

US EPA ARCHIVE DOCUMENT



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

SEP 26 1983

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: William Miller, Product Manager No. 16  
Registration Division (TS-767)

and

Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

THRU: Christine F. Chaisson, Ph.D.  
Head, Review Section IV  
Toxicology Branch  
Hazard Evaluation Division (TS-769)

*Chad S. Landrusky  
for CFC  
9/23/83*

SUBJECT: Propetamphos; Safrotin 2E; PP#2H5439; EPA Reg. No.:  
11273-23; Caswell No.: 706A

*W. Dykstra  
9.23.83*

Recommendations:

1. The registration and tolerance request can be toxicologically supported. The following study is required to be submitted within a reasonable period of time:
  - a) rat teratology study which demonstrates maternal toxicity in addition to cholinesterase depression.
2. The reproduction study phase of the Basal-3-generation rat reproduction/teratology study has been concluded to be acceptable as core-minimum data. However, the teratology phase of the study is supplementary, since no clinical maternal toxicity was demonstrated. The NOEL for the reproduction phase is 20 ppm (HDT). Other toxicological issues noted in the 8/2/82 memo from W. Dykstra to W. Miller have been addressed.
3. Toxicology studies which support the requested actions are included in the one-liners.
4. No RPAR criteria have been exceeded and no regulatory actions are pending against the pesticide.
5. The ADI is based on the cholinesterase NOEL of 0.05 mg/kg/day in the chronic mouse feeding study. A 10 fold safety factor was used to calculate the ADI.

$$\text{ADI} = 0.05 \text{ mg/kg/day} \times \frac{1}{10}$$

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6. No permanent tolerances are established for the pesticide.  
The current action utilizes 50.00% of the ADI.

*William Dykstra*

William Dykstra, Ph.D.  
Toxicology Branch  
Hazard Evaluation Division  
(TS-769C)

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File last updated 6/19/81

*NOEL change  
not included  
per*

ACCEPTABLE DAILY INTAKE DATA

| House | NOEL | S.F. | ADI       | MPI           |
|-------|------|------|-----------|---------------|
| ug/kg | ppm  |      | mg/kg/day | mg/day (60kg) |
| 0.050 | 0.33 | 10   | 0.0050    | 0.3000        |

Current Action 0H5260 [T], 2H5439

| CROP           | Tolerance | Food Factor | mg/day (1.5kg) |
|----------------|-----------|-------------|----------------|
| All foods(197) | 0.100     | 100.00      | 0.15000        |

| MPI                  | THRC                  | % ADI |
|----------------------|-----------------------|-------|
| 0.3000 mg/day (60kg) | 0.1500 mg/day (1.5kg) | 50.00 |

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