

dermal exposure of females (13–50 years) is 1,315. Prior to the application rate change agreed to by the registrants in connection with the Agency's reregistration process evaluation of thiophanate methyl, MOEs for aggregate exposure to MBC from the use of MBC as an in-can paint preservative were 670 for dermal exposure and 770 for exposure via inhalation. As a result of negotiated mitigation measures related to the reregistration review of this chemical, the registrant has now lowered the application rate for the in-can paint uses to the extent that the MOEs are now acceptable ($>1,000$). The MOEs (converted to MBC equivalents) for the total thiophanate methyl and MBC aggregate exposure are as follows: 630 for oral and dermal exposure of children (1–6 years); 770 for exposure via inhalation for females (13–50 years); and 620 for oral and dermal exposure for females (13–50 years). The aggregate short-term exposure to MBC and thiophanate methyl resulting from food, water and residential use exceeds the Agency's level of concern for children (infants, and 1–6 years), and females 13–50 years, due primarily to post-application exposures on turf. Registrants are performing a hand press study and have submitted a 5-day inhalation study to help refine this assessment. Based on these mitigation measures, and the conservative method of exposure estimation, the risks do not exceed the Agency's level of concern.

Aggregate cancer risk for U.S. population. The total thiophanate methyl and MBC+2-AB dietary cancer risk is 1.1×10^{-6} for existing and proposed new uses (incorporating the refinements and amortizations as previously described). The cancer risk from non-occupational residential exposure is 1.1×10^{-6} . Therefore, aggregate cancer risk is 2.2×10^{-6} . This risk estimate includes cancer risk from both thiophanate methyl and MBC+2-AB on food including all pending uses and section 18 uses, thiophanate methyl exposure from treating ornamentals, thiophanate methyl exposure from performing post-application lawn activities, and exposure from applying paint containing MBC. This is considered to be a high-end risk scenario since it is not expected that someone would treat ornamentals, perform high exposure post-application activities, and apply paint containing MBC every year for 70 years. Therefore, this estimate is considered to be a conservative estimate. Additionally, the cancer risk estimate for drinking water is based on the highest EEC, which is also a very high-end risk estimate since

it is based on the maximum rate being applied every season for 70 years. The risk estimate calculations also assumed that the modeled surface water EEC is equivalent to concentrations in finished drinking water. Thus, food plus water plus non-occupational residential cancer risk is 2.2×10^{-6} which is within the range considered as negligible. Therefore, the risks do not exceed the Agency's level of concern.

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 thiophanate methyl and MBC+2-AB residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for thiophanate methyl residues in/on various plant and animal commodities. Codex MRLs for thiophanate methyl are currently expressed as MBC. The Codex MRL residue definition and the U.S. tolerance definition, previously expressed as only thiophanate methyl, have been incompatible and will remain incompatible even with the recent revision of the U.S. tolerance definition, since the revised tolerance definition includes both thiophanate methyl and MBC. Additionally, there is a 5.0 ppm Codex MRL for thiophanate methyl on tomatoes. The 0.5 ppm tolerance for fruiting vegetables, including tomatoes, being established by this document will not harmonize with Codex.

C. Conditions

The pesticide, thiophanate methyl may be applied using ground equipment, at a rate of 1 lb. of formulated product (0.7 lb. active ingredient (a.i.)) per acre, not to exceed 4 lbs. (2.8 lbs. a.i.) per acre per crop. A maximum of four applications per crop may be made at 7 to 14 day intervals, and a 2-day pre-harvest interval must be observed. Applications may not be made through any type of irrigation system.

VI. Conclusion

Therefore, the tolerance is established for residues of thiophanate methyl and its metabolite, MBC, expressed as thiophanate methyl, in or on vegetables, fruiting, group 8 at 0.5 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–2003–0242 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 September 22, 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