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

APR 17 1987

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Lindane: Toxicology Branch comments on the revised (March, 1987) protocols for rat and rabbit 90 day dermal toxicity studies.

TOX CHEM No.: 527
TOX PROJECT No.: 7-0592/7-0593
Record No.:

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Budd 4/15/87
4/16/87

In previous memos from Toxicology Branch (TB) both the rat and rabbit (two Doherty memos dated January 16, 1987 for EPA Reg. No. 359-686) protocols for 90-day dermal toxicity studies were reviewed. In both of these protocol reviews, the registrants were requested to rewrite the aspects of the study dealing with both assessment of kidney function and assessment of blood and bone marrow content.

The registrants have responded by submitting revised protocols. The following comments apply to both the rat and rabbit 90-day dermal toxicity studies.

1

The latest version of the protocol states that "all 3 kidney sections will be examined from all animals dosed at the no effect levels". This statement is vague with regard as to what they really intend to do. TB strongly recommends that three kidney sections from each kidney be examined for each animal in both the rabbit and rat studies.

4. TB strongly recommends that a test for creatinine clearance be conducted in the rabbit study in the same manner as it is scheduled to be conducted in the rat study. [This test may have been inadvertently omitted from the protocol.]

5. Both the rat and rabbit revised protocols contain an appendix which describes how bone marrow myelograms will be assessed. The procedures described are acceptable to TB.

6. The registrants may proceed with the studies as described in the protocols. The registrants are reminded, however, that it is their responsibility to provide a study that will satisfy the Agency's requirement to assess for potential kidney and bone marrow effects as well as for the usual endpoints of a subchronic study via the dermal route of exposure.

Lindane toxicology review

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Pages 3 through 21 are not included in this copy.

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