

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.3700	Prenatal developmental in rodents (rats)	<p><i>Maternal</i> NOAEL = 250 mg/kg/day LOAEL was not established.</p> <p><i>Developmental</i> NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidence of fetal variations: hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubis; and reduced number of thoracic vertebral and rib ossification sites</p>
870.3700	Prenatal developmental in non-rodents (rabbits)	<p><i>Maternal</i> NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on increased abortions, clinical signs (hematuria and decreased feces), and reduced body weight gain</p> <p><i>Developmental</i> NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on increased resorptions, decreased live fetuses per litter, and decreased fetal weights</p>
870.3800	2-Generation reproduction and fertility effects (rats)	<p><i>Parental/Systemic</i> NOAEL = 14 mg/kg/day for males and 16 mg/kg/day for females LOAEL = 33 mg/kg/day for males and 40 mg/kg/day for females based on decreased maternal body weight/body weight gain during gestation in both generation (P and F1) and reduced pre-mating body weight gain in second generation (F1) males</p> <p><i>Reproductive</i> NOAEL = 14 mg/kg/day for males and 16 mg/kg/day for females LOAEL = 33 mg/kg/day for males and 40 mg/kg/day for females based on increased duration of gestation in females and degeneration and/or atrophy of the germinal epithelium of the testes and oligospermia and intratubular degenerated seminal material in the epididymis of F1 males</p> <p><i>Offspring</i> NOAEL = 14 mg/kg/day for males and 16 mg/kg/day for females LOAEL = 33 mg/kg/day for males and 40 mg/kg/day for females based on reduced prenatal viability (fetal and litter), reduced litter size, increased number of stillborn pups, reduced pup and litter postnatal survival and decreased pup body weights throughout lactation</p>
870.3800	Reproduction and fertility effects (rat) Nonguideline	<p><i>Parental/Systemic</i> NOAEL = 20 mg/kg/day LOAEL = 51 mg/kg/day (F1 females) based on decrease in pre-mating body weight gain (10%)</p> <p><i>Offspring and Reproductive</i> NOAEL = 16 mg/kg/day LOAEL = 40 mg/kg/day based on reduced gestation day 20 fetal weights; decreased postnatal day 0, 4 and 7 pup weights; decreased pup survival; delayed vaginal patency; reduced epididymal, prostate, and testicular weights</p> <p>Additional information supports the conclusions reached in the 2-generation reproduction study in rats</p>