

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR METOLACHLOR/S-METOLACHLOR FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all population subgroups)	NOAEL = 300 mg/kg/day UF = 100x	FQPA SF = 1X aPAD = 3.0 mg/kg/day	Prenatal developmental toxicity study in rats with metolachlor- death, clinical signs of toxicity (clonic and/or tonic convulsions, excessive salivation, urine-stained abdominal fur and/or excessive salivation) and decreased body weight gain
Chronic Dietary (All population subgroups)	NOAEL = 9.7 mg/kg/day UF = 100x	FQPA SF = 1x cPAD = 0.1 mg/kg/day	Chronic study in dogs with metolachlor- endpoint is decreased body weight in females
Incidental Oral, Short-term (one to 30 days)	NOAEL = 50	Target MOE = 100	Prenatal developmental toxicity study in rats with metolachlor- increased incidence of clinical signs, decreased body weight/body weight gain, food consumption, and food efficiency
Incidental Oral, Intermediate-term (one month to 180 days)	NOAEL = 8.8	Target MOE = 100	Subchronic (6 month) toxicity study in dogs with metolachlor-decreased body weight gain
Dermal, Short- and Intermediate-Term	No systemic toxicity was seen at the limit dose (1,000 mg/kg/day) following dermal applications	None	Hazard was not identified for quantification of risk. there is no concern for developmental toxicity in rats or rabbits.
Dermal, Long-Term <sup>a</sup> (greater than 180 days)	Oral NOAEL = 9.7	Target MOE = 100	chronic toxicity study in dogs with metolachlor-decreased body weight gain in females
Inhalation, Short-Term <sup>b</sup>	Oral NOAEL = 50	Target MOE = 100	Prenatal development toxicity study in rats with S-metolachlor-increased incidence of clinical signs, decreased body weight/body weight gain, food consumption, and food efficiency
Inhalation, Intermediate-Term <sup>b</sup>	Oral NOAEL = 8.8	Target MOE = 100	subchronic (6 month) toxicity study in dogs with metolachlor- decreased body weight gain
Inhalation, Long-Term <sup>b</sup>	Oral NOAEL = 9.7	Target MOE = 100	chronic toxicity study in dogs with metolachlor- decreased body weight gain in females
Cancer	Classification: Group C, possible human carcinogen with risk quantitated using a non-linear approach.		

\* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

<sup>a</sup> Since an oral NOAEL was selected, a dermal absorption factor of 58% should be used in route-to-route extrapolation.

<sup>b</sup> Since an oral NOAEL was selected, an inhalation factor of 100% should be used in route-to-route extrapolation.

### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances for metolachlor currently cover residues of S-metolachlor on the same commodities for the same use pattern when the maximum labeled use rate of S-metolachlor is approximately 35 percent less than the historical use rate of metolachlor.

Tolerances have been established (40 CFR 180.368(a)) for the combined residues of metolachlor and S-metolachlor in or on a variety of raw agricultural commodities. Tolerances for residues of both metolachlor and S-metolachlor in or on raw agricultural commodities include the combined residues of (free and bound) metolachlor and its metabolites, determined as the derivatives, CGA-37913 and CGA-47951, each expressed as parent compound. Permanent tolerances for

metolachlor/S-metolachlor residues have been established on various plant commodities ranging from 0.1 ppm in/on numerous commodities to 30.0 ppm in/on peanut forage and hay (40 CFR 180.368(a)). Time-limited tolerances associated with section 18 emergency exemptions have been established for metolachlor residues in/on grass forage and hay, spinach, and tomato commodities (40 CFR 180.368(b)). Tolerances associated with regional registrations have also been established for metolachlor residues in/on dry bulb onions, cabbage, and various peppers (chili, Cubanelle, and tabasco) (40 CFR 180.368(c)). Risk assessments were conducted by EPA to assess dietary exposures from S-metolachlor in food as follows:

i. *Acute exposure.* 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 one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 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 acute exposure assessments: A conservative Tier I acute dietary exposure assessment was conducted for all labeled metolachlor and S-metolachlor food uses. Inputs for this assessment included tolerance-level residue values and an assumption that 100% of all labeled crops were treated with metolachlor/S-metolachlor. For all supported registered commodities, the acute dietary exposure estimates are