

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460 APR 3 0 1987

005899

MEMORANDUM:

Tetramethrin; EPA Reg. No. 10308-1; Addendum to SUBJECT:

Pathology Report

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Caswell No. 844 Record No. 187794 Project No. 7-0359

Accession No. MRID 143555

TO:

Paul Schroeder Product Manager 1

Registration Division, TS-767

THRU:

Edwin Budd, Section Head

Review Section II Toxicology Branch

Hazard Evaluation Division, TS-769

FROM:

William Dykstra

Toxicology Branch

Hazard Evaluation Division, TS-769

William Dykstra

Requested Action:

Review addendum to pathology report by Drs. Vesselinovitch and Ito.

## Conclusions and Recommendations:

1. The addendum to the pathology report is only acceptable as supplementary information. The addendum presents the summary findings based on the pathologic interpretation of interstitial cell lesions and neoplasms as determined by Sumitomo consultants, Drs. Vesselinovitch and Ito.

It should be noted that the data in the consultants report does not include the histologic details of the individual rats used in the 1974 and 1981 chronic rat studies. TB presently has the details of the individual animal, from the Hazleton studies and will perform survival disparity analyses, life-table analyses, and statistical analyses for presentation to the TB Peer Review Committee.

The pathology addendum also contains the consultant's statistical analysis of the testicular lesions and neoplasms in the three rat studies.

The summary statistical and pathology data presented in the addendum will be presented, along with TB assessments, to the Peer Review Committee.

## Review:

- 1. Addendum to: S.D. Vesselinovitch and N. Ito; Histologic Evaluationand Interpretation of Neo-Pynamin Bioassay Studies Carried Out on Sprague-Dawley (1974 and 1981) and Long-Evans (1981) Rats by Hazleton Laboratories Inc., for Sumitomo Chemical Company Ltd., (August 13, 1982).
- A. No new data were presented. The summary incidence data and statistical analyses in the addendum do not impact significantly on the Hazelton evaluation. For future reference, the addendum is attached to the present review.

ADDENDUM TO: HISTOLOGIC EVALUATION AND INTERPRETATION OF OF NEO-PYNAMIN BIOASSAY STUDIES CARRIED OUT ON SPRAGUE-DAWLEY (1974 AND 1981) AND LONG-EVANS (1981) RATS BY HAZLETON LABORATORIES INC. FOR SUMITOMO CHEMICAL COMPANY, LTD. (SEPTEMBER 9, 1982)

BY

S.D. VESSELINOVITCH AND N. ITO

Stan D. Vesselinovitch

July 27, 1984

Date

69003	TETRA	HETHR	N	FIN 2	488	<u>-73</u>
Page is not in			led.		<u></u>	··········
The material not information:	included	contains	the	following	type	of i
Identity of pr	oduct inert	: ingredien	ts.			
Identity of pr	oduct impur	rities.				× .
Description of	the produc	t manufact	uring	process.		
Description of	quality co	ntrol proc	edures	5 <b>.</b>		
Identity of th	e source of	product i	ngredi	ients.		
Sales or other	commercial	/financial	info	rmation.		
A draft produc	t label.	• *		11		
The product co	nfidential	statement	of for	rmula.		
Information ab	out a pendi	ng registi	ation	action.		. *
✓ FIFRA registra	tion data.					
The document i	s a duplica	ate of page	e(s) _	•		
The document i	s not respo	onsive to 1	the re	quest.		
The information not by product registrathe individual who	nts. If vo	u have any	quest	ions, plea	se cont	ial act