

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLOXYSTROBIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	*Special FQPA SF and LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary females 13–49 only.	NOAEL = 250 mg/kg/day UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 1X aPAD = aRfD ÷ FQPA SF = 2.5 mg/kg/day	Developmental toxicity-Rat LOAEL = 500 mg/kg/day, based upon increased fetal skeletal anomalies
Acute dietary general population including infants and children.	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including maternal effects in developmental studies in rats and rabbits. Therefore, a dose and endpoint were not identified for this risk assessment		
Chronic dietary all populations.	Parental NOAEL = 3.8 mg/kg/day UF = 100 Chronic RfD = 0.038 mg/kg/day	FQPA SF = 1X cPAD = cRfD ÷ FQPA SF = 0.038 mg/kg/day	2-generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon decreases in body weight, body weight gains, reduced food consumption and histopathological lesions in the liver, kidneys and spleen
Short-Term Oral (1–30 days). Intermediate-Term Oral (1–6 months)	Offspring NOAEL = 3.8 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	2-Generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Short-Term Dermal (1–30 days). Intermediate-term dermal (1–6 months)	Dermal study NOAEL = 100 mg/kg/day	LOC for MOE = 100 (Residential, includes the FQPA SF)	28-Day dermal toxicity study-Rat LOAEL = 1,000 mg/kg/day, based upon increases in mean absolute and relative liver and kidney weights
Long-term dermal (>6 months).	Oral study NOAEL = 3.8 mg/kg/day (dermal absorption rate = 33%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2-Generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Short-term inhalation (1–30 days). Intermediate-Term Inhalation (1–6 months) Long-Term Inhalation (> 6 months)	Oral study NOAEL = 3.8 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential, includes the FQPA SF)	2-Generation reproduction study-Rat LOAEL = 55.3 mg/kg/day, based upon reduced pup body weights during lactation
Cancer (oral, dermal, inhalation).	Trifloxystrobin is classified as “Not Likely Human Carcinogen” based on the lack of evidence of carcinogenicity in mouse and rat cancer studies		

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.555) for the residues of trifloxystrobin, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from trifloxystrobin 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 this acute dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Data base (DEEM-FCID®) which incorporates food consumption data as reported by respondents in the 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 assessment: The acute dietary exposure analysis for trifloxystrobin is a Tier I assessment because no additional data were used to refine the analysis. One hundred percent of proposed and registered crops are assumed treated with trifloxystrobin (“100% CT”), and tolerance-level residues were used in the analysis.

ii. *Chronic exposure.* In conducting this acute dietary risk assessment EPA used the DEEM® software with the DEEM-FCID® 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. The following assumptions were made for the chronic exposure assessment: The chronic dietary exposure analysis for trifloxystrobin is a Tier I assessment because no additional data were used to refine the analysis. One hundred percent of proposed and registered crops are assumed treated with trifloxystrobin, and tolerance-level residues were used in the analysis.

iii. *Cancer.* The Agency determined that trifloxystrobin should be classified as a “Not Likely Human Carcinogen.”

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for trifloxystrobin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates