



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

JUN 24 1987

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: EPA Reg. No. 359-686 - Lindane. Supplementary information related to the use of MULTISTIX Reagent Strips and CLINITEST Reagent Tablets to be used for urine analysis in the chronic feeding oncogenicity study.

TOX CHEM No.: 527

TOX PROJECT No:

Record No.:

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*Budd 6/17/87**WJ 6/22/87*

In a previous review of the protocol for the rat chronic feeding/oncogenicity study (refer to J. Doherty review dated April 21, 1987 for EPA Reg. No. 359-686) Toxicology Branch (TB) requested the registrants to provide information on CLINITEST and N-MULTISTIX methods which were proposed for usage to assess for urinalysis. The registrants have provided the information requested in the form of the manufacturers literature and this information is attached.

The registrants have also provided a memorandum from Life Science Research (refer to S.J. Amyes, Head of Oncology Department memo dated May 7, 1987). In this memo, Dr. Amyes indicates that these methods for urinalysis "are semi-quantitative or qualitative tests, and cannot therefore be evaluated in the same way as quantitative tests".

TB notes that a quantitative urinalysis assessment was originally asked for (refer to notes of the meeting between CIEL and TB dated July 22, 1986 and review of the original protocol for this study dated August 4, 1986). At a later meeting, however, it was decided that qualitative and semi-quantitative urinalysis would be sufficient to assess for the status of the kidney (refer to notes of the meeting between CIEL and TB dated December 5, 1986 and review of the revised protocol dated December 24, 1986).

TB acknowledges receipt of the manufacturers literature for these products and will retain this information to assist in the review of the final report of this study when it is eventually submitted. It should be noted that TB does not actually endorse the use of these commercial products. It is the registrants and testing laboratories responsibility to choose products that will meet the objectives of the study which are in this case a qualitative and semi-quantitative urinalysis assessment.