

phenoxy-hydroxypyrimidine metabolite. This metabolite was investigated for acute oral toxicity and point mutagenic activity in a bacterial reverse mutation assay. The phenoxy-hydroxypyrimidine metabolite did not show mutagenic activity in the reverse mutation assay and the oral LD<sub>50</sub> was >300 <500 mg/kg body weight.

8. *Endocrine disruption.* There is no evidence to suggest that fluoxastrobin has any primary endocrine disruptive potential. Reproductive and developmental findings provided no evidence of an enhanced sensitivity of the young.

#### C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Acute and chronic dietary analyses were conducted to estimate exposure to potential fluoxastrobin residues in/on the following crops and crop groups: celery, fruiting vegetables, peanuts, and potatoes. Rotational crops included in the analysis are alfalfa, grasses, legume vegetables, foliage of legume vegetables, cereal grains, and cotton. Tier I analysis were conducted for both the acute and chronic scenarios using the Dietary Exposure Evaluation Model (DEEM) (Exponent, Inc.) software. The acute dietary exposure estimates at the 95<sup>th</sup> percentile of exposure for the U.S. population was 1.4% of the acute reference dose (RfD). The population subgroup with the highest exposure was children 1 to 6 at 2.7% of the acute RfD. Chronic dietary exposure estimates from potential residues of fluoxastrobin for the U.S. population was 6.5% of the chronic RfD. The subpopulation with the highest exposure was children 1 to 6 with 12.7% of the chronic RfD used. Tier I assessments use tolerance residue values and 100% crop treated. These can be considered very conservative values.

ii. *Drinking water.* EPA's Standard Operating Procedure (SOP) for Drinking Water Exposure and Risk Assessments was used to perform the drinking water analysis for fluoxastrobin. This SOP utilizes a variety of tools to conduct drinking water assessment. These tools include water models such as Screening Concentration in Groundwater (SCI-GROW), Generic Estimate Exposure Concentration (GENEEC), Pesticide Root Zone Model-Exposure Analysis Modeling Systems (PRZM/EXAMS), and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface water and ground water. In the case of fluoxastrobin, monitoring data do not exist, therefore, PRZM/EXAMS and

SCI-GROW models were used to estimate a drinking water residue. The calculated drinking water levels of comparison (DWLOC) for acute and chronic exposures for all adults and children exceed the modeled fluoxastrobin drinking water estimated concentrations (DWECS). The acute DWLOC values are 8,624 parts per billion (ppb) for adults and 2,433 ppb for children. The worst-case DWELOC for acute scenarios is calculated to be 58 ppb using the PRZM/EXAMS surface water model. The chronic DWLOC values are 491 ppb for adults and 131 ppb for children. The DWELOC for the worst-case chronic scenario is 28 ppb PRZM/EXAMS.

2. *Non-dietary exposure.* Residential (non-dietary) exposure is limited to post-application exposure of fluoxastrobin from professional applications to residential turf and golf courses. Using the very conservative EPA SOPs for residential exposure a margin of exposure (MOE) of 7,143 was calculated for the youth golfer scenario. Adult and toddler reentry to treated turf MOEs were 784 and 468 respectively.

Aggregate exposure considers all exposures from food, drinking water, and residential uses together. Probabilistic models and methods as well as refined data for these scenarios are under development. In the interim, as a screening level analysis a worst-case deterministic calculation can be considered. For fluoxastrobin this would consist of a child (1 to 6) who has a chronic dietary exposure to potential residues in food and also plays on a maximally treated lawn (after 4 applications) on a particular day. The child's lawn exposure includes estimates of dermal exposure and oral exposure from hand to mouth, object to mouth and soil ingestion SOP scenarios. The child's estimated dose from the lawn exposure is 0.0194 mg/kg bwt/day. The child 1 to 6 chronic dietary exposure estimate is 0.001907 mg/kg bwt/day. The total dose for a child 1 to 6 with this worst-case exposure is 0.0213 mg/kg bwt/day or 8.5% of the acute RfD. The resulting aggregate acute DWLOC is 2,287 ppb still well above the acute DWELOC of 58 ppb. Total adult exposure (average dietary and dermal lawn) is 0.004804 mg/kg bwt/day or 1.9% of the acute RfD. The resulting aggregate acute DWLOC for adults is 17,164 ppb.

#### D. Cumulative Effects

Fluoxastrobin is a novel strobilurin analog. Bayer will submit information, if necessary, for EPA to consider concerning potential cumulative effects

of fluoxastrobin consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020) (FRL-5734-6), and other EPA publications pursuant to the Food Quality Protection Act (FQPA).

#### E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data it is concluded that aggregate exposure to the proposed uses of fluoxastrobin will utilize at most 1.9% of the RfD for the U.S. population, and is likely to be much less as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. DWLOC based on this exposure are much greater than conservative estimated concentrations, and would be expected to be well below the 100% level, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure to fluoxastrobin.

2. *Infants and children.* Consideration of the toxicology data base as described above leads to no additional concerns for infants and children. Therefore the FQPA safety factor can be established at 1X. Using the conservative exposure assumptions described in the exposure section above, the percent of the RfD that will be used for short-term aggregate exposure to residues of fluoxastrobin will be 8.5% for children 1 to 6 (the most highly exposed subgroup). This value is based on a worst-case aggregate exposure calculation of a child 1 to 6 who has a background dietary exposure to potential residues and plays on a maximally treated lawn. As in the adult situation, DWLOC are much higher than the worst-case DWECS and would be expected to use well below 100% of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of fluoxastrobin.

#### F. International Tolerances

Codex maximum residue levels are not yet established for fluoxastrobin. [FR Doc. 03-9746 Filed 4-22-03; 8:45 am]

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