

accounted for 31% of the total. Major sources of acute exposures for the U.S. population and children 1–6 years old included cottonseed oil and meat (beef) commodities. The %RfD for all populations was less than 0.01% of the reference dose (RfD) of 1.0 mg/kg bwt/day.

ii. *Drinking water*—a. *Acute drinking water exposure*. The estimated tier 1 maximum concentrations of butafenacil in surface water and ground water are 1.98 ppb and 0.000038 ppb, respectively. The acute RfD for butafenacil is 1.0 mg/kg bwt/day. From the acute dietary exposure analysis, acute food exposure from the uses of butafenacil were negligible for all populations. Using this information, acute drinking water levels of comparison (DWLOC) were calculated for butafenacil. The lowest DWLOC was 10,000 ppb. Based on this analysis, butafenacil estimated environmental concentrations (EECs) do not exceed the calculated acute DWLOCs.

b. *Chronic drinking water exposure*. The estimated maximum concentrations of butafenacil in surface water and ground water are 0.033 ppb Day 56 EEC/3 from Generic Expected Environmental Concentration (GENEEC) and 0.000025 parts per billion (ppb) (SCI-GROW, maximum at 0.16 lb active ingredient/acre/year, respectively. The chronic RfD for butafenacil is 1.0 mg/kg bwt/day. From the chronic dietary exposure analysis, an exposure to butafenacil is negligible for all populations. Based on EPA's "Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments" document (December 2, 1997), chronic drinking water levels of comparison were calculated for butafenacil. The lowest DWLOC was 10,000 ppb. Based on this analysis, butafenacil EECs do not exceed the calculated chronic DWLOCs.

2. *Non-dietary exposure*. There are no residential uses and therefore, no need for non-dietary exposure assessment for this use.

#### D. Cumulative Effects

The potential for cumulative effects of butafenacil and other substances that have a common mechanism of toxicity has been considered. Butafenacil is a member of the class of herbicides designated as uracil-derivatives. There is no reliable information to indicate that toxic effects produced by butafenacil 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 butafenacil in an aggregate risk assessment.

#### E. Safety Determination

1. *U.S. population*. Using the acute and chronic exposure assumptions and the proposed RfDs described above, the aggregate exposure, including drinking water to butafenacil to the U.S. population (48 contiguous states, all seasons) was calculated to be less than 0.01% of the RfD of 1.0 mg/kg bwt/day. Therefore, Syngenta concludes that there is reasonable certainty that no harm will result from the aggregate acute or chronic exposure to butafenacil residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of butafenacil, data from developmental toxicity studies in the rat and rabbit and a multi-generation reproduction study in the rat have been considered. In the rat and rabbit teratology studies there was no evidence of teratogenicity. Delayed fetal development was apparent only at maternally toxic doses of butafenacil technical in rabbits. In the rabbit study 1,000 mg/kg/day caused effects indicative of maternal toxicity. There was no indication of developmental toxicity in rabbit offspring at 100 mg/kg/day. The NOAEL for both maternal and developmental toxicity was established at 100 mg/kg/day in rabbits.

In the rat teratogenicity study there was no observation of maternal toxicity. Body weight and food consumption were comparable in all groups. Reproduction and fetal parameters were not impaired. Butafenacil was not teratogenic and not toxic to the progeny. Maternal parameters were not affected. The NOAEL for both maternal and developmental toxicity was  $\geq 1,000$  mg/kg/day, the highest dose level tested.

In a rat multi-generation study the NOAEL for systemic toxicity in both sexes and both generations of rats was 2.48 mg/kg/day. There were no effects on the reproductive parameters and the NOAEL for reproductive toxicity was  $\geq 1,000$  ppm. Offspring effects were observed only at dose levels that also produced parental toxicity. There is no evidence that developing offsprings are more sensitive than adults to the effects of butafenacil.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological requirements, the data base for butafenacil relative to prenatal and postnatal effects for children is complete. Further, for butafenacil, the developmental studies

showed no increased sensitivity in fetuses as compared to maternal animals following in-utero exposures in rats and rabbits, and no increased sensitivity in pups as compared to the adults in the multi-generation reproductive toxicity study. Therefore, it is concluded, that an additional uncertainty factor is not warranted to protect the health of infants and children and that a RfD of 1.0 mg/kg bwt/day is appropriated for assessing aggregate risk to infants and children from butafenacil.

#### F. International Tolerances

There are no codex established for residues of butafenacil on cotton, undelinted seed or cotton, gin byproducts.

[FR Doc. 03–4386 Filed 2–25–03; 8:45 am]

BILLING CODE 6560–50–S

### ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0042; FRL–7293–4]

#### Issuance of an Experimental Use Permit

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

**FOR FURTHER INFORMATION CONTACT:** Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: [greenway.denise@epa.gov](mailto:greenway.denise@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.