

are likely to be exposed to imidacloprid residues via dermal and inhalation routes during handling, mixing, loading, and applying activities. Based on the current use patterns, EPA expects duration of exposure to be short-term (1–30 days). EPA does not expect imidacloprid to result in exposure durations that would result in intermediate-term or long-term exposure.

The scenarios likely to result in adult dermal and/or inhalation residential handler exposures are as follows:

- Dermal and inhalation exposure from using a granular push-type spreader.
- Dermal exposure from using potted plant spikes.
- Dermal exposure from using a plant potting medium.
- Dermal and inhalation exposure from using a garden hose-end sprayer (dermal and inhalation exposure from using a RTU trigger pump spray is expected to be negligible).
- Dermal and inhalation exposure from using a water can/bucket for soil drench applications.
- Dermal exposure from using pet spot-on.

EPA has also determined that there is potential for short-term (1 to 30 days), post-application exposure to adults and children/toddlers from the many residential uses of imidacloprid. Due to residential application practices and the half-lives observed in the turf transferable residue study, intermediate-term and long-term post-application exposures are not expected. The scenarios likely to result in dermal (adult and child/toddler) and incidental non-dietary (child/toddler) short-term post-application exposures are as follows:

- Toddler oral hand-to-mouth exposure from contacting treated turf.
- Toddler incidental oral ingestion of granules.
- Toddler incidental oral ingestion of pesticide-treated soil.
- Toddler incidental oral exposure from contacting treated pet.
- Toddler dermal exposure from contacting treated turf.
- Toddler dermal exposure from hugging treated pet/contacting treated pet.
- Adult dermal exposure from contacting treated turf.
- Adult golfer dermal exposure from contacting treated turf.
- Adolescent golfer dermal exposure from contacting treated turf.
- Adult dermal exposure from contacting treated pet

4. *Cumulative exposure to 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 imidacloprid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, imidacloprid 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 imidacloprid 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://www.epa.gov/pesticides/cumulative/>.

### C. 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 margin of exposure (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 is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study. There is evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study, but the concern is low since:

- The effects in pups are well-characterized with a clear NOAEL.
  - The pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in pups and dams.
  - The doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study.
- Therefore, there are no residual uncertainties for prenatal/postnatal toxicity in this study.

3. *Conclusion.* There is a complete toxicity data base for imidacloprid 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 for the following reasons:

- The toxicological data base is complete for FQPA assessment.
- The acute dietary food exposure assessment utilizes existing and proposed tolerance level residues and 100 PCT information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated.
- The chronic dietary food exposure assessment utilizes existing and proposed tolerance level residues and PCT data verified by the Agency for several existing uses. For all proposed uses, 100 PCT is assumed. The chronic assessment is somewhat refined and based on reliable data and will not underestimate exposure/risk.

The dietary drinking water assessment utilizes water 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.

The residential handler assessment is based upon the residential standard operating procedures (SOPs) in conjunction with chemical-specific study data in some cases and the Pesticide Handlers Exposure Database (PHED) unit exposures in other cases. The majority of the residential post-application assessment is based upon chemical-specific turf transferable residue data or other chemical-specific post-application exposure study data. The chemical-specific study data as well as the surrogate study data used are reliable and also are not expected to underestimate risk to adults as well as to children. In a few cases where chemical-specific data were not available, the SOPs were used alone. The residential SOPs are based upon reasonable worst-case assumptions and are not expected to underestimate risk.