

NOTICE OF DEVIATION

Section 1 (To Be Completed By The Person Discovering The Deviation)

Study Number: TOX210

Source Document(s): ☒ Protocol ☐ SOP (List SOP Number(s)):

Describe the Requirement (give section numbers for SOPs):

Page 10 of the protocol states: "The formulated feeds will be fed for a period of 14 days."

Page 11 of the protocol states: "Body weights will be recorded daily for the duration of the 14 day study (**SOPs EQP034, TOX038**)."

Describe the Deviation: Date of Occurrence: April 5, 2008

The animals were fed formulated feed for 14 days. Therefore the final weighting should have been done on day 15 of the study to obtain body weight data resulting from the final day of exposure to the formulated feed. The last weighting took place on day 14 and the body weights resulting from the last day of feeding were not recorded on day 15.

Documented By: Paul H. Ayres

Date: Jan. 20, 2009

Section 2 (To Be Completed By The Study Director)

Describe the Corrective Action(s) To Be Taken In Response To The Deviation:

No corrective action is possible.

Assessment Of The Deviation's Impact Upon The Outcome Of The Study:

By the 13th day of the study, the patterns of body weight changes had stabilized and it does not appear that the lack of data resulting from day 14 of the feeding period would have a significant impact on the interpretation of the findings from the study. Therefore, the Study Director believes that this deviation had only a minor impact on the results and no effect on the interpretation of the data from this study.

Study Director's Signature:

Date:

DAT024.001.010904