Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of the objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number, [PP 0F3876/R2155]. No Confidential Business Information (CBI) should be submitted through email. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Connie B. Welch, Product Manager (PM) 21, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6900; e-mail:

welch.connie@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA
issued a notice, published in the

Federal Register of January 16, 1991 (56
FR 1631), which announced that the
Rohm & Haas Co., Independence Mall
West, Philadelphia, PA 19105, had
submitted pesticide petition (PP)
0F3876 to EPA requesting that the
Administrator, pursuant to section
408(d) of the Federal Food, Drug, and
Cosmetic Act (FFDCA), 21 U.S.C.
346a(d), establish tolerances for the

combined residues of the fungicide myclobutanil, [alpha-butyl-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile], and both the free and bound forms of its metabolite, alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile, in or on the raw agricultural commodities almond nuts at 0.1 ppm and almond hulls at 2.0 ppm.

There were no comments received in response to the notice of filing of the petition.

The data submitted in support of the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerances are sought. The toxicological data considered in support of the tolerances include the following:

 A 1-year dog feeding study using doses of 0, 10, 100, 400, and 1,600 ppm (equivalent to doses of 0, 0.34, 3.09, 14.28, and 54.22 milligrams/kilogram (mg/kg) body weight (bwt)/day in males and 0, 0.40, 3.83, 15.68, and 58.20 mg/ kg bwt/day in females). The noobserved-effect (NOEL) is 100 ppm (3.09 mg/kg/day for males and 3.83 mg/kg/ day for females) based upon hepatocellular hypertrophy, increases in liver weights, "ballooned" hepatocytes, and increases in alkaline phosphatase, SGPT and GGT, and possible slight hematological effects. The lowestobserved-effect level (LOEL) is 400 ppm (14.28 mg/kg/day for males and 15.68

mg/kg/day for females).
2. A 2-year chronic feeding/ carcinogenicity study in rats using dietary concentrations of 0, 50, 200, and 800 ppm (equivalent to doses of 0, 2.49, 9.84 and 39.21 mg/kg bwt/day in males and 0, 3.23, 12.86, and 52.34 mg/kg bwt/ day in females). The NOEL for chronic effects other than carcinogenicity is 2.49 mg/kg/day, and the LOEL is 9.84 mg/kg/ day based on testicular atrophy in males. No other significant effects were observed in either sex at the stated dose levels over a 2-year period. In addition, no carcinogenic effects were observed in either sex at any of the dose levels tested. Based on the toxicological findings, the maximum tolerated dose (MTD) selected for testing (based on the 90-day feeding study) was not high enough to fully characterize the compound's carcinogenic potential.

The study was repeated at dose levels of 0 and 2,500 ppm (125 mg/kg/day) in the diet, which approaches the MTD, in order to characterize the carcinogenic potential. At 2,500 ppm, the observed effects included: decreases in absolute and relative testes weights, increases in the incidences of centrilobular to midzonal hepatocellular enlargement and vacuolation in the liver of both

sexes, increases in bilateral aspermatogenesis in the testes, increases in the incidence of hypospermia and cellular debris in the epididymides, and increased incidence of arteritis/periarteritis in the testes. In this study, a NOEL could not be established because there were effects at the only dose level tested. Myclobutanil was not oncogenic when tested under the conditions of the study.

3. A 2-year carcinogenicity study in mice using dietary concentrations of 0, 20, 100, and 500 ppm (equivalent to 0, 2.7, 13.7, and 70.2 mg/kg/day in males and 0, 3.2, 16.5 and, 85.2 mg/kg/day in females). The NOEL for chronic effects other than carcinogenicity was 20 ppm (2.7 mg/kg/day in males and 3.2 mg/kg/ day in females). The LOEL was 100 ppm (13.7 mg/kg/day in males and 16.5 mg/ kg/day in females) based on a slight increase in liver mixed-function oxidase (MFO). Microscopic changes in the liver were evident in both sexes at 500 ppm (70.2 mg/kg/day in males and 85.2 mg/ kg/day in females). There were no carcinogenic effects in either sex at any dose level tested. The highest selected dose was satisfactory for evaluating carcinogenic potential in male mice, but was lower than the MTD in females.

The above study was reevaluated since the increase in the MFO at 3 months in females was not considered to be significant enough to establish an LOEL. The LOEL was raised to 500 ppm (70.2 mg/kg/day for males and 85.2 mg/ kg/day for females) based on increases in MFO in both sexes, increases in SGPT values in females and in absolute and relative liver weights in both sexes at 3 months, increased incidences and severity of centrilobular hepatocytic hypertrophy, Kupffer cell pigmentation, periportal punctate vacuolation and individual hepatocellular necrosis in males, and increased incidences of focal hepatocellular alteration and multifocal hepatocellular vacuolation in both sexes. The NOEL has been raised to 100 ppm (13.7 mg/kg/day for males and 16.5 mg/kg/day for females).

An 18-month study was conducted with female mice using a dose level of 2,000 ppm, which approaches the MTD, to evaluate the carcinogenic potential in female mice. In this study, a NOEL could not be established because there were effects at the only dose level tested. These effects included: decreases in body weight and body weight gain, increases in liver weights, 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