

toxicity studies (i.e., subchronic and chronic toxicity, teratology and multi-generation reproductive studies) which would suggest that BAS 510 F produces endocrine related effects.

#### C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. A chronic dietary exposure analysis was conducted for BAS 510 F including crops which are target uses as well as inadvertent residues in rotational crops. The analysis assumed 100% of the crops were treated, default processing factors (even though much lower experimentally-derived processing factors are available), and used the

tolerance value for residues. Even with these worst-case assumptions, it was determined that the Theoretical Maximum Residue Contribution (TMRC) was only 30.1% of the reference dose for the U.S. population and 62.5% for children 1–6 years (the highest exposed age-related subpopulation).

Based on the toxicology results, an acute dietary risk assessment for BAS 510 F is most likely not required, but if so only for children 1–6 years. For dietary exposure estimation, 100% crop treated and tolerance values for residues were used. The resulting acute exposure prediction for children 1–6 years (the

highest exposed age-related subpopulation) resulted in an acceptable 8.8% of the acute reference dose at the 95th percentile. If a more realistic scenario were used assuming percent crop treated and the range of residues, a much lower exposure would be obtained.

ii. *Drinking water*. Estimates of ground and surface water levels were determined using SCIGROW and FIRST models, respectively. The drinking water level of concerns (DWLOCs) for chronic exposure is obtained by subtracting the chronic dietary food. This is outlined in the following table.

PERCENTAGES OF REFERENCE DOSE FOR CHRONIC EXPOSURE TO BAS 510 F

K	U.S. Population (% of RfD)	Children 1–6 (% of RfD)
Chronic dietary exposure	30.1	62.5
Remainder of RfD available for water (%) (Drinking Water Level of Concern)	69.9	37.5
SCIGROW ground water estimation <sup>1</sup>	0.015%	0.044%
FIRST surface water estimation <sup>1</sup>	0.08%	0.24%
Total of RfD used by diet and water	30.2%	62.8%

<sup>1</sup> Used highest values predicted from the model for all agricultural uses; assumes 2L/day and 60 kg for adult; 1L/day and 10 kg for child

Overall, using worst-case parameters the predicted aggregate exposure by all potential routes for both adults and children is less than the chronic reference dose.

2. *Non-dietary exposure*. BAS 510 F is not currently planned for residential uses. Thus, residential exposure is not aggregated into the risk assessment.

#### D. Cumulative Effects

Section 408(b)(2)(D)(v) 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.” BAS 510 F is a foliar fungicide chemically belonging to the carboxin class of fungicides. BAS 510 F acts in the fungal cell by inhibiting mitochondrial respiration through inhibition of the succinate-ubiquinone oxidase reductase system in Complex II of the mitochondrial electron transport chain. BAS 510 F shares this mode of action with only one other currently registered U.S. pesticide — carboxin.

The EPA is currently developing methodology to perform cumulative risk assessments. At this time, there is no available data to determine whether BAS 510 F has a common mechanism of

toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, BAS 510 F does not appear to produce a toxic metabolite produced by other substances.

#### E. Safety Determination.

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that aggregate exposure to BAS 510 F will utilize 30.2% of the RfD for the U.S. population. For the highest exposed age-related subpopulation (children 1–6 years), the maximum aggregate exposure is predicted to be 62.8% of the reference dose. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of BAS 510 F, including anticipated dietary and drinking water exposures and non-occupational exposures.

2. *Infants and children*—i. *developmental toxicity in the Rat*. A developmental study was conducted via oral gavage in rats with dosages of 0, 100, 300 and 1,000 mg/kg bw/day with a maternal and developmental No-

Adverse-Effect Level (NOAEL) of 1,000 mg/kg. No evidence of developmental toxicity was observed up to the highest dose tested.

3. *Developmental toxicity in the rabbit*. A developmental study was conducted via oral gavage in rabbits with dosages of 0, 100, 300 and 1,000 mg/kg bw/day. The NOAEL for maternal toxicity was 100 mg/kg bw/day and was 1,000 mg/kg/day for developmental toxicity. As noted above in section 3.0, this NOAEL is based on fecal alterations and an abortion in a single dam at the next highest dose of 300 mg/kg/day. The dam which displayed the fecal alterations and abortion also displayed decreased body weight, body weight gain and food consumption, compared to the group mean, during gestation. These decreases occurred even prior to compound administration. These decreases in body weight, body weight gain, and food consumption, prior to compound administration, all indicate an animal in poor health and this poor state of health, rather than compound exposure, was likely the reason for the fecal alterations and abortion. No teratogenic effects were observed at any dose level.

i. *Reproductive toxicity*. A two-generation reproduction study in rats was conducted with dosages of 0, 12, 118, and 1,183 mg/kg bw/day. No