

values are used to account for dietary (food only) exposure. The short-term aggregate risk assessment is considered conservative because food-source dietary exposure is based on a Tier 1 DEEM assessment (tolerance level residues and 100% crop treated information were used).

A short-term risk aggregate assessment is not performed for adults because no handler exposure is expected and post-application inhalation exposure is expected to be negligible. A short-term aggregate risk assessment is required for infants and

children because there is a potential for oral post-application exposure resulting from residential uses.

Pyraflufen-ethyl is currently registered for use that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for pyraflufen-ethyl.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 122,000 for

children (1–2 years old) and 122,000 for children (3–5 years old). These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of pyraflufen-ethyl in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface water and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 4.

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO PYRAFLUFEN-ETHYL

| Population Subgroup | Aggregate MOE (Food + Residential) ¹ | Aggregate Level of Concern (LOC) | Surface Water EEC (ppb) ² | Ground Water EEC (ppb) ² | Short-Term DWLOC (ppb) ³ |
|----------------------|---|----------------------------------|--------------------------------------|-------------------------------------|-------------------------------------|
| Children (1–2 years) | 122,000 | 100 | 0.28 | 0.002 | 2,000 |
| Children (3–5 years) | 122,000 | 100 | 0.28 | 0.002 | 2,000 |

¹ Aggregate MOE = NOAEL ÷ (Avg Food Exposure + Residential Exposure).

² The crop producing the highest level was used (potatoes, 0.009 lb ai/acre).

³ DWLOC (ppb) = [maximum water exposure (mg/kg/day) × bwt (kg)] ÷ [water consumption (L) × 10⁻³ mg/μg]

*(bwt: Children—10 kg)

4. *Intermediate-term risk.* The intermediate-term aggregate risk assessment estimates risks likely to result from 1 to 6 months of exposure to pyraflufen-ethyl residues from food, drinking water, and residential pesticide uses. High-end estimates of residential exposure are used in the intermediate-term assessment, while average values are used for food and drinking water exposure.

An intermediate-term risk aggregate assessment is not performed for adults because no handler exposure is expected and postapplication inhalation

exposure is expected to be negligible. Also, an intermediate-term aggregate risk assessment is not performed for infants and children because postapplication exposure over the intermediate-term duration is not likely based on the use pattern.

5. *Aggregate cancer risk for U.S. population.* Pyraflufen-ethyl has been classified as “Likely to be Carcinogenic to Humans” by the oral route of exposure (Q_1^* of 3.32×10^{-2} (mg/kg/day)⁻¹). Using the exposure assumptions discussed in this unit for cancer, the carcinogenic risk is determined for the

U.S. population (total) only. The aggregate cancer DWLOC (1.6 ppb) is greater than EPA's estimates of pyraflufen-ethyl residues in drinking water. The estimated exposure to pyraflufen-ethyl is 4×10^{-5} mg/kg/day. Applying the Q_1^* of 0.0332 (mg/kg/day)⁻¹ to the exposure value results in a cancer risk estimate of 10^{-6} . Therefore, the aggregate cancer risk from residues of pyraflufen-ethyl in food and drinking water does not exceed EPA's level of concern as shown in the following Table 5.

TABLE 5.—CANCER DWLOC CALCULATIONS FOR THE U.S. POPULATION

| Q_1^* (mg/kg/day) ⁻¹ | Negligible Risk Level ¹ | Chronic Food Exposure mg/kg/day | Ground Water EEC ² (ppb) | Surface Water EEC ² (ppb) | Cancer DWLOC ³ (ppb) |
|-----------------------------------|------------------------------------|---------------------------------|-------------------------------------|--------------------------------------|---------------------------------|
| 0.0332 | 3.0E-6 | 4.0E-5 | 0.002 | 0.28 | 1.6 |

¹ Negligible risk is that below 10^{-6} . 3.0E-6 is statistically within the range that EPA generally accepts as “negligible risk”.

² The crop producing the highest level was used (potatoes). (3 Cancer DWLOC (ppb) = [maximum water exposure (mg/kg/day) × bwt (kg)] ÷ [water consumption (L) × 10⁻³ mg/μg].

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to pyraflufen-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Nichino America, Inc., has submitted a petition method validation (PMV) and an independent laboratory validation for a Gas Chromatography/Mass Spectrometry (GC/MS) method proposed for the enforcement of tolerances for residues of pyraflufen

ethyl and its acid metabolite, E-1. The proposed plant method is adequate for enforcement of tolerances in/on field corn, potato, and soybean.

Adequate enforcement methodology (example—gas chromatography) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental