

Ground Water (SCI-GROW) model is used to predict pesticide concentrations in shallow ground water. 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. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes 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 pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in 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 from residential uses. Since DWLOCs address total aggregate exposure to trifloxysulfuron they are further discussed in the aggregate risk sections Unit E.

Based on the PRZM/EXAMS and SCI-GROW models the EECs of trifloxysulfuron and its metabolites of concern for acute exposures are estimated to be 6.47 parts per billion (ppb) for surface water and 0.054 ppb for ground water. The EECs for chronic exposures are estimated to be 0.52 ppb for surface water and 0.054 ppb for ground water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Trifloxysulfuron will be registered for use on the following non-dietary sites:

Turf—golfcourses. The risk assessment was conducted using the following exposure assumptions: The Agency has examined the potential postapplication exposure to individuals over 12 years of age from the proposed use of trifloxysulfuron on golf courses. Duration of such exposure is anticipated to be short-term. The short-term dermal post-application exposure for golfing was estimated to be 0.0005 mg/kg/day. The estimate assumes that 18 holes of golf are played in 4 hours, that there are 0.015 µg ai/cm² of turf, that the transfer coefficient for turf is 500 cm²/hour, and that the average golfer weighs 60 kg. Transfer coefficients are based on surrogate data, from chlorothalonil and chlorpyrifos, describing actual, median-value exposures to golfers.

The vapor pressure of trifloxysulfuron is very low and, therefore, inhalation exposure to trifloxysulfuron vapor is not expected to occur. The Agency has not assessed inhalation exposure to trifloxysulfuron due to residential activities.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA does not have, at this time, available data to determine whether trifloxysulfuron has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to trifloxysulfuron and any other substances and trifloxysulfuron does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that trifloxysulfuron has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity study in rats or in the 2-generation reproduction study in rats. In the developmental toxicity study in rabbits, there was an increase in quantitative susceptibility based upon the presence of abnormally shaped heart in one fetus at 100 mg/kg/day. Three additional fetuses from two litters at 250 mg/kg/day also had abnormally shaped hearts. The degree of concern for this finding was low because there was a clear NOAEL for this effect, only 1 fetus had the effect at the LOAEL, and this effect was used as a toxicological endpoint in appropriate risk assessments. There are no residual uncertainties for prenatal and/or postnatal toxicity.

3. *Conclusion.* There is a complete toxicity data base for trifloxysulfuron and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X. This determination was based on the following:

- The toxicological data base is complete for FQPA assessment.
- There was no evidence of increased quantitative or qualitative susceptibility in the developmental toxicity study in rats. At the limit dose, maternal effects were decreased food consumption during treatment and decreased body weight gain during post-treatment. The only fetal findings noted at the limit dose were a slight decrease in fetal body weights, and an increase in minimal skeletal findings and poor/absent skeletal ossification.
- There was evidence of increased quantitative susceptibility in the developmental toxicity study in rabbits. The maternal NOAEL was 100 mg/kg/day based on increased mortality and