MEMORANDUM

OFFICE OF TOXIC SUBSTANCES

SUBJECT: Validation Review of 197 Study 1711 Three Phase Reproduction Study in Albino Pats of Irapa

FROM: Gary J. Burin
Toxicology Branch, HEI (TS-769)

TO: Jan Auerbach, Chief
Laboratory Audit and Regulatory Analysis Branch
SPRO (TS-751)

THRU: William Burnan, Acting Chief
Toxicology Branch, HEI (TS-750)

Based upon my evaluation of the SPRO "Preliminary Review", the sponsor validation report and the final report itself, it is recommended that the teratology phase of this study be considered invalid and the reproductive phase of this study be considered supplementary data. The basis for these recommendations include the following:

1. The primary reason for the classification of the teratology study is the lack of raw data to support findings regarding visceral or skeletal examinations of progeny.

2. Diet preparation records are missing for both the teratology and reproductive phases of this study. Food consumption was only measured for a 5-day period of the reproductive phase.

Deficiencies noted below pertain to the reproductive phase of the study:

3. No written records exist to document daily observations of behavior or mortality.

4. Final report states that each female was given a maximum of 2 different males. Raw data shows that some females were given as many as 5 different males.

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

SUBJECT: EPA (MED) Review of IBT Validation Report

FROM: C.K. Ram-Turk, R.A. Beyer (MED)

TO: Branch Chief
  Regulatory Analysis and Lab Audits Branch
  Special Pesticide Review Division

Validation Submitted by:

Date of Validation:
2/29/80

IBT Report Number:
D 7118

Date of Final Report:

Type of Study:

Compound:

EPA Accession Number:

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Conclusions:  
- VALID 
- INVALID (-) 
- NO CONCLUSION 
- Supplementary Data (Reproduction Issue)