

113601
SHAUGHNESSEY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 8/24/81 OUT 10/1/81

FILE OR REG. NO. 11273-22

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 8/10/81

DATE RECEIVED BY HED 8/20/81

RD REQUESTED COMPLETION DATE 10/30/81

EEB ESTIMATED COMPLETION DATE _____

RD ACTION CODE/TYPE OF REVIEW 310/ Amendment -- Me-Too

TYPE PRODUCT(S): I, D, H, F, N, R, S Insecticide/Acaricide

DATA ACCESSION NO(S). none available

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Safrotin EC

COMPANY NAME Sandoz, Inc.

SUBMISSION PURPOSE Proposed conditional registration of outdoor

Perimeter spray recommendations plus other changes

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION % A.I.

113601 Propetamphos 50

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100 Pesticide Label Information

100.1 Proposed Label Changes

The registrant, Sandoz, Inc., has requested an amended registration of Safrotin EC insecticide (Reg. No. 11273-22) to permit the following changes to the current label:

(1) addition of the following target insects:

- a. brown dog ticks
- b. boxelder bugs
- c. ground beetles

The current label lists the following target insects:

- a. cockroaches
- b. ants
- c. crickets
- d. firebrats
- e. silverfish
- f. earwigs
- g. long-bodied cellar spiders
- h. American house spider
- c. fleas
- j. carpet beetles

(2) specific insect recommendation changes:

- a. inclusion of all spiders as target organisms
- b. a specific carpenter ant recommendation

(3) addition of an outdoor use for this product. Instructions "for the control of the insects listed on this label which are commonly found on and around the exterior of buildings" are included (see Section 100.3).

(4) further clarification on presently - permitted indoor sites of application.

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100.2 Formulation Information

Propetamphos - - - - - 50%
Inert ingredients - - - - - 50%

100%

100.3 Application Methods, Directions, Rates

(Outdoor Use)

Apply a 1.0% a.i. general treatment to a 6-10 ft. band of soil and vegetation around the house, as well as the house foundation wall to a height of 2-3 ft. Spot treatments to exterior surfaces around windows and doors should also be made.

100.4 Target Organisms

See Section 100.1

100.5 Precautionary Labeling

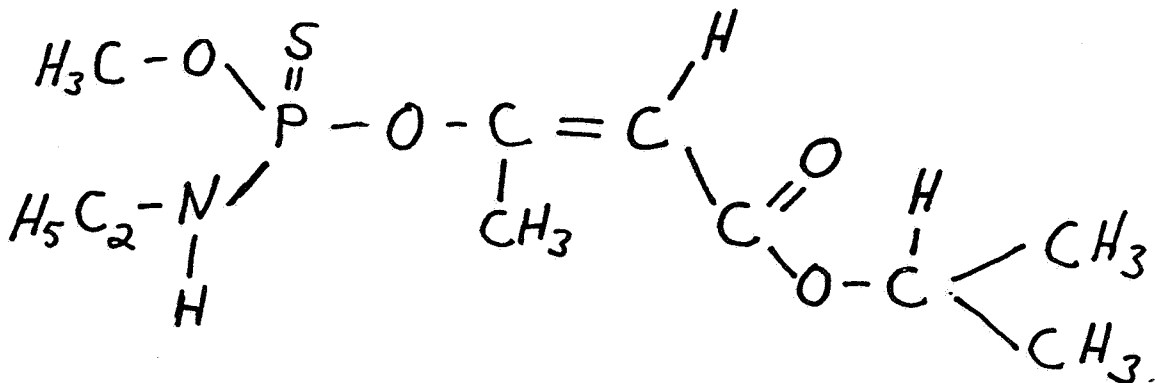
No Environmental Hazard labeling is provided on the proposed label.

101 Physical and Chemical Properties

101.1 Chemical Name

(E) -1-methylethyl 3- [[(ethylamino) methoxyphosphinothioyl] oxy]-2-butenoate

101.2 Structural Formula



101.3 Common Name

Propetamphos

101.4 Trade Name
Safrotin™ Emulsifiable Concentrate Insecticide

101.5 Molecular Weight (from EEB 6/15/79 Review of technical material)

281.3

101.6 Physical State (from EEB 6/15/79 Review of technical material)

- oily liquid
- light brown to straw color

101.7 Solubility (from EEB 6/15/79 Review of technical material)

- soluble in organic solvents (e.g., xylene, hexane, acetone)
- soluble in water at 110 ppm, 24°C

102 Behavior in the Environment

The following information is from the EEB 3/16/79 and 6/15/79 Reviews and EFB 5/2/79 Review. As of 9/28/81, additional data is not available from EFB.

102.2 Water

According to the 3/16/79 EEB Review and 5/2/79 EFB Review, Propetamphos is hydrolyzed slowly with the following half-lives estimated at 22-24°C:

pH 5	370 days
pH 7	570 "
pH 9	220 "

The EEB 6/15/79 Review describes a shorter half-life in buffered aqueous solution at 20°C:

pH 5	44 days
pH 7	47 "
pH 9	37 "

The half-life in water exposed to sunlight is reported to be about 5 days.

The octanol/water partition coefficient is reported to be > 100,000 (EEB 3/16/79 Review).

103 Toxicological Properties

103.1 Mammalian Toxicity (from EEB 6/15/79 Review)

Acute Oral LD₅₀ (rat) 82.8 mg/kg

Acute Dermal LD₅₀ (rabbit) 474.0 mg/kg

Subacute (28-day) Oral (rat) NOEL = 10 ppm

103.2 Minimum Requirements

103.2.1 Avian Acute Oral LD50

<u>Species</u>	<u>Material</u>	<u>LD50</u>	<u>Status</u>	<u>Reviewer</u>
Mallard	technical (92%)	197 mg/kg	Core	Leitzke
Mallard	assumed 100% a.i.	45 mg/kg	Core	Matheny

103.2.2 Avian Dietary LC50

<u>Species</u>	<u>Material</u>	<u>LC50</u>	<u>Status</u>	<u>Reviewer</u>
Mallard	technical (91%)	>1780 ppm	Suppl.	Hopkins
Mallard	48.3% EC	4752 ppm	Inv.	Leitzke
Mallard	assumed 100% a.i.	671 ppm	Inv.	Matheny
Bobwhite Quail	Technical (91%)	258 ppm	Core	Hopkins
Bobwhite Quail	48.3% EC	568 ppm	Inv.	Leitzke
Bobwhite Quail	assumed 100% a.i.	138 ppm	Core	Matheny

103.2.3 Fish Acute LC50

<u>Species</u>	<u>Material</u>	<u>LC50(96-hr.)</u>	<u>Status</u>	<u>Reviewer</u>
Bluegill sunfish	technical (91%)	188 ppb	Core	Hopkins
Bluegill sunfish	48.3% EC	0.28 ppm	Inv.	Leitzke

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Bluegill sunfish	assumed 100% a.i.	0.13 mg/1	Core	Matheny
Rainbow trout	technical (91%)	944 ppb	Suppl.	Hopkins
Rainbow trout	48.3% EC	4.69 ppm	Inv.	Leitzke
Rainbow trout	assumed 100% a.i.	0.36 mg/1	Core	Matheny
Carp (<u>Cyprinus carpio</u>)	assumed 100% a.i.	3.7 ppm	Inv.	Matheny

103.2.4 Aquatic Invertebrate LC50

<u>Species</u>	<u>Material</u>	<u>LC50 (48-hr.)</u>	<u>Status</u>	<u>Reviewer</u>
<u>Daphnia magna</u>	technical (92%)	14.27 ppm	Core	Leitzke
<u>Daphnia magna</u>	assumed 100% a.i.	0.68 ug/1	Core	Matheny

104 Hazard Assessment

104.2 Likelihood of Adverse Effects to Non-target Organisms

For outdoor use, the label instructs the user to prepare a 1.0% a.i. solution by mixing 2.5 oz. of Safrotin™ EC per gallon of water or oil. Although the label instructs the user to apply the 1.0% a.i. to a 6-10 ft. band of soil and vegetation around the exterior of buildings, it does not provide an application rate (e.g., the label does not state how much solution is to be applied per square foot or yard). Hence, it is not possible to accurately calculate soil contamination levels, estimate leaching or runoff potential, or in other ways precisely predict the exposure of non-target organisms to the pesticide. This problem is compounded by the extremely limited environmental chemistry data available.

Core toxicity data from earlier reviews (see Section 103) indicates that Propetamphos is "highly toxic" to both bluegill sunfish and rainbow trout and "slightly toxic" to "very highly toxic" to aquatic invertebrates [following EPA-accepted toxicity category terminology of Brooks, H., et. al. (1973)]. Hence, the levels of pesticide in water bodies necessary to surpass EPA Classification Triggers (1/10 and 1/2 the LC50 values of aquatic organisms for Restricted Use and RPAR criteria, respectively) are quite low. For example, 1/10 the lowest fish LC50 would be 13 ppb and 1/10 the lowest aquatic invertebrate LC50 would be 0.068 ppb. Depending on the application rate and environmental chemistry of the

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pesticide, and the proximity of the application sites to water bodies, such levels may or may not be easily surpassed. We note that Safrotin EC is proposed as a Restricted Use pesticide (see below). Clarification of the application rate and provision of environmental chemistry data are needed for a complete hazard assessment.

Birds and mammals found around dwellings could be exposed to the pesticide by consumption of contaminated vegetation and/or insects. As with the above aquatic hazard assessment, however, an application rate and more information on the behavior of the pesticide after its application are needed.

Overall, it would appear that the proposed outdoor use is not a major one in terms of total acreage to be treated nationwide. Further, Safrotin™ EC is proposed as a Restricted Use pesticide and the application method, given the restricted 6-10 ft. band treatment, would likely be by hand. Thus, it would not be likely that applications by the certified applicators (or persons under their direct supervision) would result in direct contamination of water bodies, for example. Any further assessment of potential hazard to non-target organisms would depend on an application rate and further environmental chemistry information, as is noted above.

104.3 Endangered Species Considerations

Exposure to endangered species would not be expected for this use pattern.

104.4 Adequacy of Toxicity Data

See Section 107.4

104.5 Additional Data Required

See Section 107.5

105 Classification

See Section 107.2

107 Conclusions

107.2 Classification Labeling

Without an application rate, residues in/on feed cannot be calculated and compared to LD₅₀ or LC₅₀ values (per 7/3/75 FIFRA Regulations). The proposed amended label submitted by the registrant continues the existing Restricted Use Classification labeling for Safrotin™ EC.

Environmental Hazards Labeling

The following statement should appear on the label:

"This pesticide is toxic to wildlife and fish. Do not contaminate water by cleaning of equipment or disposal of wates."

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107.4 Data Adequacy Conclusions

No new data was submitted for evaluation with this Review. Of the basic six fish and wildlife studies prescribed by the proposed subpart E guidelines (7/10/78), only the requirement for an avian dietary study on a species of wild waterfowl (sect. 163.71-2) has not been fully satisfied by previously - submitted data (see Section 103 of this Review). In this case, a study was submitted but considered not to meet guideline specifications by the EEB reviewer (S. Hopkins) since a specific LC₅₀ was not generated or shown to be >5000 ppm. However, mallard dietary levels up to 1780 ppm were tested without mortality. Severe dose-related reductions in feeding occurred such that the actual amount of toxicant consumed at the highest (1780 ppm) dose level was only 78 mg/kg. Since the birds were not consuming the toxicant at the levels tested, testing at still higher levels would seem of questionable value. Also, birds that display a dose-related reduction in food consumption under conditions in the laboratory, where all food available to them is contaminated, would be likely to avoid similarly-contaminated food in the wild.

Further, and critical to the issue of whether additional avian dietary testing is needed, EEB usually relies on the dietary LC₅₀ value for the more sensitive species for hazard evaluation purposes. In this case the bobwhite quail (which also showed a dose - related reduction in food consumption) had an LC₅₀ of 258 ppm in the diet, indicating that it is more sensitive than the mallard. Hence, EEB can use the 258 ppm dietary figure for hazard evaluation purposes and does not require further avian dietary testing.

107.5 Data Requests

Data from the six basic fish and wildlife studies (required to support the registration of all formulated products intended for outdoor application) are sufficient for the proposed registration (See Section 107.4). Given the proposed use pattern, no additional ecological effects data are needed at this time. EEB defers to the Environmental Fate Branch regarding the environmental chemistry data needed to characterize the environmental fate of Safrotin™ EC.

107.7 Recommendations

EEB has reviewed the proposed conditional registration of Safrotin™ Emulsifiable Concentrate Insecticide for use on 6-10 ft. bands around the exterior of buildings. While sufficient data exists to characterize the acute toxicity of the active ingredient, Propetamphos, and a general assessment of hazard can be made given the use pattern (see Sections 103 and 104 of this Review), a complete incremental risk assessment [3(c)(7) finding] is not possible because pertinent application rate and environmental chemistry data are lacking. EEB defers to the Environmental Fate Branch regarding environmental chemistry data needs.

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Reference

Brooks, H.L., et. al. 1973. Insecticides.
Cooperative Extension Service, Kansas State Univ.,
Manhattan, Kansas.

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