

7. A chronic mouse feeding/carcinogenicity study with a systemic NOEL of less than 7.5 mg/kg/day (lowest dose tested) in which increased alkaline phosphatase activity in males was observed. There was no evidence of carcinogenicity under conditions of the study. Levels tested were 50, 200, and 800 ppm.

8. A three-generation rat reproduction study with a NOEL of 7.5 mg/kg/day for reproductive effects and a systemic NOEL of 2.5 mg/kg/day. Decreased viability and decreased pup body weights were observed. Levels tested were 50, 150, and 450 ppm.

9. A rat oral developmental study with no clinical signs resulting from the test article. Levels tested were 1, 3, and 10 mg/kg/day.

A second rat oral developmental study with a maternal NOEL of 3 mg/kg/day and a LOEL of 10 mg/kg/day (high-stepping gait, occasional ataxia, and reduced motility). There were no developmental effects. Levels tested were 3, 10, and 30 mg/kg/day.

10. A rabbit oral developmental study with a developmental NOEL and LOEL of 20 mg/kg/day and 60 mg/kg/day, respectively, in which increased numbers of resorptions and percent incidence of postimplantation loss were observed at the LOEL. The maternal NOEL and LOEL were 20 mg/kg/day and 60 mg/kg/day, respectively, with decreased body weight gain and food consumption observed at the LOEL. Levels tested were 20, 60, and 180 mg/kg/day administered by gavage on gestational days 6 to 18, inclusively.

11. A rat inhalation developmental study with a developmental NOEL and LOEL of 0.00059 mg/L and 0.0011 mg/L, respectively, with unspecified sternal anomalies and increased runt incidence observed at the LOEL. The maternal NOEL and LOEL were 0.0011 mg/L and 0.0047 mg/L, respectively, with reduced motility, dyspnea, piloerection, ungroomed coats, and eye irritation observed at the LOEL.

12. A rat inhalation developmental study with a NOEL and LOEL of 0.46 and 2.55 mg/m³, respectively, with reduced fetal and placental weight, reduced ossification in the phalanx, metacarpals and vertebrae observed at the LOEL. The maternal LOEL was less than 0.46 mg/m³ with decreased body weight gain and reduced relative food efficiency observed at this dose level.

13. Mutagenicity studies including a CHO/HGPRT gene mutation test, a structural chromosome aberration: sister chromatid exchange, and an unscheduled DNA synthesis, which were all negative for mutagenic effects.

14. Two metabolism studies in rats showing that the test material was rapidly and nearly completely absorbed and that the radioactivity was rapidly and nearly completely excreted in the urine and feces by 48 hours. The studies showed that the parent is cleaved at the ester bond and then oxidized to yield 3-phenoxy-4-fluorobenzoic acid. This intermediate is then either hydroxylated and subsequently conjugated and excreted, or first bound to glycine and then hydroxylated, conjugated, and excreted.

The Reference Dose (RfD) is established at 0.025 mg/kg day, based on an NOEL of 2.5 mg/kg/day from the 2-year rat feeding study and an uncertainty factor of 100. The Theoretical Maximum Residue Contribution (TMRC) from established tolerances and the current action is estimated at 0.002730 mg/kg bwt/day and utilizes 11.0 percent of the RfD for the U.S. population. The TMRC for the subgroup most highly exposed, nonnursing infants less than 1-year old, utilizes 32.0 percent of the RfD.

Because there was a sign of developmental effects seen in animal studies, the Agency used the rabbit developmental toxicity study with a maternal NOEL of 20 mg/kg/day to assess acute dietary exposure and determine a margin of exposure (MOE) for the overall U.S. population and certain subgroups. Since the toxicological end-point pertains to developmental toxicity, the population group of concern for this analysis is women aged 13 and above, the subgroup which most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOEL to the exposure. For this analysis the Agency calculated the MOE for women aged 13 and above to be 1,250. Generally speaking, MOE's greater than 100 for data derived from animal studies are acceptable to the Agency.

The nature of the residues in plants is adequately understood. The nature of residue in animals is adequately understood for the purpose of the requested tolerances. An adequate analytical method, gas chromatography, is available for enforcement purposes.

The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Volume II (PAM). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division

(7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)-305-5232.

Any secondary residues occurring in milk and the meat, fat, and meat by-products (mbypp) of cattle, goats, hogs, horses, and sheep will fall within existing tolerances for these commodities. There is no reasonable expectation that secondary residues will occur in eggs, and the meat, fat, and mbypp of poultry as a result of this action. The pesticide is considered useful for the purpose for which the tolerance is sought.

To be consistent with the conditional registration and the regulation for establishing a time-limited tolerance for residues of another insecticide, O-[2-(1,1-dimethylethyl)-5-pyrimidinyl] O-ethyl-O-(1-methylethyl) phosphorothioate, which are being issued both in conjunction with, and concurrently with, this regulation, the Agency is limiting the period of time that the regulation is to be in effect. The conditional registration is for a product consisting of cyfluthrin in combination with the other insecticide as the two active ingredients. Upon receipt and evaluation of the additional data/information required as a condition of the time-limited tolerance for the other insecticide and of the conditional registration for the use of these two insecticides on corn, the Agency will reassess the tolerances and the registration and, if appropriate, will issue permanent tolerances and an unconditional registration for the insecticides on corn.

There are currently no actions pending against the continued registration of this chemical.

Elsewhere in this issue of the **Federal Register**, the Agency is concurrently issuing a notice of conditional registration for the use of the combination product on corn and for a time-limited tolerance for residues of the other insecticide referenced above in/on corn commodities.

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR 180.436 will protect the public health. Therefore, the tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections to the regulation and may also request a hearing on those objections.