permissible level for residues of this broad-spectrum fungicide/insecticide/miticide on all greenhouse and terrestrial food crops when used according to good agricultural practice.

EFFECTIVE DATE: This rule becomes effective on December 13, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 5F4467/R2193], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. 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 Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. 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 objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@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 5F4467/R2193]. No Confidential Business Information (CBI) should be submitted through e-mail. 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: Paul Zubkoff, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8694; e-mail: zubkoff.paul@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of September 29, 1995 (60 FR 50582), which announced that W.R. Grace Co.-Conn., 7379 Route 32, Columbia, MD 21044, had submitted a pesticide petition (PP) 5F4467 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 an exemption from the requirement of a tolerance for the use of clarified hydrophobic extract of neem oil on all greenhouse and terrestrial food crops when used according to good agricultural practice. There were no adverse comments or requests for referral to an advisory committee received in response to the notice of filing of PP 5F4467.

Existing Food Clearances

The clarified hydrophobic extract is prepared from the crude botanical extract of the seed kernels of the neem tree, *Azadiracta indica*. The constituents of clarified hydrophobic extract of neem oil are long-chain fatty acids and glycerides. Long-chain fatty acids and glycerides are Generally Recognized As Safe (GRAS) for use in foods by the U.S. Food and Drug Administration (FDA). Under title 21 of the Code of Federal Regulations (CFR) (21 CFR 172.860), oleic acid derived from tall oil fatty acids (21 CFR 172.862), and linoleic acid (21 CFR 184.1065), glyceryl monooleate (21 CFR 184.1323), glyceryl monostearate (21 CFR 184.1324), and mono- and diglycerides (21 CFR 184.1505) are considered as GRAS.

Natural Occurrence

Long-chain fatty acids and glycerides are readily synthesized by most forms of life and are common constituents of human, avian, and other mammalian diets. In most soil and aquatic environments, these constituents of clarified hydrophobic extract of neem oil would be readily metabolized by endemic microbial populations and should not accumulate. Because clarified hydrophobic extract of neem oil is a naturally occurring compound which displays a nontoxic mode of action to the target pest, the Agency classified the active ingredient as a biochemical pesticide.

Toxicology Assessment

All studies submitted for acute mammalian toxicology support the registration of the technical manufacturing product (Reg. No. 11688-8) and the end-use product for use on all terrestrial and greenhouse food crops. Summarized below are data and information for the registration of clarified hydrophobic extract of neem oil. EPA has examined the acute mammalian toxicology data related to human health submitted for clarified hydrophobic extract of neem oil. The mammalian toxicology data for clarified hydrophobic extract of neem oil indicate low acute toxicity following all routes of exposure. With the exceptions of the primary eye irritation study (toxicity category III) and the acute dermal study (toxicity category III), all other acute studies (oral, dermal irritation, and inhalation toxicity) were classified toxicity category IV. Based on the results from the sensitization test (Buehler), the clarified hydrophobic extract of neem oil is considered to be a mild (minimal) contact sensitizer. In addition, clarified hydrophobic extract of neem oil was shown not to be cytotoxic or mutagenic via the Ames test (Salmonella/reverse mutation assay). Further genotoxicity tests to address structural chromosomal aberrations and forward mutations have been waived based on the known composition (fatty acids and glycerides) and GRAS status of the technical manufacturing product (clarified hydrophobic extract of neem oil, the lack of mammalian and avian toxicity, and the negative results observed in the Ames tests). Consequently, at levels used on plants, human exposure is expected to be negligible and acute toxicity from such exposure is not expected.

Tolerance exemptions are usually, in part, based on the results of subchronic (90-day) feeding and developmental toxicity studies submitted to support registration. However, these studies were waived for clarified hydrophobic extract of neem oil because of the low demonstrated acute toxicity, the GRAS nature of the naturally occurring components (saturated fatty acids and glycerides) of the active pesticidal ingredient, and the negligible exposure to humans and the environment owing to the low use rates. Such use rates would not significantly increase dietary intake over routine exposure from general consumption of fatty acids in foods. Moreover, the Agency knows of no reported cases of adverse effects from exposure to low amounts of fatty acids.

Residue Chemistry Data

Residue chemistry data are usually required for biochemical pesticides only if the submitted mammalian toxicology studies indicate that additional Tier II or Tier III toxicology data would be required as specified in 40 CFR 158.165(e). The submitted toxicology data for this use indicate that the product is of low mammalian toxicity; it has naturally occurring components in many food plants and, therefore, it is