

mg/kg/day for female dogs in the control through high-dose groups, respectively, with a NOAEL of 24.9 mg/kg/day for males and 29.6 mg/kg/day for females based on hematology effects and microscopic liver changes.

An 18-month feeding/carcinogenicity study in mice was conducted with dietary intake of 0, 46.6, 93.9, 160.5, or 337.6 mg/kg/day for males and 0, 58.0, 116.9, 198.0, or 407.1 mg/kg/day for females. A NOAEL of 93.9 mg/kg/day in males and 116.9 mg/kg/day in females was based on decreases in Hgb and HCT. There were no treatment-related increases in tumors of any kind observed at any dose level.

In a 24-month chronic feeding/carcinogenicity study in rats at dietary doses of 0, 24.3, 40.0, 82.8, or 123.5 mg/kg/day for males and 20.0, 36.4, 67.0, or 124.7 mg/kg/day for females, an overall NOAEL of 40.0 mg/kg/day in males and 36.4 mg/kg/day in females was based on hematology effects and reduced body weights. There was no evidence of a carcinogenic response.

**6. Animal metabolism.** A metabolism study in rats indicated that approximately 84 to 104% of the orally administered dose of sulfentrazone was excreted in the urine, and that the pooled urinary radioactivity consisted almost entirely of 3-hydroxymethyl sulfentrazone. Pooled fecal radioactivity showed that the major metabolite consisted of 3-hydroxymethyl-sulfentrazone (1.26 to 2.55% of the administered dose). The proposed metabolic pathway appeared to be conversion of the parent compound mainly to 3-hydroxymethyl-sulfentrazone (excreted in urine and feces).

**7. Endocrine disruption.** An evaluation of the potential effects on the endocrine systems of mammals has not been determined; however, no evidence of such effects were reported in the chronic or reproductive toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that sulfentrazone causes endocrine effects.

#### C. Aggregate Exposure

**1. Dietary exposure—i. Food.** A Tier 3 short-term exposure analysis has been performed to estimate the exposure for all adults, adult females, and toddlers (3 to 4 years of age) in the U.S. population for these raw commodities and processed commodities. This analysis utilized Novigen's (Novigen Sciences, Inc.) Dietary Exposure Evaluation Model (DEEM) software; field trial data for registered and pending crop uses; percent crop treated information; and

consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals (CSFIs), conducted from 1994–1996.

**ii. Drinking water.** A Tier 1 short-term drinking water exposure assessment was conducted to determine exposure risk of sulfentrazone residues from consumption of water. This analysis was performed utilizing EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure Risk Assessments (DUS EPA, 1997b), the absorbed (systemic) aggregate exposure estimates, and water data from FMC Corporation ground water study conducted in North Carolina.

**2. Non-dietary exposure.** The primary source for human non-dietary exposure to sulfentrazone will be from post-application exposure to treated residential turf grass. The routes of sulfentrazone exposure were dermal post-application exposure for adults and toddlers, and post-application incidental ingestion of sulfentrazone due to the hand-to-mouth behavior of toddlers. A worst case short-term non-dietary exposure analysis was conducted using algorithms and default factors published in EPA's SOPs for Residential Exposure Assessments.

#### D. Cumulative Effects

*Cumulative exposure to substances with common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers "available information" concerning the cumulative effects of a particular pesticide residue and "other substances that have a common mechanism of toxicity."

In the case of sulfentrazone, EPA has determined that it does not have the capability to apply the information in its files to a resolution of common mechanism issues in a manner that would be useful in a risk assessment. This tolerance determination therefore does not take into account common mechanism issues. The Agency will reexamine the tolerances for sulfentrazone, if reexamination is appropriate, after the Agency has determined how to apply common mechanism issues to its pesticide risk assessments.

#### E. Safety Determination

**1. U.S. population.** The absorbed (systemic) aggregate exposure estimates for all adults, and adult females were found to be 0.0015 mg/kg/day and 0.0017 mg/kg/day, respectively. The acute dietary (99.9%), non-dietary, and aggregate margin of exposure (MOE) for

all adults were found to be 12,353, 7,571, and 6,726 respectively. The acute dietary (99.9%), non-dietary and aggregate MOE for adult females were 22,857, 6,327, and 5,717 respectively. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to the U.S. population from exposure to sulfentrazone.

**2. Infants and children.** The absorbed (systemic) aggregate exposure estimates for toddlers were found to be 0.0054 mg/kg/day. The acute dietary (99.9%), non-dietary, and aggregate MOE for toddlers were found to be 6,721, 2,048, and 1,869 respectively. The MOE from the limited potential for short-term exposure from residential uses was >1,000. Based on these assessments, it can be concluded that there is reasonable certainty of no harm to infants and children from exposure to sulfentrazone.

The calculated drinking water levels of concern for all adults, and adult females were estimated to be 298 parts per billion (ppb), 250 ppb, respectively. These values exceed the maximum water-monitoring residue of 42 ppb (from the North Carolina study). Therefore, the data indicate a low risk potential due to the aggregate (food, water and residential) exposures to sulfentrazone residues.

#### F. International Tolerances

There are no Codex Alimentarius Commission (Codex) maximum residue levels for sulfentrazone.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0350; FRL-7285-8]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2002-0350, must be received on or before April 7, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or