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
160-5. Chemical Identity		summaries MRID#s 92066-001 through 92066-005		to be reviewed by RD
DEGRADATION-LAB:				
161-1. Hydrolysis	MRID# 409993-03	review attached summary MRID# 92066-009	Satisfied	no
PHOTODEGRADATION:				
161-2. In Water	MRID# 404438-01	Dynamac review 3/9/88	Satisfied	no
161-3. On Soil	MRID# 417285-01	EBC review 3/7/91	Satisfied	no
161-4. In Air	None			no[1]
METABOLISM-LAB:				
162-1. Aerobic Soil	MRID# 000717-36 MRID# 000717-38	summary MRID# 92066-010	Satisfied	no
162-2. Anaerobic Soil				YES
162-3. Anaerob. Aquat.	none			YES
MOBILITY:				
163-1. Leaching and Adsorp./Desorp.	MRID# 004050-65 MRID# 001419-60	summary MRID# 92066-011	Satisfied	no
163-2. Volatil.(Lab)	MRID# 409993-02			no[1]
163-3. Volatil.(Field)	none			no[1]
DISSIPATION-FIELD:				
164-1. Terrestr.(Soil)	MRID# 000857-05 MRID# 000857-06	summary MRID# 92066-012	DNS/NSalv/NSupp	YES
	MRID# 000857-07, MRID# 000801-80[2] MRID# 417285-02	EBC review 3/7/91	DNS/Salv/Supp	YES
164-2. Aquat.(Sediment)	none			NA
164-3. Forestry	none			YES
164-4. Combin./Tank Mix	none			NA

[1] This requirement is only imposed for volatile compounds. Fenvalerate has a vapor pressure of ca. 10^{-9}, and therefore can be said to be non-volatile.

[2] This study was not cited by the applicant, but was sent to EFGWB as part of the Phase IV package.

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164-5. Long Term Terr.	none	NA
164-5. Long Term Aqua.	none	NA
ACCUMULATION STUDIES:		
165-1. Conf. Rot. Crops	none	YES
165-2. Field Rot. Crops	none	Reserved[3]
165-3. Irrigated Crops	none	NA
165-4. Fish (Lab)	none	YES
165-5. Aqua. Non-target Organ.(Field)	none	Reserved[4]
SPRAY DRIFT:		
201-1. Droplet Spect.	none	YES
202-1. Field Spray Drift Evaluation	none	YES
GROUNDWATER MONITORING:		
166-1. Small Prospect.	none	Reserved[5]
166-2. Small Retrospect.	none	Reserved[5]
166-3. Large Retrospect.	none	Reserved[5]
SURFACE WATER MONITORING:		
167-1. Field Runoff	none	Reserved[5]
167-2. Surface Water Monitoring	none	Reserved[5]

[3] This requirement may be imposed if results of the confined study so indicate.

[4] This data requirement may be imposed based on toxicity to aquatic organisms, results of the fish bioaccumulation study, and other considerations such as persistance and mobility.

[5] Available data indicate that the compound is not mobile and will not pose a risk to ground-water. It could be carried on soil particles into bodies of surface water.

KEY:

1) Addendum(EFGWB#/Date) = placed in the second column to indicate that a review (having the indicated EFGWB# and date) of the addendum identified by MRID# in the first column/same row is in the file.

2) DER(EFGWB#/Date) = placed in the second column to indicate that a data evaluation record for the study identified by MRID# in the first column/same row is in the file attached to a review with the indicated EFGWB# and date.

3) DNS/Salv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

4) DNS/Salv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).

5) DNS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

6) DNS/NSalv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).

7) DNPS/Salv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

8) DNPS/Salv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).

9) DNPS/NSalv./Supp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

10) DNPS/NSalv./NSupp. = placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.)

11) Dropped Uses(codes) = placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that all uses for which the data requirement is applicable will be dropped. Verify through the LUIS report that the uses have been dropped.

12) MRID#/MRID#A = placed in the first column to indicate that the study and adendum (A) whose MRID#s immediately precede and succeed the "/", respectively, are coupled. If a MRID# was not assigned to the addendum, substitute the date of submission for the MRID# followed by an "A" to indicate that its an addendum. If neither a MRID# or submission date is available, but the addendum was submitted as part of the Phase III response, substitute "Phase IIIA" for "MRID#A".

13) NA = placed in last (4th) column to indicate that the data requirement is not applicable to the uses listed in the LUIS report.

14) No = placed in the final (4th) column to indicate that no additional information or data is needed to completely satisfy an applicable data requirement. Identify in a footnote any studies that individually only partially satisfied the data requirement, but combined completely satisfies the data requirement. If the data requirement is not applicable to any of the uses listed in the LUIS report, use the "NA" designation defined above instead of "No".

