

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

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1 – 30 Days) Residential Only	NOAEL = 2.21 mg ai/kg/day UF = 300	FQPA SF = 1X LOC for MOE = 300	90-Day Oral Study in Dogs LOAEL = 4.42 mg ai/kg/day based on observations of increased incidence of tremors in both sexes.
Incidental Oral Intermediate-Term (1 – 6 Months) Residential Only	NOAEL = 2.21 mg ai/kg/day UF = 300	FQPA SF = 1X LOC for MOE = 300	90-Day Oral Study in Dogs LOAEL = 4.42 mg ai/kg/day based on observations of increased incidence of tremors in both sexes.
Short-Term Dermal (1 to 30 days) (Residential)	dermal study NOAEL = 47 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	21-Day Dermal Study in Rats LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb flexion).
Intermediate-Term Dermal (1 to 6 months) (Residential)	dermal study NOAEL = 47 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	21-Day Dermal Study in Rats LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb flexion).
Long-Term Dermal (several months to lifetime) (Residential)	dermal study NOAEL = 47 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	21-Day Dermal Study in Rats LOAEL = 93 mg/kg/day based on observations of clinical signs (staggered gait and exaggerated hindlimb flexion).
Short-Term Inhalation (1 to 30 days) (Residential)	oral study NOAEL = 2.21 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	90-Day Oral Study in Dogs LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Intermediate-Term Inhalation (1 to 6 months) (Residential)	oral study NOAEL = 2.21 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	90-Day Oral Study in Dogs LOAEL = 4.42 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Long-Term Inhalation (several months to lifetime) (Residential)	oral study NOAEL = 1.3 mg/kg/day	FQPA SF = 1X LOC for MOE = 300 (Residential)	1-Year Oral Study in Dogs LOAEL = 2.7 mg/kg/day based on observations of increased incidence of tremors in both sexes.
Cancer (oral, dermal, inhalation)	EPA's Carcinogenicity Peer Review Committee (CPRC) has characterized bifenthrin as a Category C (possible human) carcinogen, primarily on the basis of the mouse carcinogenicity study in which the high-dose males (81.3 mg/kg/day) showed a highly significant increased incidence of urinary bladder tumors. Other findings in the mouse study included a dose-related trend of increased combined incidences of adenoma and adenocarcinoma of the liver (males only), and increased incidences of bronchioalveolar adenomas and adenocarcinomas of the lung in females at some, but not all, doses relative to their controls. The Agency did not recommend assignment of a Q1* but has determined that the reference dose (RfD) approach should be used for quantification of human risk.		

\*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 180.442) for the residues of bifenthrin in or on a variety of raw agricultural commodities. Tolerances have been established on plant commodities ranging from 0.05 ppm for corn grain, peas, beans and eggplant to 10 ppm for dried hops and on animal commodities ranging from 0.01 ppm for meat byproducts to 1.0 ppm for milk fat and fat of cattle, goats, hogs, horses, and sheep. Risk assessments were conducted by EPA to

assess dietary exposures from bifenthrin 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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: A probabilistic dietary exposure assessment was conducted for the general U.S. population and all population subgroups, including infants and children. The highly refined assessment incorporated the most recent USDA Pesticide Data Program (PDP) monitoring data, field trial data and processing factor data (for grapes and pending uses). It assumed 100% crop treated for the new and existing uses.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the