

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR LAMBDA-CYHALOTHRIN] 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 (General population including infants and children)	NOAEL = 0.5 mg/kg/day UF = 100 Acute RfD = 0.005 mg/kg/day	FQPA SF = 1 aPAD = acute RfD ÷ FQPA SF = 0.005 mg/kg/day	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = LOAEL = 3.5 mg/kg/day based on clinical signs of neurotoxicity (ataxia) observed from day 2, 3 to 7 hours post-dosing.
Chronic Dietary (All populations)	NOAEL= 0.1 mg/kg/day UF = 100 Chronic RfD = 0.001 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.001 mg/kg/day	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 0.5 based on gait abnormalities observed in 2 dogs
Incidental Oral Short- and Intermediate-Term (1 - 30 Days and 1 - 6 Months) Residential Only	NOAEL= 0.1	LOC for MOE = 100 (Residential)	Chronic oral study in the dog (lambda-cyhalothrin) LOAEL = 0.5 based on gait abnormalities observed in 2 dogs
Dermal (All Durations; - Short-Term (1 to 7 days) - Intermediate-Term (1 week to several months) - Long-Term (several months to lifetime) (Residential)	dermal (or oral) study NOAEL= 10 mg/kg/day	LOC for MOE = 100 (Residential)	21-Day dermal toxicity study in the rat (lambda-cyhalothrin) LOAEL = 50 mg/kg/day based on clinical signs of neurotoxicity (observed from day 2) and decreased body weight and body weight gain
Inhalation (All Durations; - Short-Term (1 to 7 days) - Intermediate-Term (1 week to several months) - Long-Term (several months to lifetime) (Residential)	inhalation (or oral) study NOAEL= 0.3 Environmental protection, Cut and past remainder of subjects. µg/L (0.08 mg/kg/day) (inhalation absorption rate = 100%)	LOC for MOE = 100 (Residential)	21-Day Inhalation Study in Rats (lambda-cyhalothrin) LOAEL = 3.3 µg/L (0.90 mg/kg/day) based on clinical signs of neurotoxicity, decreased body weight gains, increased incidence of punctuate foci in the cornea, slight reductions in cholesterol in females and slight changes in selected urinalysis parameters.
Cancer (oral, dermal, inhalation)			Classification: Group D chemical (not classifiable as to human carcinogenicity)

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

### B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Currently established tolerances for residues of lambda-cyhalothrin are listed under 40 CFR 180.438 and include permanent tolerances on plants ranging from 0.01 ppm on soybeans to 6.0 ppm on alfalfa, hay; corn, forage; and tomato, pomace (dry or wet). Tolerances are also established on animal commodities ranging from 0.01 ppm in egg; poultry, meat; and poultry, meat by-products to 5.0 ppm in milk, fat (reflecting 0.2 ppm in whole milk). The Agency has recently established additional tolerances for lambda-cyhalothrin on a number of commodities ranging from 0.05 ppm on sugarcane to 3.0 ppm on peanut, hay. Risk assessments were conducted by EPA to assess dietary exposures from lambda-cyhalothrin 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. A refined Tier 3 probabilistic acute dietary risk assessment was conducted for all currently registered and proposed lambda-cyhalothrin food uses. For the acute dietary risk analysis the entire distribution of residue field trial data was used for not-blended or partially-blended commodities; average residue field trial data was used for blended commodities; information from cooking and processing studies were used when available; and market share data for proposed and established tolerances was 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 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. For the chronic dietary risk analysis the average of the residue field trials, information from cooking and processing studies, and market share data were used.

iii. *Cancer.* The data base for carcinogenicity is considered complete, and no additional studies are required at this time. The requirements for oncogenicity studies in the rat and the mouse with lambda-cyhalothrin have been satisfied by a combined chronic/ oncogenicity study in rats and an oncogenicity study in mice, both conducted with cyhalothrin. Lambda-cyhalothrin has been classified as a Group D chemical (not classifiable as to human carcinogenicity) with regards to its carcinogenic potential.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue