MEMORANDUM

SUBJECT: Tetramethrin - EPA Registration No. 10308-1 - Mouse Oncogenicity Study Issues Relating to Reformatted Pathology Tables

Caswell No. 844
Record No. 187797
Project No. 7-0360
Accession Nos. 262776 to 262788

FROM: William Dykstra
Section II Reviewer
Toxicology Branch
Hazard Evaluation Division (TS-769C)

TO: Paul Schroeder, PM Team 17
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

THRU: Edwin Budd, Section Head
Review Section II
Toxicology Branch
Hazard Evaluation Division (TS-769C)

Action Requested

Respond to registrant's request for Toxicology Branch (TB) comments regarding reformatted pathology tables for the mouse oncogenicity study with tetramethrin.

Conclusions and Recommendations

Sample sheets of individual and summary histopathology incidence tables requested by TB are attached. The proposal to submit separate tables for neoplastic and non-neoplastic lesions are acceptable to TB, as is the format for reporting organ weights. Hazleton Laboratory's method of reporting individual histopathology findings is acceptable. However,
with respect to the laboratory's method of submitting histopathology incidence summary tables, TB requests that the sample sheet provided for summary incidence tables be followed.

The reason for TB position on the summary tables provided by Hazleton is that the Hazleton summary sheets do not specify animals that were scheduled sacrifices and moribund sacrifice/deaths but only provide the total numbers examined.

It should be noted that Hazleton Laboratory has recently (1986) submitted acceptable reformatted pathology tables corresponding to TB sample sheets for other chronic studies.

Attachments
Male Mice
Scheduled Sacrifices

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LUNG

- Alveolar/Bronchiolar Carcinoma
- Malignant Lymphoma
- Malignant Lymphoma
- Undifferentiated
- Alveolar/Bronchiolar Adenoma
- Carcinoma, Metastatic
- Granulocytic Leukemia
- Sarcoma, Metastatic
- Multifocal Pleuritis
- Multifocal Pneumonitis
- Alveolar Macrophages
- Pigmented
- Focal Alveolar/Bronchiolar Hyperplasia
- Congestion
- Focal Hemorrhage
- Alveolar Macrophages
- Foci of Foamy Macrophages
- Leukocytosis
- Peribronchial/Vascular
- Mononuclear Cells
- Alveolar Proteinosis
- Multifocal
- Alveolar-Bronchiolitis

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<td>1 = Minimal</td>
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III-1
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**REGISTRATION DIVISION DATA REVIEW RECORD**

**Confidential Business Information – Does Not Contain National Security Information (E.O. 12065)**

1. CHEMICAL NAME
   - Tetramethrin

2. IDENTIFYING NUMBER
   - 10308-1

3. ACTION CODE
   - 305

4. ACCESSION NUMBER
   - 187797

5. RECORD NUMBER
   - 187797

6. REFERENCE NUMBER
   - 14

7. DATE RECEIVED (EPA)
   - 11/21/86

8. STATUTORY DUE DATE
   - 

9. PRODUCT MANAGER (PM)
   - Castillio/Schroeder

10. PM TEAM NUMBER
    - 17

14. CHECK IF APPLICABLE
   - ☐ Public Health/Quarantine
   - ☐ Substitute Chemical
   - ☐ Seasonal Concern
   - ☐ Review Requires Less Than 4 Hours
   - ☐ Minor Use
   - ☐ Part of IPM

15. INSTRUCTIONS TO REVIEWER
   - A. HED
     - ☐ Total Assessment - 3(c)(5)
     - ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977
     - ☐ Other

   - B. SPRD
     - ☐ Chemical Undergoing Active RPAR Review
     - ☐ Chemical Undergoing Active Registration Standards Review

16. RELATED ACTIONS

17. 3(c)(1)(D)
   - ☐ Use Any or All Available Information
   - ☐ Use Only Attached Data
   - ☐ Use Only Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical

18. REVIEWS SENT TO
   - ☐ TB
   - ☐ EEB
   - ☐ EF
   - ☐ PL
   - ☐ RCB
   - ☐ EFB
   - ☐ CH
   - ☐ BFSD

19. To
   - TOXICOLOGY
   - ☒
   - ECOLOGICAL EFFECTS
   - RESIDUE CHEMISTRY
   - ENVIRONMENTAL DATE
   - CHEMISTRY
   - EFFICACY
   - PRECAUTIONARY LABELING
   - ECONOMIC ANALYSIS

**NUMBER OF ACTIONS**

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20. ☐ Label Submitted with Application Attached
21. ☐ Confidential Statement of Formula
22. ☐ Representative Labels Showing Accepted Uses Attached
23. Date Returned to RD (to be completed by HED) 3/25/87
24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.