

embryotoxic or teratogenic in either species at maternally toxic doses.

4. *Subchronic toxicity.* In a 90-day dietary study in rats with S-metolachlor, no effects were observed in male or females at 208 and 236 mg/kg/day, respectively. In another 90-day dietary study in rats, decreased body weight, reduced food consumption and food efficiency in both sexes and increased kidney weight in males at 150 mg/kg/day; the NOAEL was 15 mg/kg/day. A 90-day dog study with S-metolachlor in dogs has been accepted by EPA; no effects were observed in males and females at 62 mg/kg/day and 74 mg/kg/day, respectively, the highest doses tested.

5. *Chronic toxicity.* A combined chronic toxicity/carcinogenic study in the rat satisfies the requirements for both the chronic toxicity and carcinogenicity studies. No significant chronic toxicity was found in either rats or dogs. In the rat, a decrease in body weight was observed at the highest dose tested. In the chronic dog study that supports S-metolachlor, the only adverse effect was decreased body weight gain in females at 33 mg/kg/day; the NOAEL was 10 mg/kg/day.

6. *Animal metabolism.* In animals, S-metolachlor is extensively absorbed, rapidly metabolized and almost totally eliminated in the excreta of rats, goats, and poultry. Metabolism in animals proceeds through common Phase 1 intermediates and glutathione conjugation.

7. *Metabolite toxicology.* The metabolism of S-metolachlor has been well characterized in standard FIFRA metabolism studies. S-metolachlor does not readily undergo dealkylation to form an aniline or quinone imine as has been reported for other members of the chloroacetanilide class of chemicals. Therefore, it is not appropriate to include S-metolachlor with the group of chloroacetanilides that readily undergo dealkylation, producing a common toxic metabolite (quinone imine). New toxicology data submitted by Syngenta demonstrate that the S-metolachlor metabolites ethane sulfonic acid (CGA 354743) and oxanilic acid (CGA 51202) are not absorbed by mammalian systems and / or have a significantly lower level of mammalian toxicity when compared to parent.

8. *Endocrine disruption.* S-Metolachlor does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that S-metolachlor has any effect on endocrine function in developmental or reproduction studies. Furthermore, histological investigation of endocrine

organs in the chronic dog, rat and mouse studies did not indicate that the endocrine system is targeted by S-metolachlor, even at maximally tolerated doses administered for a lifetime. There is no evidence that S-metolachlor bioaccumulates in the environment.

#### C. Aggregate Exposure

1. *Dietary exposure.* A Tier III/IV chronic dietary exposure analysis was conducted on S-metolachlor using field trial and market basket survey residues. Field trial residues were adjusted for percent of crop treated whereas market basket residues were not, since this information is inherent in the data. The percent of crop treated was assumed to be 100% for all commodities for which no percent of crop treated information was available. The chronic assessment was conducted for S-metolachlor using the Dietary Exposure Evaluation Model (DEEM<sup>TM</sup>, version 7.76) by Exponent and food consumption information from USDA's 1994-96 Continuing Survey of Food Intake by Individuals (CSFII) and the Supplemental CSFII children's survey (1998). For this chronic assessment, the field trial values were averaged and entered into the DEEM<sup>TM</sup> software.

Syngenta Market Basket Survey (SMBS) S-metolachlor data were available for the following commodities: milk, potatoes and tomatoes. The Syngenta market basket survey was conducted from September 1999 through September 2000. Following the Agency tier ranking system, these chronic dietary assessments are considered as Tier III (utilizing field trial data) and Tier IV (utilizing SMBS and PDP data) assessments.

S-metolachlor is not considered acutely toxic and therefore acute dietary exposure was not determined; however, in the October 2002 TRED EPA conducted an acute assessment of the majority of the crops included in this petition and determined acute risks to be <1% of the aPAD in the most exposed population subgroup.

The chronic RfD for S-metolachlor is 0.10 mg/kg body weight/day and is based on a one-year dog study with a NOEL of 9.7 mg/kg body weight/day and a safety factor of 100X. No additional FQPA safety factor is required; nor was applied in this assessment.

i. *Food.* The risk from chronic dietary exposure to S-metolachlor is considered to be very low. The percentages of the chronic RfD ranged from 0.17% for Seniors to 0.64% for Children 1-2 years old, theoretically the most exposure population subgroup.

ii. *Drinking water.* Other potential sources of exposure of the general population to residues of S-metolachlor are residues in drinking water and exposure from non-occupational sources. The degradation of S-metolachlor is microbially mediated with an aerobic soil metabolism primary half-life of less than 30 days and subsequently soil binding predominates. S-metolachlor Koc's vary from 110- 369. S-metolachlor is stable to hydrolysis and while aqueous and soil photolysis occur, they are not expected to be prominent pathways in the environment.

The predominant crop for S-metolachlor is corn and accordingly an Index Reservoir PRZM/EXAMS was run using EPA's standard corn scenario. The model simulated two applications to the same plot: pre-emergence (2.67 kg ai/ha) and post-emergence (1.50 kg a.i./ha). The mean annual average estimated environmental concentrations (EEC) was 11.77 ppb. It should be noted that extensive monitoring data suggests that this EEC is a conservative estimate. For the vast majority of locations sampled, the peak measured concentration does not approach 12 ppb, and the annual average would be expected to be much lower.

The Chronic drinking water levels of concern (DWLOC) was calculated based on a cRfD of 0.097 mg/kg/day. Non-nursing infants are the most sensitive subpopulation and their DWLOC is estimated to be 544 ppb which corresponds to a %cRfD value of 2.2% with an MOE value of 4621. Thus, the DWLOC is considerably higher than the EEC of 11.77 ppb and the MOE is well above the benchmark value of 100.

2. *Non-dietary exposure.* S-metolachlor is labeled for use on warm-season turf and landscape ornamentals. Although, it is primarily used on sod farms and commercial landscape ornamentals, it can be used by licensed pest control operators (PCO) or lawn care operators (LCO) on residential turf. Since S-metolachlor can only be applied to warm-season turf varieties (bermudagrass, Zoysiagrass, St. Augustinegrass, and Centipedegrass), its use on turf is limited to the southern states.

Non-dietary residential exposure may occur to homeowners or children as a result of exposure during re-entry activities. Using surrogate dislodgeable foliar residue data, and conservative standard EPA exposure scenarios, exposure through the dermal route was calculated. Based on the use pattern, which restricts to number of application to one per year, only short-term risks need to be considered. The relevant