

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: September 7, 1979

SUBJECT: Validation Report On IBT Study No. 622-01185 - Three-Generation Reproduction Study on Lasso Technical in Albino Rats.

FROM: Larry Anderson, Ph.D.  
Toxicology Branch (TS-769)

*Larry Anderson*

TO: Acting Branch Chief  
Regulatory Analysis and Lab Audits  
Special Pesticides Registration Division

THRU: Dr. M.A. Gross, Chief  
Toxicology Branch (TS-769)

*M.A. Gross*

Discussion

This study is considered to be an invalid estimate of the effect of Lasso Technical on reproduction in rats through 3 generations. The basis for this conclusion is:

1. Absence of laboratory records verifying diet preparation including calculations, mixing instructions, and weekly preparation of fresh diets as stated in the final report.
2. Lack of raw data on the F1b generation.
3. The 100 ppm F1 parental males died before mating for the F2b litters was done. Consequently, the 100 ppm F1 parental females were bred with 300 ppm F1 parental males to produce these litters.
4. Inadequate animal husbandry is indicated as follows: Of the 2,905 pups for which data were provided, 336 died from "unknown" causes, 88 died presumably of starvation when deprived of food and water for unspecified periods of time, 17 died in "accidents", and 212 were cannibalized primarily in cages housing dams without food and water. Thus, 653 or 22.5% of the 2,905 pups accounted for were not useable as a data source. Furthermore, deaths of the 100 ppm F1 parental males described earlier were attributed to acute respiratory infection, and respiratory disease was indicated for virtually all parental animals evaluated histopathologically.

Adverse effects of Lasso Technical at dietary levels as high as 300 ppm on the reproductive capacity of rats were not apparent. However, this study is not concluded to be definitive according to the aforementioned reasons, particularly in regard to animal care.

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TXR-00005

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

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SUBJECT: EPA Concurrence/Non-Concurrence with  
Canadian Validation Review

FROM: Larry Anderson  
HED/TOX (TS-769)

*Larry Anderson*

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

IBT Report Number: 622-01185

Date of Final Report: 4/8/74

Type of Study: 3-Generation Reproduction in Rats

Compound: Lasso Technical

Date of Validation: 10/3/78

Validation Submitted by: Monsanto

Performed by: Monsanto, Booz - Allen and Hamilton, Inc.

EPA Accession Numbers: Reg. No. 524-285, -296, -314, -315, -316

Registrant Validation Report

IBT Report Submitted to EPA

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Reviewed for Canada by: H.M. Cunningham

Date of Canadian review: 2/8/78

**Conclusion of Canadian review:**

Despite a number of minor errors and poor animal husbandry, the overall study is scientifically acceptable to define a no effect level of 300 ppm on reproduction potential in rats.

HED Conclusion on Canadian review: \_\_\_\_\_ Accept  
\_\_\_\_\_X\_\_\_\_\_ Reject (if rejected,  
. state reasons)

This study is concluded to be invalid based on the evidence indicating poor animal care and the lack of laboratory records verifying diet preparation.

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