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

JUL - 6 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Histopathological Reevaluation of Microscope Slides From the Biphenthrin Mouse Carcinogenicity Study

TO: Heyward/LaRocca, PM 13
SRRD (H7505C)

FROM: Byron T. Backus, Ph.D., Toxicologist Byron T. Backus 6/23/92
Toxicology Branch 2
HED (H7509C)

THROUGH: K. Clark Swentzel K. Clark Swentzel JUN 24 1992
Section Head, Review Section II
Toxicology Branch 2
HED (H7509C)

and

Marcia van Gemert, Ph.D., Branch Chief
Toxicology Branch 2 Marcia van Gemert 6/24/92
HED (H7509C)

DP Barcode: D165219 Submission: S397506

Case: 051804 Project No. 1-1539

Chemical No. 128825 (Talstar)

Tox. Chem. 463F

Action Requested:

Review a histopathological reevaluation of "selected" microscope slide sections from the Bifenthrin (Biphenthrin) mouse carcinogenicity study.

Background:

This material (in MRID 419016-01) consists of a reevaluation of slides from a mouse carcinogenicity study (study no. A83-974, conducted at the FMC Toxicology Laboratory, previously - 8/8/86 - reviewed by the Agency and classified as core minimum data; review in Caswell file document 005336). In the study as originally received and reviewed by the Agency, it was stated that incidences

of leiomyosarcomas of the urinary bladder in male mice were 2/48, 6/50, 8/50, 7/50, and 14/49 at dietary exposure levels of 0, 50, 200, 500, and 600 ppm. Because of the unusual tumor type and the dose-related trend, bifenthrin was subsequently classified as a category C carcinogen, and it was deemed appropriate to calculate a Q_1* for risk assessment purposes.

Comments and Recommendations:

1. The material in MRID 419016-01 consists, in part, of a reevaluation of the urinary bladder slides by W. H. Butler (who was not the pathologist who previously reviewed the slides). Those slides in which tumors (or lesions) were observed by Dr. Butler were also evaluated by Dr. S. M. Cohen and Dr. R. A. Squire. This pathology panel concluded that the mouse bladder tumor was not a leiomyosarcoma (as originally reported) but rather that the tumor arose in the submucosa and possibly from the vascular mesenchyme. It is stated in the reevaluation that: "these tumors have a low-grade malignant potential based upon the observation that most are confined to the submucosa and few grow to a large size." Subsequent discussion with Dr. W. H. Butler (as well as a communication from Dr. S. M. Cohen) indicated that the most appropriate terminology for this type of tumor (or lesion) is "hemangiopericytoma." However, these are not necessarily the same lesions that are termed hemangiopericytomas in human tissue, and hemangiopericytomas have not been reported from human urinary bladders.

2. In the reevaluation of the male urinary bladders, 5 or 6 additional lesions (or tumors) were identified in the controls, bringing the incidence in this group to 6/47 or 7/47. No additional hemangiopericytomas were observed in the bladders of any groups of bifenthrin-exposed mice.

3. The material in MRID 419016-01 was discussed and evaluated by the Health Effects Division Carcinogenicity Peer Review Committee on January 22, 1992 (see attached copy of the memorandum dated April 29, 1992).