

ACUTE ORAL TOXICITY

AMA REF. NO. : WP96-BERN1 /LD504881 . DP

SPONSOR:DAIWA PHARMACEUTICAL CO . , LTD .

1-16-19 Sangenjaya Setagaya-ku, Tokyo 154, Japan

PRODUCT DESCRIPTION: DAI-001 Biobran (MGN-3)

AMA LAB NO . :B-4881

REFERENCE:Acute Oral Toxicity. FHSLA, 16 CFR 1500.3.

SOP REFERENCE:101 .00

ANIMALS:Healthy, young adult Wistar derived albino rats weighing between 150 to 300 grams were obtained from ACE Animals, Inc., Boyertown, Pennsylvania. Five male and five female rats were selected for each dose level chosen for this study.

PROCEDURE: Eighteen to twenty-four hours prior to dosing the rats were fasted. During the fast period water was allowed ad-libitum. After fasting rats were individually weighed. All body weights were recorded and individual doses calculated based on these weights. The test material was then made available at dose levels chosen to achieve test groups with sufficient mortality rates to permit calculation of the LD50. Once the material had been ingested completely, feed and water were provided adlibitum. The rats were individually caged and observed for mortality or other signs of gross toxicity for 14 days. At the end of the test period, all surviving animals were weighed.

CONCLUSIONS : The above material (AMA Lab No. : B-4881 , Client No. : DAI-001 Biobran) when tested as indicated herein may be regarded as NON-TOXIC according to the reference. LD50 > 36.0 g/kg.