

TABLE 4.— AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO METOLACHLOR AND S-METOLACHLOR

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Children (1-6); Metolachlor	640	100	92	103	4,200
Children (1-6); S-Metolachlor	1,100	100	92	103	4,500

4. *Intermediate-term risk.* An intermediate-term aggregate risk assessment considers potential exposure from food, drinking water, and non-occupational (residential) pathways of exposure. However, for metolachlor, no intermediate-term non-occupational exposure scenarios (greater than 30 days exposure) are expected to occur. Therefore, intermediate-term DWLOC values were not calculated, and an intermediate-term aggregate risk assessment is not required.

5. *Aggregate cancer risk for U.S. population.* An aggregate cancer risk assessment considers potential carcinogenic exposure from food, drinking water, and non-occupational (residential) pathways of exposure. Metolachlor has been classified as a Group C, possible human carcinogen. This classification was based on the occurrence of liver tumors in rats at the highest dose level tested (150 mg/kg/day). The HED Cancer Assessment Review Committee has recommended that carcinogenic risks for metolachlor be quantitated using a non-linear approach, with a NOAEL of 15 mg/kg/day. However, the NOAEL of 15 mg/kg/day that was established based on liver tumors in rats is comparable to the NOAEL of 9.7 mg/kg/day selected for establishing the chronic reference dose for metolachlor. It is assumed that the chronic dietary endpoint is protective for cancer dietary exposure. Therefore, a separate cancer aggregate risk assessment was not conducted, and cancer DWLOC values were not calculated.

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 s-metolachlor residues.

V. Other Considerations

A. Analytical Enforcement Methodology

The Pesticide Analytical Manual (PAM) Vol. II, lists a GC/NPD method (Method I) for determining residues in/on plants and a GC/MSD method (Method II) for determining residues in livestock commodities. These methods

determine residues of metolachlor and its metabolites as either CGA-37913 or CGA-49751 following acid hydrolysis.

B. International Residue Limits

No maximum residue limits (MRLs) for either metolachlor or S-metolachlor have been established or proposed by Codex, Canada, or Mexico for any agricultural commodity; therefore, no compatibility questions exist with respect to U.S. tolerances.

VI. Conclusion

Therefore, the tolerance is established for the combined residues (free and bound) of the herbicide s-metolachlor [(S)-2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide, its R-enantiomer and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on sweet potatoes at 0.2 ppm.

VII. 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 the 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.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2002-0331 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 4, 2003.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box