ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300472; FRL–5600–1]

RIN 2070–AB78

Plant Extract Derived From Opuntia lindheimeri (Prickly Pear Cactus), Quercus falcata (Red Oak), Rhus Aromatica (Sumac), and Rhizophoria mangle (Mangrove): Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide plant extract derived from *Opuntia lindheimeri* (prickly pear cactus), *Quercus falcata* (Red oak), *Rhus aromatica* (sumac), and *Rhizophoria mangle* (mangrove) in or on all raw agricultural commodities (RACs), when applied as a nematicide/plant regulator in accordance with good agricultural practices. This exemption was requested by Appropriate Technologies, Limited.

DATES: This regulation becomes effective May 7, 1997. Objections and requests for hearings must be received by EPA on July 7, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket number, [OPP–300472], 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 docket 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 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.

An electronic copy of objections and hearing requests filed with the Hearing Clerk may be submitted to OPP by sending electronic mail (e-mail) to: opp-docket–epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP–300472]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic 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: Denise Greenway, c/o Product Manager (PM) [90], Biopesticides and Pollution Prevention Division (7501W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 5-W57, CS-1, 2800 Crystal Drive, Arlington, VA 22202. (703) 308-8263; e-mail: greenway.denise–epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 14, 1994 [59 FR 47136], EPA issued a notice (FRL–4904–7) that ATL Enterprises, Inc., had submitted pesticide petition PP 8F3635 to EPA proposing to amend 40 CFR part 180 by establishing a regulation pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to exempt from the requirement of a tolerance the residues of the biochemical pesticide aqueous extract of roots, galls, and bark from four plant species. Incorrect taxonomic names were provided for two of the plant species. The published names were *Opinta lindheimeri, Quercus falcata, Rhus aromatica, and Rhizophoria mangle* for use in or on all raw agricultural commodities when applied as a plant regulator in soil and/or foliar applications in accordance with good agricultural practices. The petition was later revised by the petitioner and reannounced by EPA, in accordance with the requirements of the Food Quality Protection Act of 1996 in the **Federal Register** of February 13, 1997 (62 FR 6777)(FRL–5588–9). The notice announced that Appropriate Technology Limited was filing the petition to exempt from the requirement of a tolerance residues of extract from *Opuntia lindheimeri* (prickly pear cactus), *Quercus falcata* (red oak), *Rhus aromatic* (sumac), and *Rhizophora mangle* (mangrove) in or on all raw agricultural commodities when applied as a nematocide or as a plant regulator in soil and/or foliar applications in accordance with good agricultural practices. EPA received misspellings for two of the plant species for the February 13, 1997 notice. The correct spellings for all four are as follows: *Opuntia lindheimeri* (prickly pear cactus), *Quercus falcata* (red oak), *Rhus aromatica* (sumac), and *Rhizophoria mangle* (mangrove). The February 24, 1997 **Federal Register** (62 FR 8244)(FRL–5591–4) announced that the comment period would end on March 17, 1997. In response to the Notice of Filing, EPA received supporting comments from 14 companies/citizens in Egypt, Honduras, Australia, Saudi Arabia, Syria, Lebanon, Chile, the Philippines, Switzerland and the United States. No comments opposing the petition were received.

The data submitted in the petition and all other relevant material have been evaluated. Following is a summary of EPA's findings regarding this petition as required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act.

I. Proposed Use Practices

Biochemical pesticide extract powder, also known as Plant Extract 620, derived from *Opuntia lindheimeri* (prickly pear cactus), *Quercus falcata* (red oak), *Rhus aromatica* (sumac), and *Rhizophoria mangle* (mangrove) will be diluted into two water-based products, Sincocin and Agrispon, both at a concentration of 0.56 percent Plant Extract 620. The maximum application rate for any use pattern would not exceed 14 grams of plant extract/acre/application; the maximum application rate for food crops would not exceed 4 grams of plant extract/acre/application. The maximum permissible amount applied per acre per year must not exceed 150.

Agrispon is diluted with water and applied at a rate of 13 fluid ounces/acre (oz/acre) for annuals and greenhouses. Timing and frequency of applications depend on the plant growth cycle length; a single application for plants with a growth cycle of 60 days or less; a second application 45 to 60 days after the first for plants with a 60 to 120 day growth cycle; every 45 to 60 days during vigorous growth stage for long season plants or those with longer than a 120 day growth cycle. Agrispon is applied to the soil surface under trees at a rate of 13 fluid oz/acre, with an additional 6 fluid oz/acre applied to the tree canopy. For evergreens, applications are made every 60 days. Deciduous trees are first treated at bud break or leaf flush in the spring with subsequent applications every 60 days until dormancy occurs.

