

exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 of the FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the 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 folpet on hop, dried cones at 100 ppm. 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 folpet 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.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 160 milligrams/kilogram/day (mg/kg/day) LOAEL = 500 mg/kg/day based on 5 percent decrease in body weight
870.3150	90-Day oral toxicity in nonrodents	NOAEL = <790 mg/kg/day (lowest dose tested)(LDT) LOAEL = 790 mg/kg/day based on decreased weight gain in males and females, testicular atrophy in males
870.3200	28-Day dermal toxicity	NOAEL = 1 mg/kg/day LOAEL = 10 mg/kg/day based on dermal irritation; systemic toxicity as reduced body weight gain occurred only at doses greater than 10 mg/kg/day
870.3700	Prenatal developmental in rodents Crl: COBS-CD-(SD) BR strain.	Maternal NOAEL = 10 mg/kg/day LOAEL = 60 mg/kg/day based on reduced body weight Developmental NOAEL = 60 mg/kg/day LOAEL = 360 mg/kg/day based on possible incomplete ossification of one or both pubes and/or eschia
870.3700	Prenatal developmental in rodents CD Rats	Maternal NOAEL = 150 mg/kg/day LOAEL = 550 mg/kg/day based on decreased body weight gain, soft feces Developmental NOAEL = <150 mg/kg/day (LDT) LOAEL = 550 mg/kg/day based on small fetuses, reduced ossification of interparietal bone as well as increase in angulated ribs
870.3700	Prenatal developmental in nonrodents HY/CR Albino Rabbits	Maternal NOAEL = 40 mg/kg/day LOAEL = 160 mg/kg/day based on decrease in body weight gain and food consumption Developmental NOAEL = 10 mg/kg/day LOAEL = 40 mg/kg/day based on delayed ossification of sternbrae and lack of ossification of caudal vertebrae distal to caudal vertebra 15.
870.3700	Prenatal developmental in nonrodents NZW Rabbits	Maternal NOAEL = 10 mg/kg/day LOAEL = 20 mg/kg/day based on decreased food consumption & body weight gain during gestation. At 60 mg/kg/day, decreased food consumption & body weight gain, hydrocephalus and related skull malformations. Developmental NOAEL = 10 mg/kg/day LOAEL = 20 mg/kg/day based on Increased incidence of hydrocephalus & domed skull & irregularly shaped fontanelles
870.3800	Reproduction and fertility effects Charles River Rat	Parental/Systemic NOAEL = 19.1 mg/kg/day in males; 22.5 mg/kg/day in females LOAEL = 112 mg/kg/day in males and 134 mg/kg/day in females based on diffuse hyperkeratosis of the non-glandular epithelium of in both sexes of both generations. Reproductive NOAEL = 370 mg/kg/day in males; 436 mg/kg/day in females highest dose tested (HDT) Offspring NOAEL = 112 mg/kg/day in males and 134 mg/kg/day in females LOAEL = 370 mg/kg/day in males and 565 mg/kg/day in females based on lower pup body weights primarily in the F1 litter generation