

Date Out EFB:

DEC 21 1982

To: Miller
Product Manager 16
Registration Division (TS-767)

From: Emil Regelman, (Acting) Chief
Review Section No. 1
Environmental Fate Branch
Hazard Evaluation Division (TS-769)

FILE COPY

Attached please find the environmental fate review of:

Reg./File No: 11273-22

Chemical: Safrotin

Type Product: Insecticide

Product Name: Safrotin EC

Company Name: Sandoz

Submission Purpose: verification of data requirements and review of hydrolysis data

ZBB Code: ?

ACTION CODE: 310

Date in: 10/7/82

EFB # 5

Date completed: 12/21/82

Tais (level II)	Days
63	1.0

Deferrals To:

Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

1.0 INTRODUCTION

Sandoz Inc. has submitted a label amendment for the use of Safrotin as an outdoor perimeter spray. Available hydrolysis data are also submitted. A review of the hydrolysis data and verification of the data requirements are requested.

1.1 Chemical Identity

Chemical name: Propetamphos [(E)-1-methylethyl 3-[[[(ethylamino) methoxyphosphinothioyl] oxy]-2-butoanoate]

Product name: Safrotin

Company code number: SAN 52.139 I

2.0 USE DIRECTIONS

Directions for use are attached to this review.

3.0 DISCUSSION OF DATA

Hydrolysis at Various pH Values. SAN 52.139 I (A.I.). Agrochemical Research Analytical Laboratory. October 15, 1973.

Registrant has indicated that this study had been submitted previously (8/12/76) and found acceptable by the Agency. There is no indication in the RD files that this study was ever submitted. No previous review of a hydrolysis study was found in the EFB files.

The submitted study is little more than an outline of what should be done with some attached data as results. The following deficiencies were found in the study:

1. There was no indication as to how the buffers were made, or the pH adjusted.
2. There was no indication that glassware was sterilized or that water was bacteria free.
3. There was no indication that the hydrolysis was conducted in the dark.
4. No material balance was reported.
5. The report stated that the P=O metabolite could not be detected, "although being stable during work-up and GLC analysis." No verification of this statement was given.
6. No parent or metabolite structures were given.

4.0 CONCLUSION/RECOMMENDATION

This hydrolysis study is not acceptable. EFB cannot concur with the proposed amendment. A valid hydrolysis study must be submitted for our concurrence. An aerobic soil metabolism study will also be needed and should be submitted within 18 months of the data of acceptance of this amendment as previously indicated.

Norma Kay Whetzel

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December 21, 1982

Review Section No. 1

Environmental Fate Branch

Hazard Evaluation Division

Propetamphos environmental fate review

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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 product 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
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
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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.
