OTHER SUPPORT:

GRAMINEX Flower Pollen Extract

Acute Oral Toxicity Study in Rats with G-63 Food Product

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Abstract

The purpose of this study was to assess the acute oral toxicity produced when the test material was administered as a single dose by the oral route (gavage) to rats.

Male and female Crl: CD (SD) rats were assigned to 3 groups (five/sex/group). Each group was given G-63 Food Product at dose levels of 2000, 3500, or 5000 mg/kg at a dose volume of 20 mL/kg.

The animals received a single dose by oral gavage. The animals were observed for 15 days postdose and then sacrificed and necropsied. No tissues were saved.

Assessment of toxicity was based on mortality, body weights, clinical observations, and macroscopic observations.

All animals survived to termination, gained weight throughout the study, and were unremarkable at necropsy except for one 3500 mg/kg male (Animal No. B04315) that had a jejunum filled with reddish-yellow, slightly viscous fluid, and one 5000 mg/kg female (Animal No. B05018) with white lesions on the left apical lobe of the lungs. These findings were not considered to be treatment related.

All animals were normal at the postdose clinical observations, the daily cageside observations, and the weekly detailed observations except for one 5000 mg/kg female (Animal No. B04323) with a sore/scab on the proximal tail at the Day 8 detailed observations and one 5000 mg/kg female (Animal No. B0518) with a sore/scab on the proximal tail that was sensitive to the touch at the Day 8 and 15 detailed observations.

In conclusion, the maximum tolerated dose when administered via oral gavage to rats as a single dose is greater than 5000 mg/kg.