

and butafenacil 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 butafenacil 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/>.

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 are no residual concerns regarding prenatal or postnatal toxicity or completeness of the toxicity or exposure data base.

3. *Conclusion.* There is a complete toxicity data base for butafenacil 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 could be reduced to 1X. The FQPA factor was reduced because:

- There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to *in utero* exposure in developmental studies or to *in utero* and postnatal exposure to rats in the 2-generation reproduction study.

- There are no residential uncertainties for prenatal or postnatal toxicity.

- The toxicological data base is complete for the assessment of toxicity and susceptibility following prenatal and/or postnatal exposures. No clinical signs of neurotoxicity or neuropathology were observed in the data base, and the developmental neurotoxicity study was not required.

- There are no residual concerns regarding prenatal or postnatal toxicity or completeness of the toxicity or exposure data base.

- The dietary food exposure assessment is Tier I, screening level, which is based on tolerance level residues or maximum field trial residues and assumes 100% of all crops will be treated with chemical. By using these screening level assessments, actual exposures/risks will not be underestimated.

- The dietary drinking water assessment utilizes water concentration values generated by health protective, high-end estimates of water concentrations which will not likely be exceeded.

- There are currently no registered residential uses of butafenacil.

- These assessments will not underestimate the exposure/risks posed by current or proposed uses of butafenacil.

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 EPA's Office of Water are used to calculate DWLOCs: 2 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, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA 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, EPA 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.* No acute risk from exposure to butafenacil is expected because there were no toxic effects of concern attributable to a single dose identified in available data.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to butafenacil from food will utilize <1% of the cPAD for the U.S. population, <1% of the cPAD for infants ages 1–2, and <1% of the cPAD for children ages 3–5. There are no proposed residential uses for butafenacil that result in chronic residential exposure to butafenacil. In addition, there is potential for chronic dietary exposure to butafenacil 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: