

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR SULFENTRAZONE FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-50 years of age)	NOAEL = 25 mg/kg/day UF = 100 Acute RfD = 0.25 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/ FQPA SF = 0.25 mg/kg/day	Developmental toxicity study in rats LOAEL = 50 mg/kg/day based on decreased live fetuses, and increased early resorptions
Acute dietary (general population including infants and children)	NOAEL = 250 mg/kg/day UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 1X aPAD = acute RfD/ FQPA SF = 2.5 mg/kg/day	Acute neurotoxicity study in rats LOAEL = 750 mg/kg/day based on increased incidence of clinical signs and FOB parameters and decreased motor activity.
Chronic dietary (all populations)	NOAEL = 14 mg/kg/day UF = 100 Chronic RfD = 0.14 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD/ FQPA SF = 0.14 mg/kg/day	2-Generation reproduction study LOAEL = 33 mg/kg/day based on decreased body weight and body weight gains
Short-term (1 to 30 days) and intermediate-term (1 to 6 months) incidental oral	Offspring NOAEL = 14 mg/kg/day	LOC for MOE = 100 (Residential)	2-Generation reproduction study LOAEL = 33 mg/kg/day based on decreased pup body weights during lactation in both generations
Short-term dermal (1 to 30 days), intermediate-term dermal (1 to 6 months) and long-term dermal (>6 months)	Dermal study NOAEL = 100 mg/kg/day (dermal absorption rate = 10%)	LOC for MOE = 100 (Residential)	Dermal developmental study in rats LOAEL = 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal variations: hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubes; and reduced number of thoracic vertebral and rib ossification sites
Short-term inhalation (1 to 30 days), intermediate-term inhalation (1 to 6 months) and long-term inhalation (> 6 months)	Oral study NOAEL = 14 mg/kg/day (inhalation rate = 100%)	LOC for MOE = 100 (Residential)	2-Generation reproduction study LOAEL = 33 mg/kg/day based on decreased body weight and body weight gains
Cancer (oral, dermal, inhalation)	Not applicable	Not applicable	No evidence of carcinogenicity in rats and mice

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.498) for the combined residues of sulfentrazone, in or on soybean, seed at 0.05 ppm. Time-limited tolerances (set to expire on December 31, 2004) are established in connection with section 18 emergency exemptions for bean, succulent seed without pod at 0.1; horseradish, roots at 0.1 ppm; chickpea, seed at 0.10 ppm; pea, dry, seed 0.10 ppm; potato at 0.10 ppm; potato, wet peel at 0.15; flax, seed at 0.20 ppm; potato, granules/flakes at 0.20 ppm; strawberry at 0.60 ppm. Time-limited tolerances (set to expire on December 31, 2005) are established in connection with section 18 emergency exemptions for sugarcane at 0.05 ppm and sunflower at 0.1 ppm. Tolerances are also established for indirect or inadvertent residues in or on cereal

grain (excluding sweet corn). Risk assessments were conducted by EPA to assess dietary exposures from sulfentrazone in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In conducting the acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM™) which incorporates food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. Separate Tier I, acute dietary exposure assessments

were performed for females 13 to 49 years old and for the general U.S. population (including infants and children) using tolerance-level residues and 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment EPA used the DEEM™ software with the Food Commodity Intake Database which incorporates food consumption data as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. An unrefined, Tier I chronic dietary exposure assessment was performed using tolerance-level residues and 100 PCT.

2. *Dietary exposure from drinking water.* Sulfentrazone and the degradate 3-carboxylic acid sulfentrazone are the residues of concern for the drinking-water risk assessment. Environmental