

acid or methylheptyl ester, in a variety of toxicological studies has produced similar effects. The principal response to sufficiently high dosages, whether administered over the short-term or, in some cases, over a lifetime, was nephrosis. Fluroxypyr is an organic acid that is actively excreted into the urine by the kidney. Thus, the target organ and dose response relationship for fluroxypyr toxicity is entirely consistent with the data on the toxicokinetics of fluroxypyr. Metabolism studies have shown that fluroxypyr MHE is rapidly and completely hydrolyzed to fluroxypyr acid and methylheptanol.

8. *Endocrine disruption.* There is no evidence to suggest that fluroxypyr and fluroxypyr MHE have an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure—Acute dietary exposure and risk.* A Tier I acute dietary exposure and risk assessment was conducted. Potential dietary exposure and risk was estimated using DEEM™ software (Dietary Exposure Evaluation Model, Version 7.075, Novigen Sciences, Inc., Washington, DC). A deterministic analysis was conducted by combining the distribution of single-day food consumption events with residues assumed at tolerance levels for each commodity to obtain a distribution of exposure. In this report, acute dietary risk was assessed at the 95th percentile of exposure.

i. *Food.* Very conservative assumptions were made in this dietary risk assessment. The dietary exposure assessment was based on all commodities with tolerances for fluroxypyr established at 40 CFR 180.535 together with proposed tolerances for field corn, sweet corn, grain sorghum, and forage grass and hay, including revised tolerances for milk and meat. It was assumed that fluroxypyr residues were present at tolerance or proposed tolerance levels and that 100% of the crops were treated. The USDA food consumption data from 1989–92 were used by DEEM in estimating acute dietary exposure. Acute dietary risk was assessed using an acute RfD of 1.25 mg/kg/day, based on a maternal NOAEL of 125 mg/kg/day from a rat developmental toxicity study and an uncertainty factor of 100 (10X for interspecies extrapolation and 10X for intraspecies variation). There was no indication of increased susceptibility in young animals to prenatal or postnatal exposure to fluroxypyr in the toxicology studies. Therefore, an FQPA additional safety factor for infants and children was not included in this assessment. Acute dietary exposure at the 95th

percentile for females 13 to 50 years old is estimated at 0.004939 mg/kg/day, which occupies 0.4% of the acute RfD. Pregnant females are estimated to have acute dietary exposure of 0.006582 mg/kg/day at the 95th percentile, which occupies 0.53% of the acute RfD. Adverse effects are not expected for exposures occupying 100% or less of the RfD. Therefore, acute dietary exposure and risk are well within acceptable levels.

A chronic dietary assessment estimated that dietary exposure would occupy only 0.4% of the RfD for the overall U.S. population and 1.3% of the RfD for children 1 to 6 years of age, the population subgroup estimated to be most highly exposed.

ii. *Drinking water—Acute drinking water exposure and risk.* There are no established Maximum Contaminant Levels for residues of fluroxypyr in drinking water and health advisory levels for fluroxypyr in drinking water have not been established.

Potential drinking water concentrations of fluroxypyr were estimated in ground water and surface water using the Screening Concentration in Ground Water (SCI-GROW) and the Generic Expected Environmental Concentration (GENEEC) models, respectively. Both GENEEC and SCI-GROW are Tier I screening level models that use conservative assumptions. SCI-GROW estimates pesticide concentrations in shallow, highly vulnerable ground water. GENEEC simulates a 1 hectare by 2 meters deep edge of the field farm pond that receives pesticide runoff from a treated 10 hectare field. The estimated concentration of fluroxypyr in ground water according to SCI-GROW is 0.16 µg/L. The estimated peak concentration of fluroxypyr in surface water using GENEEC is 20.88 µg/L.

To calculate the Drinking Water Levels of Concern (DWLOC) for acute exposure relative to an acute toxicity endpoint, the acute dietary exposure (from the DEEM analysis) was subtracted from the acute RfD to obtain the acceptable upper limit of fluroxypyr in drinking water for acute exposure. DWLOCs were then calculated using default values for adult female body weight (60 kg) and water consumption (2 L/day).

The upper-bound estimated fluroxypyr concentration in ground water (0.16 µg/L) and surface water (20.88 µg/L) are substantially below the acute DWLOCs of 37,352 µg/L and 37,303 for females 13 to 50 years old and pregnant females, respectively. Aggregated acute fluroxypyr exposure for pregnant females and females 13 to

50 years old resulting from dietary exposure and upper-bound drinking water exposure is well within acceptable limits of exposure and risk.

The chronic DWLOC for both the overall U.S. population and children 1 to 6 years of age was over 3,000-fold greater than residue levels in surface water or ground water estimated by conservative screening-level models. Therefore, chronic exposure and risk is expected to be well within acceptable levels.

2. *Non-dietary exposure.* The proposed use of fluroxypyr on residential turf presents the potential for non-occupational, non-dietary (or residential) exposure. Transferable foliar residue data from a fluroxypyr study on turf was used instead of default residue values.

Post-application dermal exposure for adults and toddlers was estimated for the day of application (day 0) since the exposure potential is greatest at this time. Transferable residue of fluroxypyr from turf was found to range from 0.03 to 0.74% (used as a high end estimate) of the fluroxypyr applied and to dissipate with a half-life ranging from 1.4 to 2.5 days.

Homeowners may be exposed to fluroxypyr during application to turf and also may have dermal exposure due to post-application activity on the treated turf.

Homeowner exposure during the application of fluroxypyr to turf includes both dermal and inhalation exposure. Surrogate dermal and inhalation exposure data from Pesticide Handlers Exposure Database (PHED V1.1) was used in estimating applicator exposure. The PHED surrogate data used to estimate exposure assumes residential applicator attire to include short pants, short-sleeve shirt, and no gloves. The applicator exposure estimate was based on a broadcast application using a garden hose end sprayer. Applicator dermal and inhalation exposure was estimated to be 0.0986 mg/kg/day and 0.00003 mg/kg/day, respectively.

Adult post-application dermal exposure from treated turf on the day of application was estimated to be 0.0172 mg/kg/day. The combined dermal exposure from application along with post-application activity is 0.1158 mg/kg/day (0.0986 mg/kg/day + 0.0172 mg/kg/day). Oral post-application exposure is not expected for adults and was not included in this assessment. The Margin of Exposure (MOE) for dermal exposure is 8,635 and for inhalation exposure 2,666,667. These MOEs are substantially greater than 100, indicating that risk