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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 21 1987

MEMORANDUM

SUBJECT: EPA Reg. No. 359-686. Lindane: Review of revised protocol for the rat chronic feeding/oncognicity study.

TOX CHEM No.: 527
TOX PROJECT No.: 7-0591
Record No.: 193465

FROM: John Doherty 4/20/87
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THRU: Theodore Farber, Ph.D.
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Mr. Charles A. O'Connor counsel for Centre International d'Etudes du Lindane (CIEL) has submitted a revised final protocol for the rat chronic feeding/oncogenicity study with lindane. Toxicology Branch (TB) has previously reviewed protocols for this study (refer to J. Doherty memo dated December 24, 1986 and February 24, 1987 as well as earlier memos).

The CIEL and the Life Science Research Institute may proceed with the study as proposed in the February 1987 version of the protocol (LSR Schedule No. CIL/001/LIN). TB has no further comments or suggestions for the protocol.

TB requests, however, that information on the usage of both the Clinitest and N-Multistix to assess for urinary parameters be provided to the Agency as soon as posible. The information provided should include the limits of differences in concentration of the several urinary constitutents which can be distinguished by these methods.

The registrants are reminded that it is their responsibility to provide a study that will satisfy the normal requirements for a chronic feeding/oncogenicity study as well as provide appropriate NOELs for the particular lesions in question for lindane toxicity (i.e. possible kidney and blood and bone marrow effects).

Lindane tox review

Page_____ is not included in this copy.

Pages 3 through 27 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.

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