

2. A developmental toxicity study in rats, which was given the chemical by gavage at doses of 0, 15, 75, and 250 mg/kg, with no developmental toxicity observed under the conditions of the study. The NOEL for maternal toxicity was established at 75 mg/kg based on decreased body weight and reduced food consumption at the LOEL (250 mg/kg/day).

3. A developmental toxicity study in rabbits, which was given the chemical by gavage at doses of 110 and 250 mg/kg, with no developmental or maternal toxicity observed under the conditions of the study.

4. A 2-year chronic feeding/carcinogenicity study in mice, which were fed diets containing 0, 100, 500, and 2,000 mg/kg/day, with a NOEL for systemic effects of 500 mg/kg. Decreased body weight was observed in male mice fed 2,000 mg/kg/day (LOEL). No carcinogenic effects were observed under the conditions of the study.

5. A 2-year chronic feeding/carcinogenicity study in rats fed diets containing 0, 5, 15, 50, and 150 mg/kg/day with a NOEL for systemic effects of 50 mg/kg/day. The LOEL was established at 150 mg/kg/day based on decreased mean body weight in females in the high-dose group. No carcinogenic effects were observed under the conditions of the study.

6. A two-generation reproduction study in rats fed diets containing 0, 150, 500, and 1,500 mg/kg/day with no observed effect on reproductive performance. A systemic NOEL of 500 mg/kg/day was established for the study based on reduced terminal body weight in the F0 generation at the 1,500 mg/kg/day level.

7. Mutagenicity studies including dominant-lethal assay in rats, *in vivo* rat cytogenetic, *in vitro* Salmonella and Saccharomyces assays, *in vivo* mouse host-mediated assay, and an unscheduled DNA synthesis assay, which were all negative.

8. In a metabolism study in rats, radio-labeled clopyralid was readily absorbed after being ingested and the majority of the radioactive dose was excreted within 24 hours of ingestion.

The reference dose (RfD) for clopyralid is established at 0.5 mg/kg body weight (bwt)/day. The RfD is based on a NOEL of 50 mg/kg/bwt/day from the 2-year feeding study in rats and an uncertainty factor of 100. The theoretical maximum residue contribution (TMRC) from established tolerances utilizes less than 2 percent of the RfD for the overall U.S. population. The TMRC for the subgroup most highly exposed, children aged 1 to 6 years, utilizes less than 4 percent of the RfD.

The dietary risk assessment indicates that there is no appreciable risk from establishment of the proposed tolerance for asparagus.

The nature of the residue in plants is adequately understood. The residue of concern is parent clopyralid. An adequate analytical method, gas chromatography, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement method in the Pesticide Analytical Manual, the analytical method is being made available, in the interim, to anyone with an interest 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)-305-5937.

No secondary residues are expected to occur in milk, eggs, or meat as a result of this use; asparagus is not considered a livestock feed commodity.

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

Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDC.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 1E3979/P632].

Electronic comments can be sent directly to EPA at:

opp-Docket@epamail.epa.gov
Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

A record has been established for this rulemaking under docket number [PP 1E3979/P632] (including comments and data submitted electronically as described below). A public version of

this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial