

chloroacetanilides that readily undergo dealkylation, producing a common toxic metabolite (quinone imine).

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 (MB) residues. Field trial residues were adjusted for PCT whereas MB residues were not, since this information is inherent in the data. The PCT was assumed to be 100% for all commodities for which no PCT information was available. The chronic assessment was conducted for S-metolachlor using the Dietary Exposure Evaluation Model (DEEM™), version 7.76) by exponent and food consumption information from Department of Agriculture (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™ software.

Syngenta Market Basket Survey (SMBS) S-metolachlor data were available for the following commodities: Milk, potatoes, and tomatoes. The SMBS 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.

The chronic reference dose (RfD) for S-metolachlor is 0.10 mg/kg body weight/day and is based on a 1-year dog study with a NOAEL 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. S-metolachlor is not considered acutely toxic and therefore, acute dietary exposure was not determined. For the purpose of aggregate assessment, the exposure values were expressed in terms of margin of exposure (MOE) which was

calculated by dividing the NOAEL by the exposure for each population subgroup. The benchmark MOE for this assessment is 100.

i. *Food.* The risk from chronic dietary exposure to S-metolachlor is considered to be very low. Based on worst-case assumptions, the chronic exposure assessment did not result in any MOE less than 55,428 for even the most impacted population subgroup (children 1–6 years). Syngenta believes that the MOE for chronic exposure would be well above 100 for any population group. A MOE of 100 or more is considered satisfactory. The percent of the chronic RfD ranged from 0.05% for seniors to 0.2% for children 1–6 and Non-nursing infants, theoretically the most exposure population subgroups.

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 a.i./hectare (ha) post-emergence (1.50 kg a.i./ha). The mean annual average EEC was 11.77 part per billion (ppb). It should be noted that extensive monitoring data suggests that this estimated environmental concentration (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 chronic reference dose (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 4,621. 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 or lawn care operators 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 toxicological endpoint for short-term dermal risks is the NOAEL of 100 mg/kg/day from a 21-day dermal toxicity study in rabbits. No acute oral hazard has been identified following an acute exposure to S-metolachlor and, therefore, no nondietary assessment is needed.

The short-term dermal post-application risks for adults and children are acceptable, ranging from 520 to 870. These risk estimates exceed the EPA's level of concern for S-metolachlor (all MOEs are greater than 100).

3. *Aggregate exposure (drinking water and dietary exposure).* Using the total MOE equation for the determination of aggregate chronic exposure (food and drinking water only) resulted in an aggregate MOE_T of 4,630 for the most sensitive subpopulation, non-nursing infants. For this particular subpopulation, there are no non-dietary exposure contributions to the MOE_T aggregate value.

D. Cumulative Effects

EPA has examined the common mechanism potential for S-metolachlor and has concluded that S-metolachlor should not be included with some pesticides that comprise the class of chloroacetanilides included in a "Common Mechanism Group". Therefore, a cumulative assessment is not necessary for S-metolachlor.

E. Safety Determination

1. *U.S. population.* Based on the aggregate assessment described above and the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to S-metolachlor (including the proposed uses) in food will utilize less than 0.1% of the cRfD for the U.S. population. EPA generally has no concern for exposures below