

TABLE 3.—SUMMARY OF EPA'S EEC'S IN SURFACE WATER AND GROUNDWATER TABLE—Continued

| Chemical | Surface Water (µg/L) | | Groundwater (µg/L) |
|--------------------|----------------------|--------------------|--------------------|
| | Acute | Non-Cancer Chronic | |
| Florida Strawberry | | | |
| Cyprodinil | 26.67 | 5.32 | 0.04 |
| CGA 249287 | 6.20 | 1.04 | 0.12 |
| Total | 32.9 | 6.4 | 0.16 |

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cyprodinil is not registered for use on any sites that would result in residential exposure. There are no registered or proposed uses of cyprodinil which result in potential residential exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA does not have, at this time, available data to determine whether cyprodinil has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cyprodinil and any other substances and cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyprodinil has a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There are no concerns or residual uncertainties for pre- and/or postnatal exposure.

3. *Conclusion.* There is a complete toxicity data base for cyprodinil and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X Safety factor to protect infants and children should be reduced to 1X because:

i. The toxicological data base is complete for the assessment of toxicity and susceptibility following pre- and/or post-natal exposures. No clinical signs of neurotoxicity or neuropathology were observed in the data base, and the developmental neurotoxicity study was not required.

ii. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with cyprodinil. There is no evidence of increased susceptibility of young rats in the reproduction study with cyprodinil.

iii. There are no residual concerns regarding pre- or post-natal toxicity or completeness of the toxicity or exposure data base.

iv. The dietary food exposure assessment is Tier 1, screening level, which is based on tolerance level residues and assumes 100% of all crops

will be treated with cyprodinil. By using these screening level assessments, actual exposures/risks will not be underestimated.

v. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

vi. There are currently no registered residential uses of cyprodinil.

vii. These assessments will not underestimate the exposure/risks posed by current or proposed uses of cyprodinil.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide’s concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide’s concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative