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Column E Explanations

1. Registration Number: 51-R-0103

2. Study: 2447-14945

   a. Number of animals on study: 32

   b. Number of animals retrospectively re-assigned under Column E conditions in this study: 1

   c. Species (common name) of animals used in the study: Rabbit

   d. Explain the procedure producing pain and/or distress.
   The purpose of this study was to determine the potential maternal and/or developmental toxicity of the test substance in pregnant New Zealand white rabbits when administered via daily oral gavage during the embryo-fetal development period from gestational day (GD) 7 through 28. The study was a dose range finding study where the data was used to establish dose levels for the definitive embryo-fetal developmental toxicity study required by ECHA in accordance with OECD 414. The test substance (chemical) had never been administered to rabbits previously and had the potential to cause toxicity after administration.

   e. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and or distress relief would interfere with test results. (For Federally mandated testing, see item 7 below).
   Data reports (food consumption, body weights, physical examinations) were reviewed daily for health monitoring purposes. Test substance related effects of decreased pelleted food consumption, body weight loss and decreased fecal output were observed. Supportive veterinary treatments included daily supplemental foods, critical care and SC fluids. Euthanasia of groups, discontinuance of test substance administration, lowering of dose levels and early termination of the study was performed. Despite veterinary supportive treatments, one mid high dose rabbit was found dead at the morning cage side observations on Gestation Day 12. This death was attributed to the relatively acute and cumulative toxicity of administration of the chemical test substance. Pain or distress relief would not have interfered with test results (supportive treatments were provided), but the rabbit was found dead acutely and before the necessity for euthanasia was determined.

   f. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR), title number, and the specific section number (e.g., APHIS, 9 CFR 113.102): No US federal regulations; European Chemical Agency (ECHA) required testing in accordance with OECD 414 Prenatal Developmental Toxicity Testing Guidelines and this study was performed to select dose levels.

3. Study: 1745-19051

   a. Number of animals on study: 94

   b. Number of animals retrospectively re-assigned under Column E conditions in this study: 6

   c. Species (common name) of animals used in the study: Rabbit

f. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR), title number, and the specific section number (e.g., APHIS, 9 CFR 113.102): European Chemical Agency (ECHA) required testing in accordance with OECD 414 Prenatal Developmental Toxicity Testing Guidelines. In addition, the study design was based on the following guidelines United States Environmental Protection Agency (USEPA). Prenatal Developmental Toxicity Test Guideline OPPTS 870.3700 and The Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) Notification of 12 Nousan-8147, Guideline 2-1-18, Teratogenicity study.