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CASWELL FILE



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

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Tetramethrin (Neo-Pynamin) - EPA Registration No. 10308-1 - Waiver Request for Oncogenicity and Reproduction for Reregistration

Project No.: 9-2137
Caswell No.: 844
Record No.: 251,523
MRID Nos.: 114366, 143556 ?

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THRU: Roger Gardner, Acting Section Head *Roger Gardner 11-1-89*
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Requested Action

Review registrant's request to waive the requirement for oncogenicity and reproduction studies for reregistration of tetramethrin. This request is a Phase 2 response to reregistration.

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Background

Tetramethrin Use Patterns

"Tetramethrin is currently registered for greenhouse nonfood, domestic indoor, domestic outdoor uses, and is formulated in various aerosol forms including total release foggers. The concentration of tetramethrin in its various commercially available formulations ranges from 0.03% to 0.5%. Most household tetramethrin sprays contain 0.2% to 0.3% tetramethrin.

"The recommended method of application of most household tetramethrin formulations for flying insects is fogging as follows:

- close all doors and windows
- direct spray in center of room for 5 to 10 seconds
- keep room closed for 15 minutes
- ventilate room thoroughly before reentry
- repeat as necessary

"For certain crawling insects, such as roaches, tetramethrin labels recommend spraying the product directly on household surfaces (e.g., baseboards, floors, shelves, etc.) until wet. For some insects, however, direct target application is recommended, which would result in a much lower level of exposure than the above-described fogging and wetting methods of application" [end of quotation].

Based on the exposure assessment by the registrant's consultant, Dr. Clive A. Edwards, the limited human exposure to tetramethrin as predicted by label directions and together with the analyses of the oncogenic potential and risks by Drs. Venedinovitch, Ito and Calborg, the registrant requests that in the reregistration of tetramethrin, the Agency waive the requirement for oncogenicity and reproduction studies.

Conclusion and Recommendation

1. Acceptable oncogenicity studies with tetramethrin (both rat and mouse) have already been reviewed by the Agency. Also the two-generation rat reproduction study with neopynamin forte is acceptable to fulfill the need for evaluating reproductive hazards associated with exposure to tetramethrin.
2. Additional oncogenicity and reproduction studies are not required for reregistration.

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3. The oncogenic risks, if any, associated with the current uses of tetramethrin will be determined by the Toxicology Branch following the completed analysis of the HED Peer Review Committee's evaluation of the oncogenic potential of tetramethrin.

Review

1. No new toxicity data were submitted.
2. Both Appendix I (MRID No. 114366) and Appendix II (MRID No. 143556) should be submitted to the Non-Dietary Exposure Branch for possible evaluation. It is to be noted that these appendices are dated September 9, 1982 and June 18, 1984, respectively, and therefore, an Agency response to these documents may have already been completed.

cc: Mike Firestone



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