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

9/20/89

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Addendum to Peer Review Document for Tetramethrin

Caswell No.: 844

FROM: William Dykstra, Reviewer
Review Section I
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

William Dykstra 9/20/89

TO: Karl Baetcke, Chief
Toxicology Branch I - Insecticide, Rodenticide Support
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THRU: Edwin Budd, Section Head
Review Section I
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

In John Doherty's memorandum of April 11, 1983 regarding the 1981 Long-Evans Rat study, Dr. Doherty states "The response of the Long-Evans strain with respect to production of hepatocellular carcinomas and total of nodules plus carcinomas is disturbing. However, considering the dose levels involved (0, 500, 1000, 5000) there is no relationship between response and the test dose level. Thus, the response in the Long-Evans strain, although disturbing, is considered to be most likely spontaneous in origin. This problem will be reconsidered when the exact number of tissues examined is provided." [End of quotation.]

The actual total incidence, found in the hard copy of the study, was as follows:

Long-Evans (1981)

	Liver			
Dose (ppm)	0	200	1000	5000
No. in Group	50	50	50	50
Neoplastic Nodules	1	5	2	2
Hepatocellular Carcinoma	0	6	2	5

These data were not statistically analyzed by the SACB statistics team.

These data were discussed with Dr. Doherty, Dr. Zendzian, and Dr. Engler on September 19, 1989. It was concluded that the neoplastic incidence in the liver of Long-Evans rats was not compound-related. Historical control data for Long-Evans rats from Hazleton could not be provided by the registrant. Historical control data for liver neoplasms in Sprague-Dawley from Hazleton are attached.

Since these data were not discussed by the Peer Review Committee for tetramethrin, they are being provided for your perusal as an addendum to the Peer Review Document.

Attachment

TETRAMETHRIN

Page_____ is not included in this copy.

Pages 3 through 9 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

X FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.