



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 *William Dykstra 9/20/89*
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THRU: Edwin Budd, Section Head
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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:

<u>Long-Evans (1981)</u>				
<u>Liver</u>				
<u>Dose (ppm)</u>	<u>0</u>	<u>200</u>	<u>1000</u>	<u>5000</u>
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.
 - ☒ FIFRA registration data.
 - ☐ The document is a duplicate of page(s) .
 - ☐ The document is not responsive to the request.
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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.
