

of exposure (MOE) for the overall U.S. population (all seasons) and the following subpopulations: all infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this refined Tier 2 analysis, all evaluated population subgroups had an exposure equal to 0% of the aRfD with a corresponding MOE of >1 million at the 95th percentile.

Foliar application use (pome fruit). Tomen has conducted an acute dietary exposure Tier 1 analysis with Dietary Exposure Evaluation Model (DEEM) using proposed tolerance of 1 ppm, 100% crop treated and no adjustment of processing factor for the overall U.S. populations and the following subpopulations: all infants, nursing infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), and females (13–50 years). The results of Tier 1 analysis for foliar use of pome fruit indicated that the highest exposure never exceeds 5.42% of the aRfD at the 95th percentile.

The chronic reference dose (cRfD) of 0.097 mg/kg bwt/day (chronic NOAEL with a 100-fold uncertainty factor) was used to assess chronic dietary exposure.

Seed treatment use. Bayer's chronic dietary analysis estimated the percent of the cRfD and corresponding MOE for the overall U.S. population (all seasons) and the following subpopulations: all infants (<1 year), non-nursing infants (<1 year), children (1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this analysis, all evaluated population subgroups had an exposure equal to 0% of the cRfD. The corresponding MOE was >1 million.

Foliar application use. Tomen has conducted a chronic Tier 1 analysis and the results indicated that the highest exposure never exceeds 8.7% of the cRfD at the 95th percentile.

i. **Food.** See above discussion.

ii. **Drinking water.** For drinking water, the models SCI-GROW (ground water), and generic expected environmental concentration (GENEEC) (surface water), were selected to calculate the potential exposure of TM-444 in drinking water. Both short-term (acute) and long-term (chronic) exposures were estimated with respect to foliar uses on apples and pears. The predicted ground water concentrations for foliar application of apples and pears were 1.17 and 1.30 μ /L, respectively. The highest estimated acute and chronic exposures from surface water were 9.10 and 3.07 μ /L, respectively. Based on the standard

exposure scenarios for drinking water (70kg adult- 2L/day; 10 kg child- 1L/day), the potential human exposure and risk can be estimated. Using the acute (0.60 mg/kg/day) and chronic (0.097 mg/kg/day) reference doses (RfD), the human risk from exposure to TM-444 in drinking water is estimated. The risk to adults and children from ground water exposure ranged from 0.006 to 0.019% of the acute RfD and from 0.038 to 0.134% of the chronic RfD; from surface water, the estimated risk ranged from 0.039% to 0.152% of the acute RfD and 0.081 to 0.316% of the chronic RfD respectively.

2. **Non-dietary exposure.** Clothianidin is currently not registered for use on any residential non-food site. Therefore, residential exposure to clothianidin residues will be through dietary exposure only.

D. Cumulative Effects

There is no information available to indicate that toxic effects produced by clothianidin are cumulative with those of any other compound.

E. Safety Determination

1. **U.S. population.** Using the conservative exposure assumptions described above and based on the completeness of the toxicity data, it can be concluded that total aggregate exposure to clothianidin from all proposed uses will be less than 9% of the RfD for the overall U.S. population. All evaluated population subgroups had an exposure less than 9% of the RfD. EPA generally has no concerns 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. Thus, Arvesta believes that it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to clothianidin residues.

2. **Infants and children.** In assessing the potential for additional sensitivity of infants and children to residues of clothianidin, the data from developmental toxicity studies in both the rat and rabbit, a two-generation reproduction study in rats and a developmental neurotoxicity study in rats have been considered.

The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through

two generations, as well as any observed systemic toxicity.

The developmental neurotoxicity studies evaluate the neurobehavioral and neurotoxic effects on the developing animal resulting from the exposure of the mother. FFDCA section 408 provides that EPA may apply an additional uncertainty factor for infants and children based on the threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity data base. Based on the current toxicological data requirements the toxicology data base for clothianidin relative to prenatal and postnatal development is complete, including the developmental neurotoxicity study. None of the studies indicated the offsprings to be more sensitive. All effects were secondary to severe maternal toxicity. The RfD for clothianidin was calculated using the NOAEL of 9.7 mg/kg bw/day from the two-year chronic/oncogenicity study. This NOAEL is lower than the NOAEL from the two-generation reproduction study, the developmental studies, and the developmental neurotoxicity study. Moreover, using a toxicologically justified UF of 100, the RfD for a non-oncogenic clothianidin was established at a level 0.097 mg/kg/day, a value that offers a measure of safety that is the highest among the other alternative compounds for control of apple and pear pests.

F. International Tolerances

No CODEX maximum residue levels (MRL's) have been established for residues of clothianidin on any crops at this time.

[FR Doc. 03-32205 Filed 12-30-03; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OW-FRL-7605-2]

National Recommended Water Quality Criteria for the Protection of Human Health

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 304(a) of the Clean Water Act (CWA), the Environmental Protection Agency (EPA) is announcing the availability of updated national recommended water quality criteria for the protection of human health for the following fifteen pollutants: chlorobenzene; cyanide; 1,2-dichlorobenzene; 1,4-dichlorobenzene; 1,1-dichloroethylene; 1,3-