

Summary: No formal comment letter was sent to the preparing agency.

Dated: May 6, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0162; FRL-7306-3]

Rhamnolipid Biosurfactant; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0162, must be received on or before June 9, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, 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-2003-0162. 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/>.

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. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select “search,” then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA’s electronic public docket. EPA’s policy is that copyrighted material will not be placed in EPA’s electronic public

docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA’s electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA’s electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA’s electronic public docket.

For public commenters, it is important to note that EPA’s policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA’s electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA’s electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA’s electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA’s electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA’s electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked “late.” EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do

not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0162. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP-2003-0162. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid

the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2003-0162.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2003-0162. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 29, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Jeneil Biosurfactant Company

PP 1F6288

EPA has received a pesticide petition 1F6288 from Jeneil Biosurfactant Company, 400 N. Dekora Woods Boulevard, Saukville, Wisconsin 53080, proposing pursuant to section 408(d) of

the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide rhamnolipid biosurfactant in or on all food commodities.

Pursuant to section 408(d)(2)(A)(I) of the FFDCA, as amended, Jeneil Biosurfactant Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Jeneil Biosurfactant Company, and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Rhamnolipid biosurfactant is intended for the prevention and control of plant pathogenic fungi on horticultural and agricultural crops. Fungal diseases are often spread by zoospores that are transported from one plant to another and from field to field. Rhamnolipid biosurfactant kills zoospores that cause fungal disease, on contact. Target pests are any zoosporic plant pathogenic microorganisms including the following genera: *Plasmodiophora*, *Polymyxa*, *Spongopora*, *Physoderma*, *Olpidium*, *Synchytrium*, *Rhizophydium*, *Achlya*, *Aphanomyces*, *Albugo*, *Peronospythora*, *Pachymetra*, *Pythium*, *Phytophthora*, *Trachysphaera*, *Basidiophora*, *Peronosclerospora*, *Plasmopara*, *Pseudoperonospora*, *Sclerophthora*, and *Sclerospora*. End-use formulations of rhamnolipid biosurfactant are applied through conventional equipment as a spray, fog, drench or seed soak to the point of saturation, and can also be incorporated into nutrient solutions for hydroponic plants and vegetables. The product will be diluted with water and applied to growing plants and agricultural commodities at a rate of 70 to 100 parts per million (ppm). One end-use formulation, Zonix Biofungicide (8.5% active ingredient), is proposed at this time.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Rhamnolipid biosurfactant, CAS number: 147858-26-2; CAS name: Decanoic acid, 3-[[6-deoxy-2-O-(6-deoxy- α -L-mannopyranosyl)- α -L-

mannopyranosyl]oxy]-, 1-(carboxymethyl)octyl ester, mixture with 1-(carboxymethyl)octyl 3-[[6-deoxy- α -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- α -L-mannopyranosyl]oxy]-, 1-(carboxymethyl) octyl ester; and molecule 2 (defined as R2 or RRLL): Decanoic acid, 3-[[6-deoxy-2-O-(6-deoxy- α -L-mannopyranosyl)- α -L-mannopyranosyl]oxy]-, 1-(carboxymethyl) octyl ester.

Rhamnolipid biosurfactant, in particular, causes the lysis of zoospores of plant pathogens. Zoospores, the unicellular, motile spore stage in the life cycle of plant pathogens, are vulnerable to rhamnolipid biosurfactants due to the fact that the membrane-bound spore lacks a protective cell wall. The rhamnolipid destroys the permeability of the plasma membrane and results in the loss of motility and rapid lysis of the zoospore. Rhamnolipid biosurfactants are effective against all zoosporic plant pathogens, such as downy mildews, *Pythium* and *Phytophthora*.

Biosurfactants are produced by a variety of microorganisms and have been shown to play a role in enhancing bioavailability and biodegradation of petroleum hydrocarbons, in the attachment and detachment of bacteria to surfaces, and in complexing metals efficiently. Biosurfactants have application in cosmetics, personal care products, detergents, textile processing, agricultural crop protection products, metal treatment and processing, leather processing, hard surface cleaning, electronics component cleaning, pulp and paper processing, paint formulation, hydrocarbon recovery, oil tank cleaning and oil sludge remediation.

Rhamnolipids are comprised of extracellular natural substances (glycolipids) produced during a controlled aerobic fermentation process utilizing a strain of the bacterium *Pseudomonas aeruginosa*. Rhamnolipids are recovered from the process by centrifugation, extraction, and subsequent purification. No bacteria are present in the manufactured product and the production processes are strict in quality control to assure no live organisms exist. Purified rhamnolipids can be quantified by weight and rhamnose determination.

2. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable. It is not expected that, when used as proposed, rhamnolipid biosurfactant would result in residues that are of toxicological concern.

C. Mammalian Toxicological Profile

Rhamnolipid biosurfactant has been evaluated for toxicity through oral, dermal, inhalation and eye routes of exposure. Studies indicate the end-use product is Toxicity Category I for eye irritation (diluted end-use product is Toxicity Category IV for eye irritation), and Toxicity Category IV for all other routes of exposure. Studies resulted in an acute oral lethal dose (LD₅₀) >5,000 milligrams/kilogram (mg/kg), acute dermal LD₅₀ >5,000 mg/kg, acute inhalation lethal concentration (LC₅₀) 2.05 mg/L, primary eye irritation severe at 9.5% active ingredient and slight at 1.0% active ingredient, and primary skin irritation minimal.

