§ 180.1161 Clarified hydrophobic extract of neem oil; exemption from the requirement of a tolerance.

Clarified hydrophobic extract of neem oil (Reg. No. 11688-8) is exempt from the requirement of a tolerance on all raw agricultural commodities when used as a botanical fungicide/insecticide/miticide.

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40 CFR Part 180

[PP 8E3574/R2165; FRL–4973–5]

RIN 2070–AB78

Terbufos; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document extends the time-limited tolerance for combined residues of the insecticide/nematicide terbufos and its cholinesterase-inhibiting metabolites in or on the raw agricultural commodity (RAC) green coffee beans for an additional 2 years. American Cyanamid Co. submitted a petition under the Federal Food, Drug and Cosmetic Act (FFDCA) requesting the regulation to establish a maximum permissible level for combined residues of the insecticide/nematicide in or on the commodity.

EFFECTIVE DATE: This regulation becomes effective December 13, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 8E3574/R2165], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests 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 Resources 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 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: 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 8E3574/R 2165]. 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: Robert A. Forrest, Product Manager (PM) 14, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 219, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6600; e-mail: forrest.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 2, 1995 (60 FR 39299), EPA issued a proposed rule (FRL-4963-5) that gave notice that the American Cyanamid Co. had submitted data and a request under the FFDCA that a time-limited tolerance for residues of the insecticide/nematicide terbufos on coffee beans be changed to permanent status. The Agency proposed an extension of the time-limited tolerance to allow it to complete its in-depth reassessment of the current established tolerances for terbufos.

The following comments were received from the petitioner, American Cyanamid.

1. American Cyanamid believes that since the acceptance of the new rat metabolism study fulfills the condition of the time-limited coffee bean tolerance, it is sufficient to establish the regulation as permanent, regardless of any on-going analysis of tolerances for reregistration purposes.

2. Additionally, American Cyanamid believes that ''the toxicological end-point of a no-observable-effect level (NOEL) based upon plasma cholinesterase (ChE) inhibition, as mentioned in the proposed rule, is of equivocal value when used in risk assesments'' and that ''A NOEL based upon alternative tox endpoints such as red blood cell ChE inhibition, brain ChE inhibition, or clinical signs would be more appropriately used to establish reference dose for regulatory purposes.''

American Cyanamid has requested a reevaluation of plasma cholinesterase as a suitable endpoint.

The Agency acknowledges that the condition upon which the initial time-limited tolerance was based, i.e., the lack of an acceptable guideline rat metabolism study, has now been fulfilled.

However, as described in the proposed rule referenced above, the Agency currently has concern over the potential acute dietary risk posed by the current established tolerances based on the estimated margins of exposure (MOE). In light of this concern, the Agency believes that it is prudent to limit the period of time in which the coffee bean tolerance is in effect pending the Agency reassessment of the tolerances.

The Agency will take American Cyanamid's comments relative to the toxicological endpoint into consideration in its reassessment of the established tolerances.

There were no requests for referral to an advisory committee received in response to the proposed rule.

The data submitted with the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the time-limited tolerance will protect the public health. Therefore, the time-limited 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 and/or request a hearing 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 a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the