

available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for a tolerance for residues of butafenacil and CGA-293731 on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 0.05 parts per million (ppm); in or on cattle, liver; goat, liver; hog, liver; horse, liver; and

sheep, liver at 0.50 ppm; and tolerances for residues of butafenacil in or on cotton, undelinted seed at 0.50 ppm; and in or on cotton, gin byproducts at 10 ppm. EPA's assessment of exposures and risks associated with establishing these tolerances follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the

studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by butafenacil are discussed in Table 1 of this unit as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—ACUTE TOXICITY OF BUTAFENACIL

Guideline number	Study Type	Results	Toxicity Category
870.1100	Acute oral	Lethal dose (LD) ₅₀ >5,000 milligrams/kilogram (mg/kg) male and female (M/F)	IV
870.1200	Acute dermal	LD ₅₀ >2,000 mg/kg M/F	III
870.1300	Acute inhalation	Lethal concentration (LC) ₅₀ >5.10 milligrams per Liter (mg/L)	IV
870.2400	Primary eye irritation	Ocular irritation resolved within 96 hours	III
870.2500	Primary skin irritation	Not an irritant	IV
870.2600	Dermal sensitization	Not a sensitizer	Not Applicable (NA)

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline number	Study Type	Results
870.3100	90-Day oral (dietary) toxicity rodents (rat)	NOAEL = 300 ppm (18.8/20.6 mg/kg/day M/F) LOAEL = 1,000 ppm (62.3/69.3 mg/kg/day M/F), based on decreased body weight gains, decreased hemoglobin, hematocrit, mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), increased red cell volume, increased bone marrow hypercellularity; increased bilirubin and urobilinogen; increased alanine aminotransferase; hepatocyte necrosis; inflammatory liver cell infiltration
870.3100	90-Day oral (dietary) toxicity in rodents (mouse)	NOAEL = 30 ppm (4.11/5.67 mg/kg/day M/F) LOAEL = 100 ppm (13.8/20.1 mg/kg/day M/F), based on hepatic histopathology: fatty change, glycogen deposition, and hypertrophy in both sexes
870.3150	90-Day oral (capsule) toxicity in non-rodents (dog)	NOAEL = 200 mg/kg/day M/F LOAEL = 1,000 mg/kg/day M/F, based on decreases in MCV and MCH in males; increases in RDW, HDW, platelets and triglycerides in males; and hemosiderosis in spleen and liver and extramedullary hematopoiesis the spleen in males
870.3200	28-Day dermal toxicity (rat)	NOAEL = 1,000 mg/kg/day LOAEL = not determined
870.3700	Prenatal developmental toxicity in rodents (rat)	Maternal NOAEL = 1,000 mg/kg/day Maternal LOAEL = not determined Developmental NOAEL = 1,000 mg/kg/day Developmental LOAEL = not determined
870.3700	Prenatal developmental toxicity in non-rodents (rabbit)	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decreased body weight gains and food consumption during the treatment period, and on blood-stained vaginal discharge (related to total litter loss) in two doses Developmental NOAEL = 100 mg/kg/day Developmental LOAEL = 1,000 mg/kg/day based on increased early resorptions and post-implantation loss