

SPONSOR: Lorillard

INITIATION DATE: 1-21-83

COMPLETION DATE: 3-07-83

MATERIAL: A-44

ISSUE DATE:

SUBJECT: RANGE-FINDING STUDY IN ALBINO RATS WITH A-44: PHASES I AND II  
Borrison Project No. 1488(1)  
FINAL REPORT

#### SUMMARY

A range-finding study was conducted to determine the estimated maximum tolerated dose (MTD) level for the test material, A-44. Based on the results of this study, the estimated maximum tolerated dose of A-44 is 3750 mg/kg for male and 1750 mg/kg for female rats.

#### TEST ARTICLE

The test article, A-44, is a clear liquid and was received from the sponsor in an amber glass vial on November 19, 1982 and January 28, 1983. The test article was stored under refrigeration in the container in which it was received. Methylcellulose (1%) was used as the vehicle in this study. Stability information is retained by the sponsor.

#### TEST ANIMALS

Eight male and eight female Sprague-Dawley albino rats, purchased from Charles River Breeding Laboratories (Wilmington, Massachusetts), were selected for this study. Prior to placement on study, the animals were quarantined for at least seven days and observed daily for appearance and behavior. The animals were individually housed in suspended stainless steel cages with wire mesh bottoms. Purina® Rodent Laboratory Chow® #5001 and water were available ad libitum. At the end of the quarantine period, healthy animals between 169 g and 192 g for males and 149 g and 165 g for females were assigned to

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