



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

MAR 20 1987

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

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)

*William Dykstra*  
3/17/87

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)

*Budd*  
3/20/87  
*W.B.*  
3/20/87

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

III-1

Key: P = Present      N = No Section      A = Autophagy      X = Post Autophagy  
1 = Minimal      2 = Slight      3 = Moderate      4 = Moderate to Severe

EVERY PATHOLOGY REPORT SHOULD HAVE:  
SUMMARY INCIDENCE TABLE

Female Mice

	Group 1			Group 5			Group 6			Group 7		
	Scheduled Sacrifice	Morbund Sacrifice & Death	Total	Scheduled Sacrifice	Morbund Sacrifice & Death	Total	Scheduled Sacrifice	Morbund Sacrifice & Death	Total	Scheduled Sacrifice	Morbund Sacrifice & Death	Total
UNG (NO. EXAMINED)	(43)	(7)	(50)	(42)	(8)	(50)	(38)	(12)	(50)	(39)	(11)	(50)
Alveolar/Bronchiolar Carcinoma	2		2	2		2	2		2	3		5
Malignant Lymphoma					1	1		4	4		1	1
Malignant Lymphoma, Undifferentiated		2	2				1		1		1	1
Alveolar/Bronchiolar Adenoma	3		3	3		3	5	2	7	4		4
Carcinoma, Metastatic	1	1	2		1	1		2	2			
Granulocytic Leukemia					1	1						
Sarcoma, Metastatic												
Multifocal Pleuritis							1		1	3		3
Multifocal Pneumonitis	5		5	2		2	4		4	3		3
Alveolar Macrophages, Pigmented	7		7	4		4				1	1	2
Focal Alveolar/Bronchiolar Hyperplasia												
Congestion	2		2	2		2	2		2	1		1
Focal Hemorrhage	2	2	4	4	5	9	3	5	8	3	8	11
Alveolar Macrophages				2		2	1		1	1		1
Foci of Foamy Macrophages	2		2	2		2	2		2	1		1
Leukocytosis	4		4	3		3				2		2
				1	2	3					3	3

# REGISTRATION DIVISION DATA REVIEW RECORD

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

1. CHEMICAL NAME

*Tetramethrin*

*7-0360*

2. IDENTIFYING NUMBER

*10308-1*

3. ACTION CODE

*305*

4. ACCESSION NUMBER

TO BE COMPLETED BY PM

5. RECORD NUMBER  
*187797*

6. REFERENCE NUMBER

*14*

7. DATE RECEIVED (EPA)

*11/21/86*

8. STATUTORY DUE DATE

9. PRODUCT MANAGER (PM)

*Castillo/Schroeder*

10. PM TEAM NUMBER

*17*

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS

*01/14/87*

12. PRIORITY NUMBER

*49*

13. PROJECTED RETURN DATE

*03/25/87*

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.

C. ☐ BFSD  
D. ☐ TSS/RD  
E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)  
☐ Chemical Undergoing Active RPAR Review  
☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

*Review format for toxicology study for mouse carcinogenicity study requested in 9/15/86 letter*

16. RELATED ACTIONS

17. 3(c)(1)(D)

☒ Use Any or All Available Information ☐ Use Only Attached Data  
☐ Use Only the 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	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY	X							
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	ENVIRONMENTAL DATA								
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

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)

*3/20/87*

24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.