

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR FENHEXAMID 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 (General Population including infants and children)	None UF = NA Acute RfD = None	FQPA SF = 1X aPAD = acute RfD ÷ FQPA SF = None	Not selected. No appropriate toxicological endpoint attributable to a single exposure was identified in the available toxicology studies.
Chronic Dietary (All populations)	NOAEL = 17 mg ai/kg/day UF = 100 Chronic RfD = 0.17 mg/kg/day	1X cPAD = chronic RfD ÷ FQPA SF = 0.17 mg/kg/day	1-Year Feeding-Dog. Decreased RBC count, hemoglobin and hematocrit and increased Heinz bodies in males and females; increased adrenal weights and intracytoplasmic vacuoles in adrenal cortex in females at the LOAEL of 124 mg/kg/day.
Short-Term (1–30 days) and Intermediate-Term (1–6 months) Dermal	NOAEL = 1,000 mg ai/kg/day Dermal absorption rate = 20%	Residential MOE = Not applicable	21-Day Dermal-Rabbit. In the developmental toxicity study in rabbits, decreased body weight gain and food consumption at LOAEL of 1,500 mg/kg/day (dermal equivalent dose using 20% dermal absorption factor); NOAEL was 500 mg/kg/day (dermal equivalent dose). Dermal exposure is not expected since there are no residential uses.
Long-Term Dermal (> 6 months)	None Dermal absorption rate = 20%	Residential MOE = Not applicable	Not selected. Long-term dermal exposure is not expected since there are no residential uses.
Short-Term (1–30 days), Intermediate-Term (1–6 months), and Long-term (> 6 months) Inhalation	None	Residential MOE = Not applicable	Not selected. Inhalation exposure is not expected since there are no residential uses.
Cancer (oral, dermal, inhalation)	None	Not applicable	Fenhexamid is classified as a “not likely” human carcinogen based on the lack of evidence of carcinogenicity in mice and rats and the lack of genotoxicity in a battery of mutagenicity studies.

\* 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 180.553) for the residues of fenhexamid, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures from fenhexamid 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. An acute risk assessment was not performed. No toxicological endpoint attributable to a single (acute) dietary exposure was identified.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (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. An unrefined, Tier 1 chronic dietary exposure assessment was performed using tolerance level residues (established and recommended) and 100% crop treated. DEEM™ default processing/concentration factors were used for all processed commodities.

iii. *Cancer.* Fenhexamid has been classified as a “not likely” human carcinogen. Therefore, a quantitative cancer dietary exposure assessment was not performed.

The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for fenhexamid 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 fenhexamid.

2. *Dietary exposure from drinking water.* The Agency uses the FQPA Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. FIRST and PRZM/EXAMS incorporate an index reservoir environment, and include a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of