A waiver has been requested for dermal sensitization based on the fact that the active ingredient is not toxic or irritating dermally, and a lack of reported effects by users of the surfactant in a variety of products. Rhamnolipid biosurfactants have been marketed for over 3 years as an emulsifier, dispersant and wetting agent. Since its discovery, no incidents of hypersensitivity have been reported by researchers, manufacturers or users. A waiver has been requested for genotoxicity based on the fact that rhamnolipid biosurfactant is not related to any known mutagen and does not belong to a chemical class of compounds containing known mutagens. The rhamnolipid molecules are simply glycolipids composed of a rhamnose sugar ring and a fatty acid tail. Individually these molecules are not considered toxic or mutagenic. Rhamnose is a comparatively rare sugar listed by FDA as a food additive. Fatty acids are ubiquitous in animals and plants, and are the major source of energy in the body. Consequently the breakdown products of rhamnolipids are of little toxicological concern. A waiver has been requested for 90-day oral toxicity, teratogenicity and immunotoxicity based on the physical mode of action of the product, the demonstrated lack of oral, dermal and inhalation toxicity, and the innocuous nature of the potential breakdown products of rhamnolipid biosurfactants. The mode of action of rhamnolipid biosurfactants is a physical action on the plant pathogen rather than a specific

toxic action. Rhamnolipid biosurfactant is virtually non-toxic to rats as demonstrated in the acute oral, dermal and inhalation studies submitted. The lack of mammalian toxicity supports the position that the physical action of rhamnolipid biosurfactants is a physical interaction with the zoospore membrane rather than a specific toxic mechanism that might be of concern. The chemical structures of the rhamnolipids suggest that there is little potential for chronic toxicity, teratogenicity or immunotoxicity in animals or humans as a result of exposure. The rhamnolipid molecules are simply glycolipids composed of a rhamnose sugar ring and a fatty acid tail. Individually these molecules are not considered toxic.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Dietary exposure from use of rhamnolipid biosurfactant, as proposed, is minimal. The use of rhamnolipid biosurfactant involves low levels of active ingredient applied to growing plants prior to harvest. Residues of rhamnolipid biosurfactant are not expected to be of toxicological concern. The rhamnolipid molecules are simply glycolipids composed of a rhamnose sugar ring and a fatty acid tail. Individually these molecules are not considered toxic.

ii. *Drinking water*. Similarly, exposure to humans from residues of rhamnolipid biosurfactant in consumed drinking water would be unlikely. Rhamnolipid biosurfactant is a naturally occurring extra-cellular substance that is produced by a microorganism known to exist in plant habitats; it is not known to grow or thrive in aquatic environments. Potential exposure to surface water would be negligible and exposure to drinking water (well or ground water) would be impossible to measure.

2. *Non-dietary exposure*. The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are agricultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern. Personal protective equipment mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings.

E. Cumulative Exposure

It is not expected that, when used as proposed, rhamnolipid biosurfactant would result in residues that are of toxicological concern. The rhamnolipid molecules are simply glycolipids composed of a rhamnose sugar ring and

a fatty acid tail. Individually these molecules are not considered toxic.

F. Safety Determination

1. *U.S. population*. Acute toxicity studies have shown that rhamnolipid biosurfactant is not toxic, but is irritating via ocular exposure. Residues of rhamnolipid biosurfactant are not expected to be of toxicological concern. The rhamnolipid molecules are simply glycolipids composed of a rhamnose sugar ring and a fatty acid tail. Individually these molecules are not considered toxic. There is a reasonable certainty of no harm to the general U.S. population from exposure to this active ingredient.

2. *Infants and children*. As mentioned above, residues of rhamnolipid biosurfactant are not expected to be of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to rhamnolipid biosurfactant from the proposed uses.

G. Effects on the Immune and Endocrine Systems

To date there is no evidence to suggest that rhamnolipid biosurfactant functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Existing Tolerances

There is no U.S. EPA tolerance for rhamnolipid biosurfactant.

I. International Tolerances

A Codex Alimentarium Commission Maximum Residue Level is not required for rhamnolipid biosurfactant.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7496-7]

Office of Environmental Information Draft Data Standard for Exchanging Permitting Information and Draft Data Standard for Federal Facility Identification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of information availability and request for comments.

SUMMARY: Notice of availability is hereby given for a 45-day public comment period for the draft data standards: Draft Data Standard for Permitting Information; and the Draft Federal Facility Identification Data Standard. These draft standards consist

of a list of data elements, definitions for these elements, formats, notes, and explanatory preamble language. The draft standards were developed through the partnership efforts of States, tribes, and the U.S. Environmental Protection Agency participating in the Environmental Data Standards Council (EDSC). The EDSC convened one Action Team to develop a more comprehensive set of data elements to facilitate the sharing permit related information. The EDSC also formed an Action Team whose purpose was to reach consensus on standardized means of identifying facilities that are owned or operated, or were owned or operated, by the Federal government. The EPA and the EDSC invite comment on these standards from States, EPA, tribes, database managers in the public and private sectors, and the general public with interest in exchanging information concerning environmental permits and Federal facilities.

DATES: Comments must be submitted on or before June 23, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, by facsimile, or through hand delivery/courier. Follow the detailed instructions as provided in Unit 1.A. of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Draft Data Standard for Permitting Information, Tim Crawford, Office of Environmental Information, Office of Information Collection, MC-2822T, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington DC 20460; Telephone (202) 566-1652.

Draft Federal Facility Identification Data Standard, John Harman, Office of Environmental Information, Office of Information Collection, MC-2822T, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington DC 20460; Telephone (202) 566 0748.

SUPPLEMENTARY INFORMATION:

I. General Information

A. How Can I Get Copies of These Draft Standards and Other Related Information ?

1. Docket. EPA has established an official public docket for this action under Docket ID No. OEI-2003-0028. 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