

associated processed commodities, citrus, almonds and tomatoes. Acute exposure to the female population (13–50 years old) was compared to a RfD of 0.30 mg/kg/bwt/day based on a NOAEL of 30 mg/kg/bwt/day from a rat teratology study and a 100X uncertainty factor. Acute exposure to the general population and all other population subgroups (including infants and children) was compared to a RfD of 6.0 mg/kg/bwt/day based on a NOAEL of 600 mg/kg/bwt/day from an acute neurotoxicity study in rats and a 100X uncertainty factor. The analyses were conducted using the Dietary Exposure Evaluation Model (DEEM™) from Novigen Sciences and the USDA's 1994–96 CSFII. Secondary residues in animal commodities were not considered in this evaluation since calculations showed that transfer from livestock and poultry was minimal and would result in residue levels significantly below current analytical method capabilities. The acute exposures are presented at the 99.9th percentile of exposure although the Agency accepts the 95th percentile when conservative Tier I estimates are made (tolerance-based residues and 100% crop treated assumptions). Even at the 99.9th percentile, exposure and subsequent risk was found to be 0.2% of the acute reference dose (aRfD) for the female population (13–19 years not pregnant or nursing) and essentially zero with less than 0.1% of the aRfD utilized for all other populations. These exposure calculations are conservative in that 100% of the crop was assumed as treated, and tolerance-based residue levels were entered into the dietary model.

ii. *Drinking water.* For chronic exposure in water, the estimated maximum concentrations of trifloxysulfuron-sodium in surface water at day 56/3 was 0.35 parts per billion (ppb) generic expected environmental concentration (GENEEC) (sugarcane) and 0.051 ppb in ground water (SCI-GROW) (turf). The chronic drinking water levels of concern (DWLOC) values were calculated and compared to these estimated water concentrations. From the chronic dietary exposure analysis, an exposure estimate of 0.000015 mg/kg/day was determined for the U.S. population and less than or equal to 0.000037 mg/kg/day for all subgroups. Using this information, chronic drinking water levels of concern (DWLOC_{chronic}) were calculated for trifloxysulfuron-sodium. The trifloxysulfuron-sodium estimated ground water (0.051 ppb) and surface water (0.35 ppb) concentrations do not exceed the calculated chronic

DWLOC values (µg/L): 1,500 to 5,250). Therefore, trifloxysulfuron-sodium exposures would not exceed the exposure allowable by the chronic risk cup.

The estimated maximum proposed rates for the “worst case” estimation of the proposed use concentrations of trifloxysulfuron-sodium in surface water at Peak Day–0 was 2.56 ppb GENEEC (sugarcane) and 0.051 ppb in ground water (SCI-GROW) (turf). The acute DWLOC values were calculated and compared to these estimated water concentrations.

From the acute dietary exposure analysis, the lowest margin of exposure (MOE) from the use of trifloxysulfuron-sodium was at the 95th percentile for the U.S. population and all population subgroups. This indicates a food exposure of less than or equal to 0.00016 mg/kg/day for all populations. Based on the EPA's “Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments” document (draft 12/2/97), acute drinking water levels of concern (DWLOC_{acute}) were calculated for trifloxysulfuron-sodium. The lowest acceptable MOE for any pesticide is 100. This value was used in the DWLOC calculations. Based on this analysis, trifloxysulfuron-sodium estimated surface water (2.56 ppb) and ground water (0.051 ppb) concentrations, for sugarcane, do not exceed the calculated acute DWLOC values (µg/L: 8997 to 209,965). Therefore, trifloxysulfuron-sodium exposures would not exceed the exposure allowable by the risk cup.

2. *Non-dietary exposure.* The acute MOE for children ingesting pesticide-treated turf exceeds 190 million. The risk estimate does not exceed the level of concern (MOE = 100), indicating there are no oral exposure concerns for children ingesting trifloxysulfuron-sodium-treated turf.

D. Cumulative Effects

The potential for cumulative effects of trifloxysulfuron-sodium and other substances that have a common mechanism of toxicity has also been considered. Trifloxysulfuron-sodium is a member of the class of herbicides designated as sulfonylureas. There is no reliable information to indicate that toxic effects produced by trifloxysulfuron-sodium would be cumulative with those of any other chemical including another pesticide. Therefore, Syngenta believes it is appropriate to consider only the potential risks of trifloxysulfuron-sodium in an aggregate risk assessment.

E. Safety Determination

1. *U.S. population.* In assessing the potential for additional sensitivity of infants and children to residues of trifloxysulfuron-sodium, data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat have been considered.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of trifloxysulfuron-sodium, data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat have been considered. In rabbit (0, 50, 100, 250, 500 mg/kg/day) and rat (0, 30, 300, 1,000 mg/kg/day) teratology studies there was no evidence of teratogenicity. Delayed fetal development was apparent only at maternally toxic doses of trifloxysulfuron-sodium technical in rats. In rabbits, 500 mg/kg/day was clearly toxic to does and at 250 mg/kg/day, lesser toxicity was seen. For the control (50, 100, and 250 mg/kg) groups, pre-implantation losses, number of implantation sites, and post-implantation losses were not affected by treatment. The findings after fetal post mortem examination and fetal visceral examination revealed no treatment related effects. Similarly, there were no skeletal malformations in this study and the incidence of anomalies and variations were not affected by treatment. The no observed adverse effect levels (NOAEL) for maternal toxicity was 100 mg/kg/day and the NOAEL for fetal toxicity was 250 mg/kg/day. There was no indication of embryotoxic, fetotoxic, or teratogenic potential for trifloxysulfuron-sodium in rabbits.

In the rat teratology study developmental toxicity was secondary to maternal toxicity and consisted of slightly reduced fetal body weights and an increase in minor skeletal anomalies and variations. The NOAELs for maternal and developmental toxicity were both 30 mg/kg/day. Trifloxysulfuron-sodium was not embryotoxic, fetotoxic, or teratogenic in rats when tested under the conditions of this study.

In a rat multigeneration study, trifloxysulfuron-sodium had no effect on reproductive parameters. The NOAEL for systemic toxicity in both sexes and both generations was 1,000 ppm. The mean dose in mg/kg/day for all weekly means for both sexes, both generations, all time points at this dietary level was 83.4 mg/kg/day. There were no effects on the reproductive parameters and the NOAEL for