

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO FLUDIOXONIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
All infants (< 1 year old)	460	100	49	0.11	780
Children (1-2 years old)	410	100	49	0.11	760
Children (3-5 years old)	490	100	49	0.11	800

4. Intermediate-term risk.

Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Fludioxonil is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food

and water and intermediate-term exposures for fludioxonil.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 200 for all infants <1 year old; 180 for children 1–2 years old; and 220 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, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of fludioxonil in ground and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO FLUDIOXONIL

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
All infants (< 1 year old)	200	100	49	0.11	130
Children (1-2 years old)	180	100	49	0.11	140
Children (3-5 years old)	220	100	49	0.11	180

5. *Aggregate cancer risk for U.S. population.* EPA's Cancer Peer Review Committee (CPRC) classified fludioxonil as a Group D - not classifiable as to human carcinogenicity.

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 fludioxonil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The methods used in the field trial studies were similar to a method validated by the Analytical Chemistry Branch. Since adequate method validation and concurrent recoveries were attained in the field trial studies, EPA concludes that the ACB validated method is appropriate for enforcement of the tolerances associated with this petition. No further validation is necessary.

Adequate enforcement methodology (high pressure liquid chromatography method AG-597B) is available to

enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

Canada, Codex, and Mexico do not have maximum residue limits (MRLs) for residues of fludioxonil in/on the subject crops. Therefore, harmonization is not an issue.

V. Conclusion

Therefore, the tolerances are established for residues of fludioxonil, (4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile) in or on brassica, head and stem, subgroup 5A at 2.0 ppm; brassica, leafy greens, subgroup 5B at 10 ppm; carrot at 0.75 ppm; herb, fresh, subgroup 19A at 10 ppm; herb, dried, subgroup 19A at 65 ppm; longan, lychee, pulasan, rambutan, and spanish lime at 1.0 ppm; and turnip, greens at 10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.