

6. *Animal metabolism.* The metabolism of cyromazine has been adequately characterized in the rat, goat, and chicken.

7. *Metabolite toxicology.* EPA has removed melamine, a metabolite of cyromazine, from the tolerance expression as a residue of toxicological concern. For more information on melamine, see the **Federal Register** of September 15, 1999 (64 FR 50043) (FRL-6098-7).

8. *Endocrine disruption.* Cyromazine does not belong to a class of chemicals proven to have adverse effects on the endocrine system. There is no evidence that cyromazine has any effect on endocrine function in developmental or reproduction studies.

### C. Aggregate Exposure

1. *Dietary exposure—Food.* For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established.

i. *Acute.* There were no toxicological effects attributed to a single exposure (dose) observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. Therefore, there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic.* The cyromazine chronic dietary exposure assessment utilized the Dietary Exposure Evaluation Model (DEEM®), version 7.76 from Exponent. All consumption data from this assessment were taken from the USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994-96 consumption database and the Supplemental CSFII children's survey (1998) consumption database.

The cyromazine Tier III chronic dietary exposure assessment was based upon residue field trial results, and tolerance residues for crops when no field trial data were available. Anticipated residue estimates were used for milk, meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep; and for all other commodities tolerance level residues were assumed. The maximum percent crop treated values for cyromazine were obtained from the Doane's Market Survey Database (1999-2001) and used for lima beans (0.8%), cantaloupe (3.9%), peppers (8.6%), tomatoes (2.9%), celery (68.9%), lettuce (9.7%), spinach (19.5%), and onions (0.2%). For all other registered or proposed crop uses, it was assumed that 100% of these crops were treated.

2. *Drinking water.* EPA uses the FQPA Index Reservoir Screening Tool (FIRST)

to estimate pesticide concentrations in surface water and screening concentration in ground water (SCI-GROW) to estimate pesticide concentrations in ground water. FIRST incorporates an index reservoir environment and includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact that processing (mixing, dilution, or treatment) would have on the removal of pesticides from the water source. The primary use of these models by EPA is to provide a Tier I assessment to estimate the concentration of pesticides in drinking water.

Estimated Environmental Concentrations (EECs) of cyromazine in drinking water were determined for the highest use rate of cyromazine. Based on the model outputs, the EECs of cyromazine are 1.8 parts per billion (ppb) for chronic exposure to ground water and 10 ppb for chronic exposure to surface water.

3. *Non-dietary exposure.* Cyromazine is currently registered for commercial outdoor use on landscape ornamentals and commercial interiorscapes. There are no lawn or indoor residential uses and significant residential exposure is not expected.

### D. Cumulative Effects

When considering whether to establish, modify, or revoke a tolerance, section 408(b)(2)(D)(v) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residue and "other substances that have a common mechanism of toxicity." Neither Syngenta nor EPA has at this time, data available to determine whether cyromazine has a common mechanism of toxicity with other substances or the methodology to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyromazine does not appear to produce a toxic metabolite produced by other substances.

### E. Safety Determination.

1. *Acute risk.* There were no toxicological effects observed in oral toxicity studies, including the developmental toxicity studies in rats and rabbits, that could be attributed to a single exposure (dose). Since there is a reasonable certainty of no harm from acute dietary exposure, an acute

aggregate risk assessment was not performed for cyromazine.

2. *Chronic risk.* The chronic dietary exposure risk analysis (food only) showed that exposure from all established and these proposed tolerances would be 2.9% of the chronic reference dose (cRfD) for the most exposed subpopulation, children 1 to 2 years old. EPA has determined that reliable data support using the standard margin of exposure and uncertainty factor (100 for combined interspecies and intraspecies variability) for cyromazine and an additional safety factor of 10X is not necessary to protect infants and children.

3. *Drinking water.* The chronic drinking water level of concern (DWLOC) for the most exposed subpopulation (children 1-6 years) is 728 ppb. Based upon the SCI-GROW and FIRST model outputs, the EECs of cyromazine in surface water and ground water are below the chronic DWLOC; therefore, EPA should not have a concern regarding cyromazine in drinking water.

4. *Non-dietary exposure.* Due to the nature of the non-dietary use, the commercial use of cyromazine on landscape ornamentals will not result in any significant residential exposure.

Syngenta has considered the potential aggregate exposure from food, water, and non-occupational exposure routes and concluded that aggregate exposure is not expected to exceed 100% of the cRfD. Therefore, Syngenta has concluded that there is reasonable certainty that no harm will result from aggregate exposure to cyromazine residues.

### F. International Tolerances.

The U.S. tolerances and Codex Maximum Residue Levels (MRLs) are compatible for ruminant tissue, bell pepper, and tomato. Codex MRLs and U.S. tolerances are incompatible for milk, celery, cucumber, lettuce, melon, and mushroom.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0234; FRL-7317-6]

### Benoxacor; 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.