

US EPA ARCHIVE DOCUMENT



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

OFFICE OF TOXIC SUBSTANCES

BRIEFING MEMORANDUM

SUBJECT: Request for Conditional Registration of the
New Chemical, Propetamphos for Control of
Household Pests.

TO: Edwin Johnson
Deputy Assistant Administrator
for Pesticide Programs (TS-766)

This memo transmits further background information on the subject request and updates the attached memo dated August 4, 1980.

Conclusions Reached by Toxicology Branch, HED on Toxicity Studies

A. Additional Studies

Subsequent to the August 4, 1980 memo, Tox Branch's review of the following additional studies submitted in support of a temporary food additive tolerance for the chemical has been received and the following NOEL were determined based on these studies:

1. 13-week feeding study in rats-NOEL of 4ppm based on RBC CHE inhibition; the LEL is 8ppm based on RBC CHE inhibition.
2. 6-month feeding study in dogs-NOEL of 2ppm; the LEL is 4ppm in the diet for CHE inhibition.

Both studies were found to be acceptable as core-minimum data and no treatment related effects were observed. (Memo of 6-18-80 from Tox Branch, attached) Note that, though these studies were found acceptable, the temporary food additive tolerance was found not to be toxicologically supported. The proposed tolerance of 0.1ppm in food exceeds the provisional maximum permissible intake of 0.03 mg/day based on the NOEL of 2ppm in the 6-month dog study and using a 100 fold safety factor, by a factor of 5.

To date, review of the residue data submitted with the food additive petition has not been completed by Residue Chm. Branch, HED. (Residue data on food from home use or food handling establishments has been identified as a data gap for the subject use as cited in the attached copy of Tox Branch's April 29, 1980 review).

B. Studies previously submitted in support of the subject use. (Tox memo of 7-2-79 attached)

1. Studies on formulated product.

- (a) Acute oral-rats-114.2 mg/kg
- (b) Acute dermal-rabbits-LD₅₀ between 200-2000 mg/kg
- (c) Acute inhalation-rats LC₅₀ between 2.0-200 mg/L for 4 hours.
- (d) Eye irritation-rabbits, Cat. Tox I
- (e) Skin irritation-Cat. Tox IV
- (f) 21-day dermal-rabbits produces cholinergic effects at 20,60,180 mg/kg/day
- (g) 3 week dermal-rabbits - dose of 1mg/day produced transitory RBC cholinesterase inhibition
- (H) 14 day inhalation-rats -dose related cholinesterase inhibition (plasma and RBC) occurred at 1,3 and 6 mg/L
- (i) 2-week inhalation-rats. "Under present test conditions the lowest concentration without changes can be expected to be below 0.053mg product/L air by inhalation. Without consideration of the decreased plasma cholinesterase, the lowest concentration without toxicity is between 0.053 mg/L and 0.097 mg/L".

2. Studies on the technical material

- (a) Acute delayed neurotoxicity-chickens. The material was not a delayed neurotoxic agent in the submitted study. (4-29-80 memo)
- (b) Teratology-rabbits (1976) the chemical "---administered on days 6 through 18 of gestation was not teratogenic or embrolethal at the dosage levels studies, but a dose-related increase in maternal toxicity was seen with a statistically significant increase present at 10 mg/kg/day (7-2-79 memo).
- (c) Teratology-rabbits (1978) "----results do not suggest any pattern of induced teratogenic activity---" (7-2-79 memo)

Data Gaps as Cited by Tox Branch, HED Memo of 4-29-80

The following tests are required by the proposed guidelines published in the Federal Register, August 22, 1978 for those uses likely to result in repeated or significant exposure to the product.

1. Reproduction
2. Chronic/Oncogenic

Additionally, because of the residual effect, residue data on food from home use or food-handling establishments has been requested by Tox Branch.

As currently proposed, the directions for use of the product for control of fleas include spraying of infested rugs, floor coverings, and upholstered furniture. The directions for use in household kitchens state to apply as a crack and crevice or spot treatment only.

Importance of the Proposed Uses (Refer to Attached Letters)

At the request of the applicant, letters attesting to the need for another chemical to control fleas have been received from several pest control operators including the National Pest Control Association, Inc. A letter has also been received from the Louisiana Department of Health and Human Resources, Office of Health Services and Environmental Quality referring to the use of DDT for the control of the Oriental rat flea under a crisis exemption.

Such disease - transmitting fleas normally are found in outdoor situations however, and the proposed labeling restricts use of the subject chemical in or on buildings.

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