

Records and Archives

observations. The internal organ weights were absolutely normal for all the animals on each treated group.

The protocol, the raw data and the final report will be preserved for 5 years at the Archives Unit of the Department. The test compounds will be stored plus 1 year after their expire date. After this period the materials will be send back to the sponsor.. Tissues preserved but not processed will be destroyed a minimum of 60 days after issue of the final report.

DISCUSSION AND CONCLUSIONS:

In this fixed dose procedure test in rat, was evaluated the acute oral toxicity of SAFE® (mycotoxins binder). All animals appeared normal by day 1 or earlier and throughout the remainder of the study. There were no clinical signs of toxicity or deaths, remarkable body weight changes or gross necropsy findings during the present study. All internal organs, of different dosed and sex groups, appeared normal and the weights were in the normal range.

The LD₅₀ of SAFE® (mycotoxins binder) was found herein to be greater than 2000 mg/kg when administered once orally via oral gavage to fasted male and female CD rats.

The product (SAFE®) category was classify as = 5/Unclassified in according to GHS [*Globally Harmonized System*] Category or Unclassified for EU category.

A handwritten signature in blue ink, appearing to read "M. Paro", written over a horizontal line.

Maurizio Dr. Paro
Study Director

12/10/2007

date