

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FLUFENPYR-ETHYL FOR USE IN HUMAN HEALTH RISK ASSESSMENT¹

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF ² and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (females 13–50 years of age)	NOAEL = None mg/kg/day UF = N/A Acute RfD = None	Special FQPA SF = 1x aPAD = acute RfD Special FQPA SF = None	A dose and endpoint of concern attributable to a single dose was not available in the data base including the developmental toxicity studies
Acute dietary (general population including infants and children)	NOAEL = None mg/kg/day UF = N/A Acute RfD = None	FQPA SF = 1x aPAD = acute RfD Special FQPA SF = None	A dose and endpoint of concern attributable to a single dose was not available in the data base including the developmental toxicity studies
Chronic dietary (all populations)	NOAEL = 40 mg/kg/day UF = 100 Chronic RfD = 0.4 mg/kg/day	Special FQPA SF = 1x cPAD = chronic RfD Special FQPA SF = 0.4 mg/kg/day	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Short-term Incidental oral (1–30 days)	NOAEL = 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Developmental toxicity study - rabbit LOAEL = 300 mg/kg/day, based on clinical signs, decreased food consumption and necropsy findings
Intermediate-term Incidental oral (1–6 months)	NOAEL = 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Developmental toxicity study - rabbit LOAEL = 300 mg/kg/day, based on clinical signs, decreased food consumption and necropsy findings
Dermal all durations	HIARC concluded quantitation of dermal risk is not required due to lack of systemic toxicity at the limit-dose following repeated dermal exposures as well as lack of concern for developmental toxicity		
Short-term inhalation (1–30 days)	NOAEL = 40 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Intermediate-term inhalation (1–6 months)	NOAEL = 40 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Long-term inhalation (>6 months)	NOAEL = 40 mg/kg/day (inhalation absorption rate = 100%)	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Carcinogenicity study - mice LOAEL = 401.8 mg/kg/day based on liver toxicity (hepatocyte necrosis) in both sexes and mild anemia in males
Cancer (oral, dermal, inhalation)	Flufenpyr-ethyl classified as “not likely to be carcinogenic to humans.”		

¹ UF = uncertainty factor, FQPA SF = Special FQPA safety factor, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

² 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 the residues and the combined residues of flufenpyr-ethyl, in or on raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from flufenpyr-ethyl 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. An endpoint of concern attributable to a single oral dose was not identified for either the general U.S. population (including infants and children) and all population subgroups, or the females 13–50 years old population subgroup for flufenpyr-ethyl; therefore, an acute dietary exposure analysis was not performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEMTM) analysis evaluated the individual food consumption as

reported by respondents in the U.S. 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 chronic exposure assessments: An unrefined, chronic dietary exposure assessment was conducted for the general U.S. population and various population subgroups. Proposed tolerance-level residues and 100 percent crop treated (%CT) information were used for all