

Subgroup	Maximum Dietary Exposure (mg/kg/day)	% RfD
Non-Nursing Infants (<1 year old)	0.000063	0.3
Children (1–6 years)	0.000238	1.2
Children (7–12 years)	0.000126	0.6
Females (13+, nursing)	0.000073	0.4
Males (13–19 years)	0.000090	0.5

ii. *Acute dietary exposure.* Acute dietary exposure resulting from the currently approved use of indoxacarb on apples, Crop Group 5 (brassica vegetables), cotton, pears, peppers, sweet corn, tomatoes, eggplant, alfalfa, head and leaf lettuce, peanuts, soybeans, potatoes, cranberries (current Section 18 use) and the proposed use on grapes are well within acceptable limits for all sectors of the population. The Dietary Exposure Evaluation Model (DEEM™, Exponent, Inc., formerly Novigen Sciences, Inc., Version 7.76) was used to conduct the assessment. Margins of exposure (MOE) were calculated based on an acute NOAEL of 2 mg/kg/day for women of childbearing age and a NOAEL of 12 mg/kg/day for children and the general population (Pesticide Fact Sheet for Indoxacarb). The Tier 3 analysis used distributions of field trial residue data adjusted for projected peak percent crop treated. Secondary residues in milk, meat and poultry products were also included in the analysis. The results of this analysis are given in the table below. The percent of the acute population adjusted dose (a PAD) for all population subgroups shows that an adequate margin of safety exists in each case. Thus, the acute dietary safety of indoxacarb for established and the follow-on use clearly meets the Food Quality Protection Act (FQPA) standard of reasonable certainty of no harm and presents acceptable acute dietary risk.

Subgroup	99.9 th Percentile of exposure	
	Exposure (mg/kg/day)	% Acute population adjusted dose (aPAD)
U.S. population	0.008795	7.3

Subgroup	99.9 th Percentile of exposure	
	Exposure (mg/kg/day)	% Acute population adjusted dose (aPAD)
All infants	0.024729	20.6
Non-nursing (<1 year)	0.026036	21.7
Children (1–6 years)	0.013973	11.6
Children (7–12 years)	0.006882	5.7
Females (13–19 years)	0.005119	25.6
Females (20+, not pregnant or nursing)	0.005358	26.8
Females (13–50 years)	0.005307	26.5

iii. *Drinking water.* Indoxacarb is highly unlikely to contaminate groundwater resources due to its immobility in soil, low water solubility, high soil sorption, and moderate soil half-life. Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of indoxacarb and its R-enantiomer for acute exposures are estimated to be 6.84 parts per billion (ppb) for surface water and 0.0025 ppb for ground water. The EECs for chronic exposures are estimated to be 0.316 ppb for surface water and 0.0025 ppb for ground water. Drinking water levels of comparisons (DWLOCs), theoretical upper allowable limits on the pesticide's concentration in drinking water, were calculated to be much higher than the EEC's. The chronic DWLOC's ranged from 198 to 697 ppb. The acute DWLOC's ranged from 440 to 3,890 ppb. Thus, exposure via drinking water is acceptable.

2. *Non-dietary exposure.* Indoxacarb product registrations for residential non-food uses are pending. Non-occupational, non-dietary exposure for DPX-MP062 has been estimated to be extremely small. Therefore, the potential for non-dietary exposure is insignificant.

D. Cumulative Effects

EPA's consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of indoxacarb would be cumulative with those of any other chemical compounds. Oxadiazine chemistry is new, and

indoxacarb has a novel mode of action compared to currently registered active ingredients.

E. Safety Determination

1. *U.S. population.* Dietary and occupational exposure will be the major routes of exposure to the U.S. population, and ample margins of safety have been demonstrated for both situations. The chronic dietary exposure to indoxacarb is 0.000089 mg/kg/day, which utilizes 0.4% of the RfD for the overall U.S. population, using mean field trial values, processing factors and projected peak percent crop treated values. The percent of the acute population adjusted dose (7.3% aPAD) for the overall U.S. population shows that an adequate margin of safety exists. Using only pesticide handlers exposure data base (PHED) data levels A and B (those with a high level of confidence), margin of exposure (MOEs) for occupational exposure are 650 for mixer/loaders and 1,351 for airblast applicators (worst-case). Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is a reasonable certainty that no harm will result from the aggregate exposure of residues of indoxacarb including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* Chronic dietary exposure of the most highly exposed subgroup in the population, children age 1–6 years, is 0.000238 mg/kg/day or 1.2% of the RfD. For infants (non-nursing, <1 yr.), the exposure accounts for 0.3% of the RfD. For acute exposure at the 99.9th percentile (based on a Tier 3 assessment) the exposure was 0.013973 mg/kg/day (11.6% a PAD) for children 1–6 and 0.026036 mg/kg/day (21.7% a PAD) for non-nursing infants. There are residential uses of indoxa carb pending, but exposure is calculated to be extremely minimal. The estimated levels of indoxa carb in drinking water are well below the DWLOC. Based on the completeness and reliability of the toxicity data, the lack of toxicological endpoints of special concern, the lack of any indication that children are more sensitive than adults to indoxa carb, and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of indoxa carb, including all anticipated dietary exposure and all other non-occupational exposures. Accordingly, there is no need to apply an additional safety factor for infants and children.