

B. P Generation Female Rats**B.1. Mortality and Clinical Observations - P Generation Female Rats (Summary - Table C1; Individual Data - Table C24)****B.1.a. Mortality**

No deaths related to the test substance occurred.

One P generation female rat in each of the 0 and 1 mg/kg/day dosage groups were moribund sacrificed. The moribund conditions of these rats were attributed to accidents resulting in a broken palate or a fractured limb, respectively. Observations in these rats are described below. All other P generation female rats survived to scheduled sacrifice.

P generation female rat 13804 in the vehicle control group was moribund sacrificed on DS 68. This rat was administered 67 daily dosages of the vehicle. Adverse clinical observations before sacrifice included chromorhinorrhea, chromodacryorrhea, swollen snout, misaligned upper incisors and broken palate on DS 68. This rat gained weight from DSs 1 to 64 and feed consumption values were unremarkable. Necropsy confirmed the clinical signs. All other tissues examined appeared normal at necropsy.

P generation female rat 13836 in the 1 mg/kg/day dosage group was moribund sacrificed on DS 59. This rat was administered 59 daily dosages of the test substance. Adverse clinical observations before sacrifice included a swollen left forelimb and paw on DSs 57 to 59 and fractured left forelimb on DS 59. This rat gained weight from DSs 1 to 57 and feed consumption values were unremarkable. Necropsy revealed a broken radius and ulna in the left forelimb. All other tissues examined appeared normal at necropsy.

P generation female rat 13822 in the vehicle control group was sacrificed on DL 8 and dam 13852 in the 1 mg/kg/day dosage group was sacrificed on DL 11. The litters from these two dams were inadvertently mixed together. Both dams and litters were sacrificed because it was not possible to identify to which litter the pups belonged.

P generation female rat 13822 in the vehicle control group was sacrificed on DL 8. This rat was administered 101 daily dosages of the vehicle. Adverse clinical observations before sacrifice included a scab on a forelimb on DSs 15, 16 and 22 to 26. Body weight gains and feed consumption values throughout the prehabitation, gestation and lactation periods were unremarkable. All tissues examined appeared normal at necropsy. This dam delivered 12 normal pups that appeared normal at necropsy.

P generation female rat 13852 in the 1 mg/kg/day dosage group was sacrificed on DL 11. This rat was administered 102 daily dosages of the test substance. There were no adverse clinical observations before death. Body weight gains and feed consumption values throughout the prehabitation, gestation and lactation periods were unremarkable. All tissues examined appeared normal at necropsy. This dam delivered 12 pups, one pup had a mass on the forelimb on DLs 5 to 6. All pups appeared normal at necropsy.