

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

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13-49)	Developmental NOAEL = 50 mg/kg/day UF = 100 Acute RfD = 0.5 mg/kg	Special FQPA SF = 1 aPAD = acute RfD/Special FQPA SF = 0.5 mg/kg	Developmental Toxicity Study in Rabbits. Developmental LOAEL = 100 mg/kg/day based on increased incidence of abnormal shaped hearts in fetuses.
Acute dietary (general population)	NOAEL = 600 mg/kg UF = 100 Acute RfD = 6.0 mg/kg	Special FQPA SF = 1 aPAD = acute RfD/Special FQPA SF = 6.0 mg/kg	Acute Neurotoxicity Studies in Rats. LOAEL = 2,000 mg/kg based on decreased motor activity on day 1 and histopathological lesions in nervous system tissues of males and females.
Chronic dietary (all populations)	NOAEL = 23.7 mg/kg/day UF = 100 Chronic RfD = 0.237 mg/kg/day	Special FQPA SF = 1 cPAD = chronic RfD/Special FQPA SF = 0.237 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Study in Rats. LOAEL = 99.3 mg/kg/day based on increased tubular atrophy in the kidneys of females (developing after 12 months).
Incidental oral short-term (1 - 30 days)	Offspring NOAEL = 78.8/83.5 (M/F) mg/kg/day	Residential LOC for MOE = 100	2-Generation Reproduction Study in Rats. Offspring LOAEL = 631/676 (M/F) mg/kg/day based on decreased pup body weights on day 21.
Dermal short-term (1 - 30 days)	Dermal study Systemic NOAEL = 100 mg/kg/day	Residential LOC for MOE = 100	28-Day Dermal Toxicity Study in Rats. Systemic LOAEL = 1,000 mg/kg/day based on decreased body weight gain in females.
Inhalation short-term (1 - 30 days)	Oral study NOAEL = 50 mg/kg/day (inhalation absorption factor = 100%)	Residential LOC for MOE = 100	Developmental Toxicity Study in Rabbits. LOAEL = 100 mg/kg/day based on increased incidence of abnormal shaped hearts in fetuses.
Cancer (oral, dermal, inhalation)	Classification: Not Likely to be carcinogenic to humans		

*The reference to the Special 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.* No tolerances have been previously established for trifloxysulfuron. Tolerances being established under § 180.591 include almond; almond hulls; cotton, undelinted seed; cotton, gin byproducts; fruit, citrus, Group 10; sugarcane, and tomato. No tolerances are required for meat, milk, poultry or eggs. Risk assessments were conducted by EPA to assess dietary exposures from trifloxysulfuron 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. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption 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. The following assumptions were made for the acute exposure assessments: 100% of the crops from registered uses are treated and that residues of trifloxysulfuron are at tolerance levels. Anticipated residues were not used.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996 and 1998 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: 100% of the crops from registered uses are treated and that residues of trifloxysulfuron are at tolerance levels. Anticipated residues were not used.

iii. *Cancer.* Trifloxysulfuron has been classified as “not likely to be carcinogenic in humans.” Therefore a quantitative assessment of aggregate cancer risk was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for trifloxysulfuron in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of trifloxysulfuron.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentrations in