

folpet may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for folpet in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of folpet.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS), to produce estimates of pesticide concentrations in an index reservoir. The SCI-GROW model is used to predict pesticide concentrations in shallow groundwater. For a screening-level assessment for surface water EPA will use FIRST (a tier 1 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model 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 processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in 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 from residential uses. Since DWLOCs address total aggregate exposure to folpet they are further discussed in the aggregate risk sections in Unit III.E..

Based on the FIRST and SCI-GROW models the estimated environmental concentrations (EECs) of folpet for acute exposures are estimated to be 309 parts per billion (ppb) for surface water and 0.83 ppb for ground water. The EECs for chronic exposures are estimated to be 0.62 ppb for surface water and 0.83 ppb for ground water.

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).

Folpet is currently registered for use as an additive in paints and stains for use both occupationally and by the homeowner. Four major exposure scenarios for homeowner handlers using folpet containing paints and stains labeled for pesticidal use and three major scenarios for homeowners using folpet containing products not labeled for pesticidal use were evaluated. The highest exposure level for combined inhalation and dermal exposures were based upon a homeowner applying a ready-to-use stain formulation with an airless sprayer. This exposure level was used to estimate the short- and intermediate-term risks for folpet.

4. *Cumulative exposure to 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 folpet has a common mechanism of toxicity with other substances or how 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, folpet 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 folpet 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

Captan and folpet share a common metabolite, thiophosgene, which the

Agency believes to be responsible for the carcinogenic effects of these compounds. Thiophosgene is a highly reactive, short-lived compound. Studies indicate that thiophosgene causes local irritation of the site with which it comes in contact, and is believed to cause tumors through irritation of the duodenum. Because they are so short-lived, thiophosgene residues cannot be quantified. Without measurable residues of the common metabolite, it is difficult to relate exposures of captan to those of folpet since the formation of thiophosgene may be different for both compounds. However, assuming that the carcinogenic effects observed in both pesticides are due solely to the metabolite thiophosgene, the Agency believes it is reasonable to add the estimate cancer risks from the individual aggregate risks from both folpet and captan to obtain a worst-case estimate.

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.* The data provided no indication of increased susceptibility in two prenatal developmental toxicity studies in rats following in utero or in the two (2) generation reproduction studies in rats. Two developmental toxicity studies in rabbits are also available. In a study with New Zealand rabbits, folpet caused an increase in the incidence of hydrocephalus in fetuses and with the associated dome skull and irregularly-shaped fontanelles at the mid and high dose groups in the presence of maternal toxicity. Both fetal and litter incidences of this malformation were increased in a dose-related manner. There were no toxicological effects noted on litter size, resorptions, sex ratio, or number of skeletal malformations. For maternal toxicity, the NOAEL was 10 mg/kg/day and the LOAEL was 20 mg/kg/day, based on decreased body weight gain and food consumption. For developmental toxicity, the NOAEL was