

TABLE 3.—TOXICOLOGICAL DOSE AND ENDPOINTS FOR BUTAFENACIL—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term inhalation (>6 months)	Oral NOAEL = 1.2 mg/kg/day	Residential LOC for MOE = 100 Occupational = 100	Mouse oncogenicity study The LOAEL is 6.96 mg/kg/day, based on enlarged livers with increased weights, and hepatic microscopic lesions including Kupffer cell hyperplasia, inflammatory cell infiltration, and single cell necrosis in both sexes and on deposits of lipofuscin in males
Cancer (oral, dermal, inhalation)	NA	NA	Classified as “not likely to be carcinogenic to humans”

\* The reference to the Special FQPA SF refers to any additional SF retained due to concerns unique to the FQPA.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have previously been established for butafenacil. Risk assessments were conducted by EPA to assess dietary exposures from butafenacil in food as follows:

i. *Acute exposure.* Quantitative acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No appropriate endpoint attributable to a single exposure was identified for butafenacil in either the general population or to the subpopulation of females 13–50 years old, therefore no acute exposure assessment was performed.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment, the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1994–1996, and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: The dietary exposure analysis assumed 100% crop treated and tolerance level residues or maximum field trial residues. Based on total food exposure for butafenacil, all population subgroups are below 1% cPAD.

iii. *Cancer.* Butafenacil showed no evidence of carcinogenicity in animal tests in two different species, and therefore, a quantitative cancer risk assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure

analysis and risk assessment for butafenacil in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of butafenacil.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The screening concentration in 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 I model) before using PRZM/EXAMS (a Tier II 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 LOC.

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 butafenacil they are further discussed in Unit III.E.

Based on the FIRST and SCI-GROW models, the EECs of butafenacil for chronic exposures are estimated to be 0.049 parts per billion (ppb) for surface water and 0.00095 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). Butafenacil is not proposed for registration for use on any sites that would result in residential exposure.

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 butafenacil 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 butafenacil and any other substances