

C. Safety Factor for Infants and Children

1. *In general.* FFDCA section 408 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 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 is no indication of increased susceptibility of rat and rabbit fetuses to *in utero* and/or postnatal exposure.

3. *Conclusion.* There is a complete toxicity data base for spinosad 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 removed. This recommendation is based on:

i. There is no evidence of increased susceptibility of rat or rabbit fetuses following *in utero* exposure in the developmental studies with spinosad, and there is no evidence of increased susceptibility of young rats in the reproduction study with spinosad.

ii. There are no residual uncertainties identified in the exposure data bases; the dietary food exposure assessment (chronic only; no acute endpoint was identified) is refined using Anticipated Residues calculated from field trial data and available PCT information (100% crop treated is assumed for proposed new uses).

iii. The dietary drinking water exposure is based on conservative modeling estimates.

iv. EPA's Health Effect Division Residential Standard Operating

Procedures were used to assess post-application exposure to children as well as incidental oral exposure of toddlers, so these assessments do not underestimate the exposure and risks posed by spinosad.

v. A developmental toxicity study is not required.

D. 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. 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 + chronic non-dietary, non-occupational 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 EPA 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 drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to spinosad in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of spinosad on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Acute aggregate risk consists of the combined dietary exposures from food and drinking water sources. The total exposure is compared to the acute RfD. An acute RfD was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. Therefore, the Agency concludes that there is a reasonable certainty of no harm from acute aggregate exposure to spinosad.

2. *Chronic risk.* Using the exposure assumptions described in unit C for chronic exposure, EPA has concluded that exposure to spinosad from food will utilize 30% of the cPAD for the U.S. population, 41% of the cPAD for infant <1 year old and 69% of the cPAD for children 1–6 years old (subpopulation at greatest exposure). Based on the use pattern, chronic residential exposure to residues of spinosad is not expected. In addition, there is potential for chronic dietary exposure to spinosad in drinking water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 2:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SPINOSAD

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.027	30	2.3	0.037	660
All infants (<1 year old)	0.027	41	2.3	0.037	160
Children (1–6 years old)	0.027	69	2.3	0.037	85
Children (7–12 years old)	0.027	45	2.3	0.037	150
Females (13–50)	0.027	24	2.3	0.037	620