ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2003–0281; FRL–7347–7]

Rhamnolipid Biosurfactant; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical, rhamnolipid biosurfactant, on all food commodities when applied/used as a fungicide. Jeneil Biosurfactant Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of rhamnolipid biosurfactant.

DATES: This regulation is effective March 31, 2004. Objections and requests for hearings, identified by docket ID number OPP–2003–0281, must be received on or before June 1, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2003–0281. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available on E-CFR Beta Site Two at *http://gpoaccess.gov/ecfr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. Background and Statutory Findings

In the **Federal Register** of May 9, 2003 (68 FR 25026) (FRL–7306–3), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(e), as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 1F6288) by Jeneil Biosurfactant Company, 400 N. Dekora Woods Boulevard, Saukville, Wisconsin 53080. This notice included a summary of the petition prepared by the petitioner Jeneil Biosurfactant Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of rhamnolipid biosurfactant.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. In determining whether an exemption is safe, the Administrator is directed to take into account the same factors set forth in section 408(b)(2)(C) and (D) for determining whether a tolerance is safe. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this

action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Rhamnolipid biosurfactant (pc code 110029, CAS number 147858–26–2) has the CAS name decanoic acid, 3-[[6-deoxy-2-O-(6-deoxy-[alpha]-L-mannopyranosyl)-[alpha]-L-mannopyranosyl]oxy]-, 1-(carboxymethyl)octyl ester, mixture with 1-(carboxymethyl)octyl 3-[(6-deoxy-[alpha]-L-mannopyranosyl)oxy]decanoate. The basic composition of the active ingredient consists of a well-known carbohydrate (rhamnose sugar) and fatty acid (hydroxydecanoic acid). The active ingredient is a mixture of two types of rhamnolipid molecules, R1 (RLL) and R2 (RRLL) at a ratio of R2:R1 = 0.7 - 2.0. Chemical name of the rhamnolipid molecules is as follows: Molecule 1 (defined as R1 or RLL): Decanoic acid, 3-[(6-deoxy-[alpha]-L-mannopyranosyl) oxy]-, 1-(carboxymethyl) octyl ester; and molecule 2 (defined as R2 or RRLL): Decanoic acid, 3-[[6-deoxy-2-O-(6-deoxy-[alpha]-L-mannopyranosyl)-[alpha]-L-mannopyranosyl] oxy]-, 1-(carboxymethyl) octyl ester.

Adequate mammalian toxicology data are available and support registration of the product containing the active ingredient rhamnolipid biosurfactant. Rhamnolipid molecules are simple glycolipids consisting of a carbohydrate (rhamnose) ring and a fatty acid (hydroxydecanoic acid) tail. Individually, these molecules are not toxic. Rhamnose is a comparatively rare sugar approved by FDA as a food additive, and fatty acids are ubiquitous in animals and plants and are a major energy source in the body. Consequently, the breakdown products of rhamnolipids are of little toxicological concern. The mode of action of rhamnolipid biosurfactants is a physical action on the plant pathogen, rather than a toxic action. Rhamnolipid biosurfactant products are currently in use as emulsifiers, dispersants, wetting agents, and agricultural adjuvants. There have been no reports of adverse effects from any uses of rhamnolipid biosurfactants to date. The information submitted indicates there is already widespread exposure to rhamnose sugar, fatty acids, and rhamolipid biosurfactants without any reported adverse effects to human health. The acute toxicity studies, in conjunction with data or other information obtained from the open literature and the expected low exposure to humans, demonstrate that no risks to human health are expected from the pesticidal use of rhamnolipid biosurfactant.

A. Acute Toxicology

1. Acute oral toxicity (OPPTS Harmonized Guidline 870.1100; 152-10; MRID 45376702). Male and female rats (5 per sex) were dosed once with 5,000 milligrams/kilograms (mg/kg) and observed for 14 days. The acute oral lethal dose $(LD)_{50}$ was >5,000 mg/kg. The study was acceptable and placed the test material in Toxicity Category IV.

2. Acute dermal toxicity (OPPTS Harmonized Guidline 870.1200; 152-11; MRID 45376703). Male and female rats (5 per sex) were dosed with 5,000 mg/kg for 24 hours and observed for 14 days The acute dermal LD_{50} was >5,000 mg/kg. The study was acceptable and placed the test material in Toxicity Category IV.

3. Acute inhalation toxicity (OPPTS Harmonized Guidline 870.1300; 152-12, MRID 45376704). Male and female rats (5 per sex) were exposed whole-body to a gravimetric concentration of 2.05 mg/liter (L) 9.5% rhamnolipid biosurfactant in water for 4 hours, and observed for 14 days. The lethal concentration $(LC)_{50}$ was >2.05 mg product/L (0.20 mg active ingredient (a.i.)/L). The study was acceptable and placed the test material in Toxicity Category IV.

Other acute toxicology data also reviewed in support of the rhamnolipd biosurfactant registration include the following.

1. Primary eye irritation (OPPTS Harmonized Guidline 870.2400; 152-13; MRID 45376705).

2. Primary eye irritation (OPPTS Harmonized Guidline 870.2400; 152-13; MRID 45376706).

3. Primary eye irritation (OPPTS Harmonized Guidline 870.2400; 152-13; MRID 45376707).

4. Primary dermal irritation (OPPTS Harmonized Guidline 870.2500; 152-14; MRID 45376708).

A data waiver was requested for the following study, and granted by the Agency. Although no study was conducted by the registrant, acceptable information/data was submitted to support the data waiver request.

