

6-25-80

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20450

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MEMORANDUM

OFFICE OF TOXIC SUBSTANCES

SUBJECT: Validation Review of IST Study # 7113 Three Phase Reproduction Study in Albino Rats of Irgasan

FROM: Gary J. Burin *GB*
Toxicology Branch, IED (TS-769) *186-135*

TO: Jan Auerbach, Chief
Lab Audits and Regulatory Analysis Branch *WJB*
SPRD (TS-791)

THRU: William Burnan, Acting Chief
Toxicology Branch, IED (TS-769)

Based upon my evaluation of the SPRD "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

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SUBJECT: EPA (HED) Review of IBT Validation Report

FROM: *Cory Runn, T. B. / HED (TS-667)*

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

Validation Submitted by:

Ciba-Geigy

Date of Validation:

2/24/80

IBT Report Number:

2113

Date of Final Report:

2/1/80

Type of Study:

Three Phase Registration, Toxicity & Efficacy

Compound:

Irgasan

EPA Accession Number:

Registrant Validation Report
IBT Report Submitted to EPA

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Conclusions:

☐ VALID

☐ INVALID

☐ NO CONCLUSION

☒ Supplementary Data (Reproduction Toxicity)