Sincocin is applied to food crops and orchards at a rate of 26 fluid oz/acre. For both food crops and orchards, the first

application is made during initial root flush with subsequent applications every 60 days during active growth. The application rate for turf and ornamentals is 2.75 gallons (87 fluid ounces)/acre. Golf fairways are treated every 30 days. Ornamentals are treated at root flush with subsequent applications every 30 to 60 days during active growth.

II. Toxicological Profile

The toxicological data considered in support of the exemption from the requirement of a tolerance include: acute oral, acute dermal, acute inhalation, eye irritation, dermal irritation, and Ames mutagenicity tests. The following table summarizes the Agency's findings for the submitted toxicological data.

Guideline No.	Study	Product	Results	Toxicity Category
152–10	Acute Oral (Rat)	Plant Extract 620 (TGAI)	LD_{50} > 5050 mg/kg	IV
152–11	Acute Dermal (Rabbit)	Plant Extract 620	LD_{50} > 5050 mg/kg	IV
152–12	Acute inhalation (Rat)	Sincocin (End-use product)	LC_{50} > 2.04 mg/L	IV
152–13	Primary eye irritation	Plant Extract 620	Severe Irritation in Non-Washed Eyes	I
			Mild Irritation in Washed Eyes at 0.1 ml	III
		Sincocin	Minimal irritation, reversible in 2 days at 0.1 ml	IV
		Agrispon	No irritation at 0.1 ml	IV
152–14	Primary dermal irritation (Rabbit)	Plant Extract 620	Moderate Irritation at 72 Hours	III
152–15	Hypersensitivity		Must be reported if/when it occurs	
	Mutagenicity	Sincocin & Agrispon	Negative	

The Agency granted a data waiver request for the acute inhalation toxicity test based on the aqueous end-use product, Sincocin, since Plant Extract 620, the technical grade active ingredient (TGAI) which is also the manufacturing use product, could not undergo inhalation testing by virtue of it being a powder. The end-use products, Agrispon and Sincocin, are Toxicity Category III for primary dermal irritation. The remaining acute toxicity tests were waived since the results from the TGAI were adequate to characterize the responses for the end-use products which are 0.56% dilutions of the TGAI. The results of the submitted acute toxicology and mutagenicity data, indicated that plant extract from *Opuntia lindheimeri, Quercus falcata, Rhus aromatica*, and *Rhizophoria mangle* are of a low acute toxicity such that test requirements for subchronic, chronic, immune, endocrine, dietary and non-dietary studies were not triggered. The Agency has determined that all toxicology data requirements have been satisfied. There were no toxic endpoints identified as a result of the submitted studies and therefore no reference dose or no observable effect level to be established.

III. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures. The primary non dietary sources of exposure the Agency considers include drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary Exposure*— a. *Food*. Dietary exposure from use of this plant extract is possible but the magnitude of the residues is expected to be minimal to negligible since the application rate is 4 grams per acre per application on food crops. The maximum total amount permitted for application for 1 year is 150 grams. Moreover, washing off of foliage and fruit by rainfall or during food processing and handling, and likely degradation of the plant extracts by soil microflora would further reduce the amount of dietary exposure.

b. *Drinking water.* Oral exposure, at very low levels, may occur from ingestion residues of the plant extract in the drinking water. However a lack of mammalian toxicity for the plant extract has been demonstrated.

2. *Non-dietary, non-occupational exposure.* The primary non-dietary sources of exposure the Agency looks at include exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Products containing the plant extract are not registered for use on residential lawns or indoor residences or buildings.

IV. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to this plant extract, there is no reason to expect any cumulative effects from this plant extract and other substances.

V. Endocrine Disruptors

The Agency has no information to suggest that the plant extract, also known as Plant Extract 620, a composite of plant extract powder, will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical plant extract pesticide at this time; Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

VI. Determination of Safety

1. *U.S. population.* The results of acute toxicity tests and, mutagenicity tests demonstrate a low to minimal toxicity profile for the plant extract. Moreover, when Plant Extract 620 is incorporated into the end-use product formulation and following dilution of the product according to label instructions, the result is an extremely low amount of 2 to 14 grams of active ingredient applied per acre per application. A maximum limit of 150 grams per acre of the active ingredient per year will be in effect for this biochemical pesticide. The submitted data do not lead the Agency to suspect any acute or chronic dietary risks. The low toxicity, the low application rate, and the use patterns leads the Agency to conclude that residues from use of the biochemical pesticide extract from *Opuntia lindheimeri* (prickly pear cactus), *Quercus falcata* (Red oak), *Rhus aromatica* (sumac), and *Rhizophoria mangle* (mangrove) will not pose a

dietary risk of concern under reasonably foreseeable circumstances. Therefore, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure under this exemption.