Dermal sensitization (OPPTS Harmonized Guidline 870.2600; 152-15).

B. Mutagenicity and Developmental Toxicity

The requested waiver was granted by the Agency based on the fact that rhamnolipid biosurfactant is not related to any known mutagens and does not belong to a chemical class of compounds containing known mutagens. Rhamnolipid biosurfactant consists of rhamnose sugar and hydroxydecanoic acid, both of which have food-related uses.

C. Subchronic Toxicity, Immunotoxicity

Requested waivers for 90–day oral toxicity and immunotoxicity were granted by the Agency based on the physical mode of action of the active ingredient; the lack of acute oral, dermal, and inhalation toxicity; and the innocuous nature of the potential breakdown products of rhamnolipid biosurfactants.

D. Chronic Exposure and Oncogenicity Assessment

Repeated-dose studies are conditionally required if the potential for adverse chronic effects are indicated based on: (1) The subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, (2) the pesticide use pattern, or (3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies any morphologic effects in any organ that potentially could lead to neoplastic changes. None of the results of the submitted studies triggered the need for chronic exposure or oncogenicity testing.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food*. There is a great likelihood of exposure in the normal human diet to rhamnolipid biosurfactant's components for most, if not all individuals, including infants and children. Rhamnolipid biosurfactant constituents, rhamnose sugar and fatty acid, are normal parts of the human diet. To date, there have been no known reports of any hypersensitivity incidents from users of the surfactant. Even if exposure increased due to pesticidal use of rhamnolipid biosurfactant, given the low toxicity of the components (or of the surfactant) and the widespread dietary exposure to the components, the

Agency believes the risk associated with dietary exposure to the biosurfactant by the oral route would be low to non-existent.

2. *Drinking water exposure*. Because rhamnolipid biosurfactant has low acute mammalian toxicity, the constituent rhamnose sugar is a food additive, and constituent fatty acids are ubiquitous in plant and animals, no risk is anticipated should exposure occur through drinking water.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to rhamnolipid biosurfactnt residues for the general population, including infants and children, is unlikely because potential use sites are horticultural and agricultural crops. Rhamnolipid biosurfactant's constituent carbohydrate (rhamnose sugar) and fatty acid (hydroxydecanoic acid) are not considered toxic; rhamnose sugar is a food additive and fatty acids, ubiquitous in plants and animals, are a major energy source in the body. Rhamnolipid biosurfactant's toxicity has been determined to be very low through the oral, dermal and inhalation routes. Therefore, while there exists a great likelihood of prior exposure to rhamnolipid biosurfactant's components, any risk from increased exposure due to the proposed product would be negligible.

VI. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether rhamnolipid biosurfactant has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to rhamnolipid biosurfactant and any other substances and rhamnolipid biosurfactant does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that rhamnolipid biosurfactant has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative/*.

VII. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population*. The Agency has determined that there is reasonable certainty that no harm will result from aggregate exposure to residues of rhamnolipid biosurfactant to the U.S. population. This includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. The Agency arrived at this conclusion based on the anticipated low exposure estimates from its pesticidal use; the low mammalian toxicity of rhamnolipid biosurfactant; and the already widespread human exposure to rhamolipid biosurfactant constituents, rhamnose sugar and hexadecanoic acid, without any reported adverse effects to human health.

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure for infants and children in the case of threshold effects unless the Agency determines, based on reliable data, that a different margin is safe. Margins of exposure are referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness of the data base. Based on all the reliable available information the Agency reviewed on rhamnolipid biosurfactant, including that showing a lack of threshold effects, the Agency concluded that the additional margin of safety is not necessary to protect infants and children and that not adding any additional margin of safety will be safe for infants and children.

VIII. Other Considerations

A. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including low toxicity and low exposure from the pesticidal use of rhamnolipid biosurfactant. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for rhamnolipid biosurfactant.

B. Codex Maximum Residue Level

There are no CODEX maximum residue levels for rhamnolipid biosurfactant.

IX. Conclusions

Based on the toxicology information/data submitted and other information available to the Agency, there is a reasonable certainty that no harm will result from aggregate exposure of residues of rhamnolipid biosurfactant to the U.S. population, including infants and children, under reasonably foreseeable circumstances, when the biochemical pesticide is used in accordance with good agricultural practices. This includes all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information. The Agency has arrived at this conclusion based on the information/data submitted (and publically available) demonstrating no toxicity. As a result, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of rhamnolipid biosurfactant in or on all food commodities.

X. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2003–0281 in the subject line on the first page of your submission. All requests must be in writing, and must be

mailed or delivered to the Hearing Clerk on or before June 1, 2004.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(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). 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.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit X.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP–2003–0281, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid 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 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: March 22, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346(a) and 371.

■ 2. Section 180.1245 is added to subpart D to read as follows:

§ 180.1245 Rhamnolipid biosurfactant; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of rhamnolipid biosurfactant when used in accordance with good agricultural practices as a fungicide in or on all food commodities.

[FR Doc. 04–6933 Filed 3–30–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0052; FRL–7349–3]

Zoxamide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of zoxamide in or on ginseng. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on ginseng. This regulation establishes a maximum permissible level for residues of zoxamide in this food commodity. The tolerance will expire and is revoked on December 31, 2006.

DATES: This regulation is effective March 31, 2004. Objections and requests for hearings, identified by docket ID number OPP–2004–0052, must be received on or before June 1, 2004.

ADDRESSES: Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address:*Madden.Barbara@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0052. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document