

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 number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: February 15, 1995.

Daniel M. Barolo,
Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

b. By adding § 180.480, to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) Time-limited tolerances, to expire on December 31, 1998, are established for combined residues of the fungicide fenbuconazole [*alpha*-[2-(4-chlorophenyl)-ethyl]-*alpha*-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile] and its metabolites, *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone, expressed as fenbuconazole, in or on the following raw agricultural commodities:

Commodity	Parts per million
Pecans	0.1
Stone fruit crop group (except plums and prunes)	2.0

(b) Residues in these commodities not in excess of the established tolerance resulting from the uses described in paragraph (a) of this section remaining after expiration of the time-limited tolerance will not be considered to be actionable if the fungicide is applied during the term of and in accordance

with the provisions of the above regulation.

[FR Doc. 95-5019 Filed 2-28-95; 8:45 am]
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40 CFR Part 180

[PP 4F4351/R2108; FRL-4938-1]

RIN 2070-AB78

Candida Oleophila Isolate I-182; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a tolerance for residues of the post-harvest biological fungicide *Candida oleophila* isolate I-182. Ecogen, Inc., requested this tolerance exemption.

EFFECTIVE DATE: This regulation becomes effective on March 1, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4351/R2108], 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 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 request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., 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.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: CS51L6, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8263.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of September 28, 1994 (59 FR 49396), which announced that Ecogen, Inc., 2005 Cabot Blvd. West, Langhorne, PA 19047, had submitted pesticide petition (PP) 4F4351 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 residues of *Candida oleophila* isolate I-182 in or on all raw agricultural commodities. Errors in the September 28, 1994 notice of filing were corrected in the **Federal Register** of November 2, 1994 (59 FR 54911), to specify that *C. oleophila* isolate I-182 is a biological fungicide, not an insecticide, and that the area of title 40 of the Code of Federal Regulations (CFR) to be amended is 40 CFR part 180, not 40 CFR 180.1001(c) and (d).

There were no comments received in response to these notices of filing. The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance are summarized as follows:

Rats have been challenged with high doses of the pure preparations of *C. oleophila* by the oral, pulmonary, and interperitoneal routes of exposure. In each of these tests, the test animals survived to the end of the study without visible signs of toxicity or pathogenicity from the presence of *C. oleophila*. The test microbe was not isolated from any organs or tissues on day 3 in the oral and pulmonary studies and on day 7 in the interperitoneal injection study. These findings indicate that the test microbe was recognized by the immune system and cleared from the rats by the normal routes. In addition, the end-product formulation of *C. oleophila* was tested for dermal toxicity/irritation, eye irritation, and acute oral toxicity and showed no mortality or significant signs of toxicity.

Candida oleophila isolate I-182 is a microbial pesticide as defined by 40 CFR 158.65. The toxicity studies provided are sufficient to show that there are no foreseeable human or domestic health hazards likely to arise from the use of the product to control post-harvest decay in citrus and pome fruit.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition. Enforcement actions based on the level of residue found in a commodity are not expected. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request. *Candida oleophila* isolate I-182 is considered useful for the purposes for which the exemption from tolerance is sought. Based on the information and data considered, the Agency concludes

that the establishment of a tolerance is not necessary to protect the public health. Therefore, the exemption from requirement of a 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 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).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in 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 referred to 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 the rights and obligations or recipients thereof; 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 the 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 number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 14, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1144, to read as follows:

§ 180.1144 *Candida oleophila* isolate I-182; exemption from the requirement of a tolerance.

Candida oleophila isolate I-182, when used as a post-harvest biological fungicide, is exempted from the requirement of a tolerance in or on all raw agricultural commodities.

[FR Doc. 95-4599 Filed 2-28-95; 8:45 am]

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40 CFR Part 721

[OPPTS-50620; FRL-4868-4]

RIN 2070-AB27

Significant New Uses of Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances

Control Act (TSCA) for certain chemical substances which were the subject of premanufacture notices (PMNs) and subject to TSCA section 5(e) consent orders issued by EPA. Today's action requires persons who intend to manufacture, import, or process these substances for a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing of the substance for a use designated by this SNUR as a significant new use. The required notice will provide EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs. EPA is promulgating this SNUR using direct final procedures.

DATES: The effective date of this rule is May 1, 1995. This rule shall be promulgated for purposes of judicial review at 1 p.m. Eastern Standard Time on March 15, 1995. If EPA receives notice before March 31, 1995 that someone wishes to submit adverse or critical comments on EPA's action in establishing a SNUR for one or more of the chemical substances subject to this rule, EPA will withdraw the SNUR for the substance for which the notice of intent to comment is received and will issue a proposed SNUR providing a 30-day period for public comment.

ADDRESSES: Each comment or notice of intent to submit adverse or critical comment must bear the docket control number OPPTS-50620 and the name(s) of the chemical substance(s) subject to the comment. All comments should be sent in triplicate to: Environmental Protection Agency, OPPT Document Receipt Officer (7407), 401 M St., SW., Rm. E-G099, Washington, DC 20460. All comments which are claimed confidential must be clearly marked as such. Three additional sanitized copies of any comments containing confidential business information (CBI) must also be submitted. Nonconfidential versions of comments on this rule will be placed in the rulemaking record and will be available for public inspection.

FOR FURTHER INFORMATION CONTACT:

James B. Willis, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This SNUR will require persons to notify EPA at least 90 days before commencing manufacturing or processing a substance for any activity designated by this SNUR as a significant new use. The supporting rationale and background to this rule are