2. *Infants and children.* The Agency has considered available information on the variability of the sensitivities of major identifiable subgroups of consumers including infants and children and the physiological differences between infants and children and adults and effects of *in utero* exposure to biochemical pesticides. As noted previously, the Agency has concluded that dietary exposure to the plant extract will be minimal due to the very low amounts, 4 grams per application, and the maximum of 150 grams permitted per acre per year. Natural degradation processes including soil microbial activity and rain fall plus food processing steps such as washing and cooking will further reduce the amounts available for exposure. Accidental ingestion of this product by children is possible but the end-use products have been classified as Toxicity Category IV, practically non-toxic with regards to oral toxicity. While the manufacturing product is Toxicity Category I, acutely toxic with regards to primary eye irritation, unwashed eyes, the end-use products will contain a hundredfold dilution of the plant extract which are further diluted upon spraying. Furthermore, the end-use products will not be used on lawns where children play.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. In this instance, EPA believes there is reliable data to support the conclusion that this plant extract is not toxic to mammals, including infants and children, and thus there are no threshold effects. As a result, the provision requiring an additional margin of exposure does not apply.

VII. Analytical Method

The Agency has determined that an analytical method is unnecessary due to the low toxicity of the plant extract and due to the low application rate of up to 4 grams per acre on food crops and up to 14 grams per acre for ornamentals and turf per application. The yearly maximum will be 150 grams of active ingredient per acre.

VIII. International Tolerances

There are no CODEX tolerances nor international tolerances for the plant extract at this time.

IX. Conclusion

There is a reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to residues of plant extract from *Opuntia lindheimeri* (prickly pear cactus), *Quercus falcata* (red oak), *Rhus aromatica* (sumac), and *Rhizophoria mangle* (mangrove). This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, no toxicity to mammals has been observed for the plant extract. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA section 408(j)(3) for *Opuntia lindheimeri, Quercus falcata, Rhus aromatica,* and *Rhizophoria mangle.*

X. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance exemption regulation issued by EPA under new section 408(e) as was provided in the old section 408. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person adversely affected by this regulation may, by July 7, 1997, 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 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). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

XI. Public Docket

A record has been established for this rulemaking under the docket number [OPP–300472] (including any comments and data submitted electronically). 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 8:30 a.m. to 4 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 22202.

Electronic comments can be sent directly to EPA at:

opp-docket–epamail.epa.gov

Electronic comments 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 hearing requests 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 comments submitted directly in writing. The official rulemaking record is the paper record maintained at the address in

''ADDRESSES'' at the beginning of this document.

XII. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (FRA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable. Nonetheless, the Agency has previously assessed whether establishing tolerances or exemptions from tolerance, raising tolerance levels, or expanding exemptions from tolerance, adversely impact small entities and concluded, as a generic matter that there is no adverse impact (46 FR 24950, May 4, 1981).

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

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

Dated: April 24, 1997.

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. Section 180.1179 is added to read as follows:

§ 180.1179 Plant extract derived from Opuntia lindheimeri, Quercus falcata, Rhus aromatica, and Rhizophoria mangle; exemption from the requirement of a tolerance.

The biochemical pesticide plant extract derived from *Opuntia lindheimeri, Quercus falcata, Rhus aromatica,* and *Rhizophoria mangle* is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a nematicide/plant regulator in accordance with good agricultural practices.

[FR Doc. 97–11900 Filed 5–6–97; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–53; RM–9003]

Radio Broadcasting Services; Garden City, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action in this document allots Channel 287A to Garden City, Missouri, as that community's first local FM broadcast service in response to a proposal filed by R. Lee Wheeler and Sarah H. Wheeler. *See* 62 FR 6927, February 14, 1997. There is a site restriction 0.6 kilometers (0.4 miles) west of the community. The coordinates for Channel 287A at Garden City are 38–33–49 and 94–11–53. With this action, this proceeding is terminated.

DATES: Effective June 16, 1997. The window period for filing applications for Channel 287A at Garden City, Missouri, will open on June 16, 1997, and close on July 17, 1997.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 97–53, adopted April 23, 1997, and released May 2, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., Suite 140, Washington, DC. 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: Secs. 303, 48 Stat., as amended, 1082; 47 U.S.C. 154, as amended.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by adding Garden City, Channel 287A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–11823 Filed 5–6–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 96–235; RM–8909]

Radio Broadcasting Services; Forest City, PA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Vixon Valley Broadcasting, allots Channel 261A at Forest City, Pennsylvania, as the community's first local aural transmission service. *See* 61 FR 54309, December 4, 1996. Channel 261A can be allotted to Forest City in compliance with the Commission's minimum distance separation requirements with a site restriction of 10.1 kilometers (6.2 miles) northeast to avoid short-spacings to the licensed sites of Station WODE-FM, Channel 260B, Easton, Pennsylvania, and Station WDST(FM), Channel 261A, Woodstock, New York, at petitioner's requested site.