



CASWELL FILE

4-21-87

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/oncogenicity study.

TOX CHEM No.: 527  
TOX PROJECT No.: 7-0590  
Record No.: 193465

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*Budd*  
*4/20/87*  
*4/21/87*

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 possible. The information provided should include the limits of differences in concentration of the several urinary constituents 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

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Pages 3 through 27 are not included.

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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.

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