

hepatocellular hypertrophy, hepatocellular vacuolation, necrosis of single hypertrophied hepatocytes, yellow-brown pigment in the Kupffer cells and cytoplasmic eosinophilia and hypertrophy of the cells of the zona fasciculata area of the adrenal cortex. Myclobutanil was not oncogenic when tested under the conditions of the study.

4. A rabbit developmental toxicity study at dosages of 0, 20, 60, and 200 mg/kg/day administered by oral gavage. The LOEL for maternal toxicity was 200 mg/kg/day, and the maternal toxicity NOEL was 60 mg/kg/day based on reduced body weight and body weight gain during the dosing period, clinical signs of toxicity, and possibly abortions. The LOEL for developmental toxicity is 200 mg/kg/day, and the NOEL for developmental toxicity is 60 mg/kg/day based on increases in resorptions, decreases in litter size, and a decrease in the viability index.

5. A developmental toxicity study on rats treated with dosages of 0, 31.26, 93.77, 312.58, and 468.87 mg/kg/day. The maternal toxicity LOEL was 312.6 mg/kg/day, and maternal toxicity NOEL was 93.8 mg/kg/day based on clinical signs of toxicity. The developmental toxicity LOEL was 312.6 mg/kg/day, and the developmental toxicity NOEL was 93.8 mg/kg/day based on increased incidences of 14th rudimentary and 7th cervical ribs.

6. A two-generation rat reproduction study with dosage rates of 0, 50, 200, and 1,000 ppm (equivalent to 0, 2.5, 10, and 50 mg/kg/day). The parental (systemic) toxicity LOEL was 200 ppm (10 mg/kg/day), and the parental (systemic) toxicity NOEL was 50 ppm (2.5 mg/kg/day) based on hepatocellular hypertrophy and increases in liver weights. The reproductive toxicity LOEL was 1,000 ppm (50 mg/kg/day) and reproductive toxicity NOEL was 200 ppm (10 mg/kg/day) based on an increased incidence in the number of stillborns and atrophy of the testes and prostate. The developmental toxicity LOEL was 1,000 ppm (50 mg/kg/day) and the developmental toxicity NOEL was 200 ppm (10 mg/kg/day) based on a decrease in pup body weight gain during lactation.

7. A reverse mutation assay (Ames), point mutation in CHO/HGPRT cells, *in vitro* and *in vivo* (mouse) cytogenetic assays, unscheduled DNA synthesis, and a dominant-lethal study in rats, all of which were negative for mutagenic effects.

The Reference Dose (RfD) based on the 2-year rat chronic feeding study (NOEL of 2.49 mg/kg bwt/day) and using a hundredfold uncertainty factor, is calculated to be 0.025 mg/kg bwt/day.

The theoretical maximum residue contribution (TMRC) from previously established tolerances and the tolerance established here is 0.002075 mg/kg bwt/day for the general population and utilizes 8% of the RfD. The percentage of the RfD for the most highly exposed subgroup, nonnursing infants (less than 1 year old) is 49%. The TMRC was calculated based on the assumption that myclobutanil occurs at the maximum legal limit in the dietary commodity for which a tolerance is proposed. Even with this probable large overestimate of exposure/risk, the TMRC is well below the RfD for the population as a whole and for each of the 22 subgroups considered. Thus, the dietary risk from exposure to myclobutanil appears to be minimal for the use on cottonseed.

The nature of the residues is adequately understood, and adequate analytical methodology is available for enforcement. Prior to their publication in the Pesticide Analytical Manual, Vol. II, the enforcement methodology is being made available in the interim to anyone who is interested in pesticide enforcement when requested from: Calvin Furlow, Public Information Branch, Field Operations Division (7505C), 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 Hwy., Arlington, VA 22202, (703)-305-5232.

The pesticide is considered useful for the purpose for which the tolerance is sought. Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerances are established as set forth below. By way of public reminder, this document also reiterates the registrant's responsibility under section 6(a)(2) of FIFRA, to submit additional factual information regarding adverse effects on the environment and to human health by these pesticides.

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.

Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40

CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33 (i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 4F4317/R2125] (including any objections and requests for hearings 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 Room 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 Highway, Arlington, VA.

Written objections and requests for hearings, identified by the document control number [4F4317/R2125], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and requests for hearings can be sent directly to EPA at:  
opp-Docket@epamail.epa.gov

A copy of electronic objections and requests for hearings must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

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 any copies of objections and requests for hearings 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