

iii. The developmental toxicity study in the rabbits did not exhibit either quantitative or qualitative susceptibility.

3. *Conclusion.* Exposure data for sethoxydim are complete or are estimated based on data that reasonably accounts for potential exposures. The toxicity data base, however, is not complete. Due to evidence of developmental (Tail) abnormalities in the rat developmental and reproductive studies, EPA has required submission of subchronic and developmental neurotoxicity studies. After reviewing the data base, EPA concluded that there was not a reliable basis for establishing an additional safety factor for the protection of children at a value different than the statutory default of 10X. Accordingly, EPA has retained the additional 10X FQPA safety factor in the form of a Data base Uncertainty Factor.

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 U.S. EPA Office of Water are used to calculate DWLOCs: 2 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, OPP concludes with reasonable certainty that exposures to the pesticide 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 residues of the pesticide in 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 sethoxydim will occupy 52% of the aPAD for the U.S. population, 92% of the aPAD for children aged 1–2 and 92% of the aPAD for children aged 3–5. In addition, there is potential for acute dietary exposure to sethoxydim in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO SETHOXYDIM

Population Subgroup	aPAD (mg/kg)	Acute Food Exp mg/kg/day	Surface Water EEC (ppb) ¹	Ground Water EEC (ppb) ¹	Acute DWLOC (ppb) ²
General U.S. population	0.18	0.096	100	1.0	2,940
Children 1–2 years	0.18	0.165	100	1.0	150
Children 3–5 years	0.18	0.165	100	1.0	152

¹ The crop producing the highest risk level was used.

² Chronic DWLOC (μg/L) = maximum chronic water exposure (mg/kg/day) x body weight (kg) water consumption (L) x 10³ mg/μg.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to sethoxydim from food will utilize 24% of the cPAD for the U.S. population, and 75% of the cPAD

for infants <1 year old. Based on the use pattern, chronic residential exposure to residues of sethoxydim is not expected. In addition, there is potential for chronic dietary exposure to sethoxydim in drinking water. After calculating

DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO SETHOXYDIM.

Population Subgroup	cPAD (mg/kg)	Chronic Food Exp mg/kg/day	Surface Water EEC (ppb) ¹	Ground Water EEC (ppb) ¹	Chronic DWLOC (ppb) ²
General U.S. population	0.014	0.0038	20	1.0	358
Infants (<1 year)	0.014	0.0105	20	1.0	35.3

¹ The crop producing the highest level was used.

² Chronic DWLOC (μg/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)] ÷ [water consumption (L) x 10^{−3} mg/μg.]