

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO BUTAFENACIL

Population	cPAD (mg/kg/day)	% cPAD (mg/kg/day)	Chronic Food Exposure ¹ (mg/kg/day)	Ground Water EEC ² (ppb)	Surface Water EEC ² (ppb)	Chronic DWLOC ³ (ppb)
General U.S. population	0.012	<1%	0.000041	0.00095	0.049	420
All infants (< 1 year old)	0.012	<1%	0.000014	0.00095	0.049	120
Children (1–2 years old)	0.012	<1%	0.000097	0.00095	0.049	120
Children (3–5 years old)	0.012	<1%	0.000104	0.00095	0.049	120
Children (6–12 years old)	0.012	<1%	0.000069	0.00095	0.049	120
Youth (13–19 years old)	0.012	<1%	0.000036	0.00095	0.049	360
Adults (20–49 years old)	0.012	<1%	0.000033	0.00095	0.049	420
Females (13–49 years old)	0.012	<1%	0.000030	0.00095	0.049	360
Adults (50+ years old)	0.012	<1%	0.000031	0.00095	0.049	420

¹ Maximum chronic water exposure (mg/kg/day) = cPAD (mg/kg/day) - chronic food exposure from DEEM (mg/kg/day); no res. exp.

² Parent plus CGA-293731; cotton application scenario - 1 x 0.141 lb ai/acre; maximum proposed rate

³ DWLOC(μg/L) = (allowable water exposure (mg/kg/day) x body weight (kg) x 1,000 μg/mg) ÷ (water consumption (liters)) Consumption = 1 L/day for populations <13 years old and 2 L/day for populations ≥ 13 years old. Default body weights = 70 kg for general U.S. population and adult males, 60 kg for youth and females ≥ 13 years old, and 10 kg for all others.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Butafenacil is not proposed for registrations for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Butafenacil is not proposed for registrations for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's LOC.

5. *Aggregate cancer risk for U.S. population.* Butafenacil is not expected to pose a cancer risk because no evidence of carcinogenicity was found in adequate animal tests in two different species, therefore no aggregate cancer risk assessment was performed.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to butafenacil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Syngenta Crop Protection, Inc. proposed Syngenta Method 131–99 for enforcement of the proposed cotton tolerances (adequate validation, independent laboratory validation (ILV), and radiovalidation data have been submitted). The petitioner did not propose ruminant liver and kidney tolerances and therefore did not propose a method for enforcement of the recommended ruminant liver and kidney tolerances. The petitioner has and will submit an enforcement method, adequate validation, ILV, and radiovalidation for enforcement of the ruminant liver and kidney tolerances as a condition of registration.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits for residues of butafenacil in/on cotton. Therefore, harmonization is not an issue.

C. Conditions

As a condition of registration, the petitioner must submit:

1. A ruminant liver and kidney enforcement method and submit adequate validation, ILV, and radiovalidation data.
2. Submit confirmatory data on the frozen storage stability of residues of butafenacil in or on cottonseed, cotton gin byproduct, cotton hull, cotton meal, and cotton oil.
3. Submit a ruminant feeding study to confirm the Agency's estimate of

maximum residues of butafenacil from the goat metabolism study.

V. Conclusion

Therefore, the tolerance is established for residues of butafenacil, in or on cattle, kidney; goat, kidney; hog, kidney; horse, kidney; and sheep, kidney at 0.05 ppm; in or on cattle, liver; goat, liver; hog, liver; horse, liver; and sheep, liver at 0.50 ppm; in or on cotton, undelinted seed at 0.50 ppm; and in or on cotton, gin byproducts at 10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.