15) No Information = placed in the second column to indicate that no DER or summary is available for the study identified by MRID# in the first column/same row, and that the registrant has not indicated in their Phase III response that they will submit another study or will drop uses to make the data requirement not applicable.

16) None = placed in the first column to indicate that the registrant did not list any studies or addendums in their Phase II and/or III responses for the given data requirement. In addition, EFGWB has no record of any studies or study/addendum combinations satisfying or partially satisfying the data requirement.

17) Not Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row will not satisfy or partially satisfy the data requirement and appears not to be salvageable to do so. Therefore, the study should not be reviewed.

18) Reviewable = placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row may possibly satisfy or partially satisfy the data requirement, or could possibly be salvageable to do so. Therefore, the study should be reviewed.

19) Reserved = placed in the final (4th) column to indicate that the data requirement is being held in reserve. Indicate in a footnote what information is needed to decide whether or not to impose the data requirement.

20) SIReview = placed in the final (4th) column to indicate that one or more studies is currently in review.

21) Study Withdrawn = placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that another study will be submitted.

22) Summary(MRID#) = placed in the second column to indicate that a DER is not available for the study identified by MRID# in the first column/same row, but that a study summary with the indicated MRID# was submitted as part of the Phase III response. If a summary is submitted for a study which also has a DER, identify the DER in the second column instead of the summary. (Note that the MRID# of the summary is not the same as the MRID# of the study it summarizes).

23) SWB Submitted = placed in the final (4th) column to indicate that one or more studies will be submitted by the registrant as indicated in their Phase III response.

24) Waived = placed in the final (4th) column to indicate that the data requirement has been waived. Identify the reason for the waiver and the EFGWB#/date of EFGWB's waiver recommendation in a footnote.

25) Yes = placed in the final (4th) column to indicate that additional information and/or data are needed to satisfy the data requirement. Specify in a footnote what additional information and/or data are needed.

DATA EVALUATION REVIEW 1

I. Study Type: hydrolysis, data requirement 161-1

II. Citation:

Lee, P.W. Hydrolysis of [Chlorophenyl -^{14}C] DPX-GB800 in Buffer Solutions of pH 5, 7, and 9. performed and submitted by E.I du Pont de Nemours and Co., Inc., Wilmington, DE. Laboratory Project ID AMR-1185-88, received EPA 2/15/89 under MRID# 409993-03.

III. Reviewer:

Typed Name: E. Brinson Conerly E.B. Conerly 3/15/91
Title: Chemist, Review Section 3
Organization: EFGWB/EFED/OPP

IV. Conclusion:

This study is acceptable to fulfill the requirement for hydrolysis data. Esfenvalerate (DPX-GB800) is stable to hydrolysis at pH 5, 7, and 9.

V. Materials and Methods:

test compound -- [^{14}C]-chlorophenyl-Esfenvalerate, radiopurity >98%, spec. act. 128 µCi/mg; isomeric purity > 99%

buffers -- pH 5, acetate; pH 7, phosphate; pH 9, borate

stock solution -- 2.2 µg/ml [^{14}C]Esfenvalerate in acetonitrile

test solution -- stock solution diluted into buffer to give 0.002ppm

incubation conditions -- aseptically, in the dark at 25 ^{0}C

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

sample treatment -- samples were extracted with hexane and analyzed by LSC and TLC

analyses

TLC -- in a toluene/ether/acetic acid system

LSC -- on extracts, on TLC spots

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

1) DPX-GB800 was stable in the sterile pH 5, 7, and 9 buffer solutions at 25^{0} C in darkness after 30 days.

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2) Results of this study are consistent with the data published in the literature.

3) Significant racemization of ^{14}C-DPX-GB800 was not observed since the diastereomeric S,S-isomer remained as the major component in the pH 5 and 9 buffer solution after 30 days.

4) ^{14}C-DPX-GB800 has a high tendency to adsorb onto glass surfaces. The binding/adsorption was especially evident in the pH 5 and 7 buffer solutions. The amount of adsorption increased with time. However, ^{14}C-DPX-GB800 could be easily recovered by a single hexane solvent extraction. Greater than 95% of the applied radioactivity was recovered from all three buffer solutions, and except for the pH 5 buffer solution, where 82% was recovered, an average 98% of the applied radioactivity was recovered throughout the 30-day testing period.

VII. Reviewer's Comments:

1) The investigator's conclusions appear to be correct -- ^{14}C-DPX-GB800 is stable to hydrolysis during 30 days incubation at pH 5, 7, and 9.

VIII. CBI Information Addendum: attached

FENVALERATE Sh # 109301

Page_____ is not included in this copy.

Pages 9 through 15 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.