

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

Guideline No.	Study Type	Results
870.3100	Subchronic feeding studies in rats	NOAEL = 206.7/223.0 mg/kg/day (M/F) LOAEL = 660.6/708.9 mg/kg/day (M/F) based on decreased body weight (bwt) gains; decreased erythrocyte counts, hemoglobin and hematocrit values; and increased reticulocyte counts and mean corpuscular volume
870.3150	Subchronic feeding-dogs	NOAEL = 80.5/81.2 mg/kg/day (M/F) LOAEL = 341.0/336.1 mg/kg/day (M/F) based on increased absolute and relative liver weights and alkaline phosphatase activities in both sexes; focal liver lesions in females; slight anemia in both sexes; decrease in mean bwt and bwt gain in females and decreased food consumption in both sexes
870.3200	28-Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day highest dose tested (HDT) LOAEL was not determined, but would be greater than the NOAEL
870.3700	Developmental toxicity in rodents (rat)	Maternal NOAEL < 1,000 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decrease in body weight gain and food efficiency during the first week of treatment and on increase in absolute and relative spleen weights Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL = Not determined but would be greater than the NOAEL. Note that only one dose was tested
870.3700	Postnatal developmental toxicity in rodents (rat)	Maternal NOAEL < 1,000 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decrease in bwt gain and food efficiency during the first week of treatment Developmental NOAEL < 1,000 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on marginal decreases in fetal bwt and bwt gain during lactation. Note that only one dose was tested
870.3700	Developmental Toxicity in nonrodents (rabbit)	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 250 mg/kg/day based on higher rate of abortions and marginal decreases in body-weight gain, food efficiency index and food consumption Developmental NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day based on higher rate of abortions
870.3800	Reproduction and fertility effects	Parental-Offspring/Systemic NOAEL = 57.3/76.0 mg/kg/day (M/F) Parental-Offspring/Systemic LOAEL = 306.0/392.0 mg/kg/day (M/F) based on decrease mean bwt and mean bwt gain in parents and offspring and an increase in mean spleen weight an increase in the severity (but not in the incidence) of splenic extramedullary hematopoiesis in females. Reproductive NOAEL = 306.0/392.0 mg/kg/day (M/F): HDT Reproductive LOAEL was not determined but would be greater than the NOAEL
870.4100	Chronic-feeding toxicity-dogs	NOAEL = 51.4/57.6 mg/kg/day (M/F) LOAEL = 260.2/282.2 mg/kg/day (M/F) based on high ALP levels and increased absolute and relative liver weights in both sexes and grade 1 (minimal) intrahepatic cholestasis in the liver: 2/sex
870.4300	Chronic Toxicity-Carcinogenicity rats	NOAEL = 48.5/60.0 mg/kg/day (M/F) LOAEL = 251.6/318.0 mg/kg/day (M/F) based on significant increases in reticulocyte counts
870.4300	Carcinogenicity mice	NOAEL = 350.8/463.4 mg/kg/day (M/F) LOAEL = (M/F) not determined, however, study considered adequate for carcinogenicity based on results of subchronic study
870.5265	Gene Mutation <i>Salmonella</i> and <i>E. Coli</i>	Non-mutagenic with or without activation
870.5300	Gene Mutation HGPRT with V79 cells	Non-mutagenic with or without activation
870.5375	Chinese Hamster Lung Fibroblast Assay	No clastogenic response with or without activation