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Re: Covance 6293-225, T-6314.1. Finalization.

Peter,

The Draft Report for Covance No.: 6329-225, Title: 13-Week Dietary Toxicity Study with N-Methyl Perfluorooctanesulfonamido Ethanol (N-MeFOSE, T-6314.1) in Rats, cannot be finalized.

The concern is over the conclusion that the NOAEL is stated to be less than 3 ppm based on overall body weight gain data (page 10). There was a decrease in overall body weight means in males only at the 30 and 100 ppm levels, and in females only at the 100 ppm level. Although the body weight gains were *statistically* significantly reduced at 3 ppm, the question is whether or not these are biologically significant in the absence of decreased overall body weight gains at 3ppm. Additionally there were no observable microscopic or clinical chemistry findings at 3 ppm in either males or females that would support the conclusion of an adverse effect at or below 3 ppm.

The conclusion that there was a body weight effect in males at the 30 and 100 ppm levels and in females at the 100 ppm level is valid. The no observable adverse effect level (NOAEL) appears to be less than 30 ppm, whereas the no observable effect level (NOEL) appears to be less than 3 ppm taking into account the apparent reduced weight gain in the 3ppm male and female dose groups. Please re-evaluate this conclusion. Individual body weight trends in the ppm dose groups may need to be analyzed for trend setting outliers?

Additionally, but in the same vein, the first sentence in the second paragraph under "Body Weights" on page 23 should indicate that body weights were lowered for males given 30 and 100 ppm, not for males given 3 ppm, as the trend downward is not significant and is only 5 % which is within biological variation.

Regards,

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Study Monitor

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