

The Agency concluded that the FQPA safety factor could be reduced to 1X for indoxacarb. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure. EPA did require a developmental neurotoxicity study as confirmatory data. The requirement of a developmental neurotoxicity study is not based on the criteria reflecting special concern for the developing fetuses or young which are generally used for requiring a DNT study - and a safety factor (e.g., neuropathy in adult animals; central nervous system malformations following prenatal exposure; brain weight or sexual maturation changes in offspring; and/or functional changes in offspring) and therefore, does not warrant an FQPA safety factor; and the dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children. There are no registered residential uses at the current time.

#### *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 (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 + 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 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 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 indoxacarb 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 indoxacarb on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to indoxacarb will occupy 12% of the aPAD for the U.S. population, 64% of the aPAD for females 13 years and older, 67% of the aPAD for all infants (<1 year old) and 79% of the aPAD for children 1–5 years old, the children subpopulations at greatest exposure. In addition, despite the potential for acute dietary exposure to indoxacarb in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of indoxacarb in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 1. below:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO INDOXACARB

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.12	12	13.7	0.02	3,700
All Infants (< 1year old)	0.12	67	13.7	0.02	400
Children (1–5 years old)	0.12	79	13.7	0.02	760
Females (13–40 years old)	0.02	64	13.7	0.02	218

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to indoxacarb from food will utilize 30% of the cPAD for the U.S. population, 29% of the cPAD for all infants (<1 year old) and 79% of the

cPAD for children (1–2 years old), the children subpopulation at greatest exposure. There are no residential uses for indoxacarb that result in chronic residential exposure to indoxacarb. In addition, despite the potential for chronic dietary exposure to indoxacarb

in drinking water, after calculating DWLOCs and comparing them to conservative model EECs of indoxacarb in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 2. below:

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

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population	0.02	30	3.7	0.02	490
All infants (< 1 year old)	0.02	29	3.7	0.02	65