

parameters and micropathological findings of the urinary bladder (females). The mutagenic potential of KWG 4168 N-oxide was studied *in vitro* in bacteria and mammalian cells. It did not cause mutations *in vitro* in the Ames assay, the V-79-HPRT gene mutation assay, or produce clastogenicity in the chromosome aberration assay with or without metabolic activation.

8. *Endocrine disruption.* The toxicology data base for Spiroxamine is current and complete. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short- or long-term exposure. These studies revealed no primary endocrine effects due to Spiroxamine.

#### C. Aggregate Exposure

1. *Dietary exposure.* An aggregate risk assessment was conducted for all pending uses (grape, hop (domestic and imported) and banana (imported)) to assess the potential acute and chronic dietary exposure resulting from applications of Spiroxamine to these crops. Novigen Sciences, Inc.'s Dietary Exposure Evaluation Model (DEEM®) was used to estimate the chronic and acute dietary exposure.

For the acute dietary analysis, the proposed acute reference dose (aRfD) of 0.1 mg/kg/day was used. This aRfD is based on NOELs of 10 mg/kg from an acute oral toxicity and an acute neurotoxicity screening study and applying a 100-fold uncertainty factor.

For the chronic dietary analysis, the proposed chronic reference dose (cRfD) of 0.02 mg/kg/day was used. This cRfD is based on a parental toxicity NOEL of 2.13 mg/kg/day from the two-generation reproduction study and the application of a 100-fold uncertainty factor.

Results from the acute and chronic dietary exposure analyses described below demonstrate a reasonable certainty that no harm to the overall U.S. population or any population subgroup will result from the use of Spiroxamine on grape, hop and banana.

i. *Food.* An acute, Tier 1 dietary (food) risk assessment was conducted using the highest residue values and 100% crop treated. The estimated percent of the aRfD for the overall U.S. population (all seasons) at the 95 percentile is 8.5%. The most highly exposed population subgroup, non-nursing infants, had an exposure equal to 33.3% of the aRfD at the 95 percentile. These exposure estimates are within EPA's criteria of acceptability.

A chronic, Tier 1 dietary (food) risk assessment was conducted using average residue values and 100% crop

treated. The estimated percent of the cRfD for the overall U.S. population (all seasons) is 9.1%. For the most highly exposed population subgroup, children 1 to 6 years old, the exposure consumed 30.6% of the cRfD. These exposure estimates are within EPA's criteria of acceptability.

ii. *Drinking water.* No monitoring data are available for residues of Spiroxamine in ground water, and EPA has established no health advisory levels or maximum contaminant levels for residues of Spiroxamine in drinking water.

Studies show low to no soil mobility for Spiroxamine and its primary metabolites. In addition, field studies show that Spiroxamine and its degradates do not leach below the 6-inch depth level, and show very low potential to leach into ground water. Therefore, it can be concluded with reasonable certainty that no harm will result from acute or chronic aggregate exposure to Spiroxamine residues in drinking water.

2. *Non-dietary exposure.* Spiroxamine is not registered nor are registrations pending for uses that would result in non-dietary exposure.

#### D. Cumulative Effects

Spiroxamine belongs to a new class of chemistry known as spiroketalamines. Therefore, for this tolerance petition, it is assumed that Spiroxamine does not have a common mechanism of toxicity with other substances and only the potential risks of Spiroxamine in its aggregate exposure are considered.

#### E. Safety Determination

1. *U.S. population.* Based on the above aggregate food exposure estimates for the overall U.S. population (8.5% of the aRfD and 9.1% of the cRfD), the low potential for Spiroxamine and its degradates to leach into ground water, and the completeness of the toxicity data base, there is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to Spiroxamine.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of Spiroxamine, data from developmental toxicity studies in mice, rats, rabbits and a two-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the

reproductive capability of mating animals and data on systemic toxicity.

Based on the above, aggregate food exposure estimates for the most highly exposed population subgroups, i.e., non-nursing infants and children (1–6 years old), consumed 33.3% and 30.6% of the aRfD and cRfD, respectively. This, in combination with the low potential for Spiroxamine and its degradates to leach into ground water, and on the completeness of the toxicity data base, there is reasonable certainty that no harm to infants and children will result from aggregate exposure to Spiroxamine.

#### F. International Tolerances

There are no established Codex, Canadian or Mexican MRLs for Spiroxamine.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0362; FRL-7335-5]

### Alkyl (C<sub>10</sub>–C<sub>16</sub>) Polyglycosides; 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-2003-0362, must be received on or before January 9, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-0731; e-mail address: [parker.james@epa.gov](mailto:parker.james@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural