

increased vaginal/anal bleeding at the LOAEL of 250 mg/kg/day. The developmental NOAEL was 50 mg/kg/day based on an increased incidence of abnormally shaped hearts at the LOAEL of 100 mg/kg/day (one fetus at 100 mg/kg/day). Three additional fetuses from two litters at 250 mg/kg/day also had abnormally shaped hearts. In historical control data provided by the registrant, there were no reported instances of abnormally shaped hearts. The degree of concern is low for the quantitative evidence of susceptibility seen in the rabbit developmental study because there was a clear NOAEL for this effect, only one fetus had the effect at the LOAEL, this effect was used as a toxicological endpoint in appropriate risk assessments.

- There was no evidence of increased quantitative or qualitative susceptibility in the 2-generation reproduction study in rats.
- There are no residual uncertainties for prenatal and/or postnatal toxicity.
- A developmental neurotoxicity study in rats is not required.
- The acute and chronic dietary food exposure assessments assumed tolerance level residue data and 100% crop treated. The acute and chronic risk assessments will not underestimate exposure or risk since the exposures are based on reliable data derived from studies designed to produce worst-case residues.
- The dietary drinking water assessment used concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded. Furthermore, EPA used a

highly conservative technique to estimate concentrations of non-parent residues of concern.

- The non-dietary exposure assessment will not underestimate postapplication exposure to golfers resulting from the use of trifloxysulfuron-sodium on golf course turf.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water EECs. DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined

screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to trifloxysulfuron will occupy <1% of the aPAD for the U.S. population, <1% of the aPAD for females 13-49 years, <1% of the aPAD for all infants > 1 year old and <1% of the aPAD for children 1-12 year old. In addition, there is potential for acute dietary exposure to trifloxysulfuron in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLOXYSULFURON

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	6.0	<1	6.47	0.054	210,000
All infants < 1 year old	6.0	<1	6.47	0.054	60,000
Children 1-2 year old	6.0	<1	6.47	0.054	60,000
Females 13-49 years old	0.05	<1	6.47	0.054	15,000

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to trifloxysulfuron from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for females 13-49 years, <1% of the

cPAD for all infants > 1 year old and <1% of the cPAD for children 1-2 years old. Based the use pattern, chronic residential exposure to residues of trifloxysulfuron is not expected. In addition, there is potential for chronic dietary exposure to trifloxysulfuron in

drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 4 of this unit: