

retaining the thiazolidine ring intact, measured and expressed in terms of thiacloprid, *per se* on apple, wet pomace; cattle, sheep, goat and horse meat; meat byproducts; liver; kidney; and fat; cotton, undelinted seed; cotton, gin byproducts; fruit, pome, group 11; and milk at 0.6; 0.03; 0.05; 0.15; 0.05; 0.02; 0.02; 11.0; 0.3; and 0.03 ppm, respectively. EPA's assessment of

exposures and risks associated with establishing the tolerance 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 thiacloprid are discussed in Table 2 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 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = rats: males, 7.3 mg/kg/day ; females, 7.6 mg/kg/day; mice, females, 27.3 mg/kg/day ; males 102.6 milligram/kilogram/day (mg/kg/day) LOAEL = rats: males, 28.6 mg/kg/day; females, 35.6 mg/kg/day; mice: females, 27.2 mg/kg/day; males, 542.4 mg/kg/day based on rats: decreased body weight throughout treatment: mice: females based on adrenal X-zone changes. males based on liver effects (weight and hypertrophy).
870.3150	90-Day oral toxicity in nonrodents	NOAEL = males, 8.5, females, 8.9 mg/kg/day LOAEL = ~34.9 mg/kg/day based on mainly liver enzyme changes, thyroid hormone level (T4) and binding capacity changes and prostatic weight change and prostatic hypertrophy.
870.3200	21/28-Day dermal toxicity	NOAEL = females, 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on liver and thyroid effects and clinical signs.
870.3465	28 Day inhalation toxicity	NOAEL = 0.542 mg/kg/day LOAEL = 4.93 mg/kg/day based on [liver effects (hypertrophy and increased N-DEM).
870.3700	Prenatal developmental in rodents	Maternal NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on decreased body weights, body weight gains, food consumption, increased urination, and changes in water consumption. Developmental NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on increased resorptions (complete and late), skeletal retardations, variations (wavy ribs and asymmetrical sternbrae), and malformations (dysplastic humerus, radius, and scapulae) and on decreased fetal weights
870.3700	Prenatal developmental in nonrodents	Maternal NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on decreased body weight gains, food consumption, and fecal output. Developmental NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on decreased fetal weights
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = males, 3.5 mg/kg/day LOAEL = 21 mg/kg/day based on increased liver and thyroid weights and on hepatocytomegaly, liver necrosis, and thyroid follicular cell hypertrophy. Reproductive NOAEL = females, 4 .2 mg/kg/day LOAEL = 26 mg/kg/day based on dystocia Offspring NOAEL = females, 4.2 mg/kg/day LOAEL = females, 21 mg/kg/day based on decreased pup weight during lactation.
870.4100	Chronic toxicity dogs	No firm LOAEL was established for this chronic feeding study with dogs; 1,000 ppm highest dose tested (HDT). There were no effects that were of sufficient magnitude or consistency to justify that they were definite responses to treatment. Certain effects noted in the subchronic dog study on the prostate and other male organs and an apparent effect on uterine weight in the subchronic dog study were not seen in this chronic study. This may be because the dogs in this study had reached maturity
870.4300	Combined chronic feeding/carcinogenicity rats	NOAEL = males, 1.2 mg/kg/day ; females, 1.6 mg/kg/day LOAEL = males, 2.5 mg/kg/day; females, 3.3 mg/kg/day based on [liver toxicity (hepatocellular hypertrophy and cytoplasmic change and increased enzyme activity), thyroid follicular epithelial hypertrophy in males and ocular toxicity (retinal atrophy) in females Evidence of carcinogenicity based on increased incidence of thyroid follicular cell adenomas in males and possibly also in females and increased incidence of uterine tumors (adenocarcinomas)