

may include but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer and farmworker groups; pesticide users and growers; pest consultants; State, local, and tribal governments; academia; public health organizations; food processors; and the public. 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-2004-0061. 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 agenda for the meeting will be posted by March 4, 2004, on EPA's Website at <http://www.epa.gov/pesticides/>.

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 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.

## II. Background

The Consolidated Appropriations Act of 2004, signed by President Bush on January 23, 2004, established a new section 33 of FIFRA, under which EPA is required to establish a registration service fee system for applications for pesticide registration and amended registration. Under that system, fees will be charged for new applications for registration received on or after the effective date of the statute (March 23, 2004), and for certain applications received before that date. EPA is required to render a decision on the application within the decision times specified. The fee system is authorized until September 30, 2010, although the decision times under the system do not apply after September 30, 2008.

### List of Subjects

Environmental protection, Agriculture, Agricultural workers, Chemicals, Fees, Foods, Pesticides and pests, Registration, Tolerance reassessment, Public health.

Dated: February 25, 2004.

**James Jones,**

*Director, Office of Pesticide Programs.*

[FR Doc. 04-4813 Filed 3-1-04; 11:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0020; FRL-7343-8]

### Bacillus pumilus GB34; Notice of Filing a Pesticide Petition to Establish an Exemption from the Requirement of a Tolerance for a Certain Microbial Pesticide 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-2004-0020, must be received on or before April 2, 2004.

**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:** Anne Ball, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8717; e-mail address: [ball.anne@epa.gov](mailto:ball.anne@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 manufacturer (NAICS 311)
- Pesticide manufacturer (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-2004-0020. 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-2004-0020. 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](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2004-0020. 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-2004-0020.

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-2004-0020. 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: February 23, 2004.

**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.

**Gustafson LLC**

*PP 1F6344*

EPA has received a pesticide petition 1F6344 from Gustafson LLC, 1400 Preston Road, Suite 400, Plano, TX 75093, 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 microbial pesticide *Bacillus pumilus* GB34 when used as a seed treatment in or on all food commodities and on soybeans after harvest.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Gustafson LLC has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Gustafson LLC 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*

The active ingredient *Bacillus pumilus* GB34 is formulated into the technical product GB34 Technical Biological Fungicide and the end use product GB34 Concentrate Biological Fungicide. GB34 Concentrate contains bacteria which colonize the developing root system of cotton, sugar beet, corn, and vegetable, legume group 06, suppressing disease organisms such as *Rhizoctonia* and *Fusarium* that attack root systems. GB34 Concentrate is used as a seed treatment before planting.

*B. Product Identity/Chemistry*

1. *Identity of the pesticide and corresponding residues.* *Bacillus pumilus* GB34 is a naturally occurring isolate from the soil.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* Two processing studies with soybeans were conducted. The studies showed no uptake of *Bacillus pumilus* GB34 beyond the seed hull. No residues were found in meal, oil, soymilk or tofu.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for enumeration of microorganisms is available but is not required since the petitioner is requesting an expansion of the existing exemption from the requirement of a tolerance.

*C. Mammalian Toxicological Profile*

*Bacillus pumilus* GB34 was not found to be toxic or pathogenic from acute intravenous administration of  $1.1 \times 10^7$  cfu of technical grade material. The oral LD<sub>50</sub> of GB34 Technical was greater than 5,000 milligrams/kilogram (mg/kg) of body weight. GB34 Technical was classified non-irritating to the skin and mildly irritating to the eye in primary skin irritation and eye irritation studies. The oral LD<sub>50</sub> of GB34 Concentrate was greater than 5,000 mg/kg of body weight. GB34 Concentrate was classified as non-irritating to the skin and minimally irritating to the eye in primary skin irritation and eye irritation studies. An avian oral pathogenicity and toxicity study in Northern Bobwhite showed no evidence of pathogenicity during gross necropsy. The no observed adverse effect level (NOAEL) was approximately  $3.4 \times 10^{11}$  cfu/kg/day for 5 days.

*D. Aggregate Exposure*

1. *Dietary exposure—i. Food.* *Bacillus pumilus* GB34 does not exhibit any mammalian toxicity. Therefore, any dietary exposure would not be harmful to humans. Also *Bacillus pumilus* GB34 is a naturally occurring, ubiquitous microorganism indigenous to the United States.

ii. *Drinking water.* *Bacillus pumilus* is found in the soil and the use rate of GB34 Concentrate is 0.1 ounces per 100 pounds of seed, equivalent to 1.7 grams per acre. *Bacillus pumilus* GB34 is unlikely to leach from the treated seed and would not be distinguishable from other naturally occurring *Bacillus pumilus*.

2. *Non-dietary exposure.* As a commercial seed treatment for cotton,

sugar beet, corn, and vegetable, legume group 06, the general population, including infants and children, will have a very low possibility of exposure. Occupational exposure will be limited to employees in commercial facilities handling the seed treatment product. Commercial seed treating equipment minimizes occupational exposure. Wearing protective equipment will also minimize occupational exposure. Non-dietary exposure would not be expected to pose a quantifiable risk.

#### E. Cumulative Exposure

The product strain belongs to the bacterial genus of *Bacillus*. *Bacillus pumilus* GB34 may have a similar mode of action in mammals as *Bacillus subtilis* that has been shown to be non-toxic and non-pathogenic in mammalian species. A similar mode of action of *Bacillus pumilus* GB34 and *Bacillus subtilis* would not be expected to result in an increased adverse effect since both were shown to be non-toxic and non-pathogenic in intravenous toxicity and pathogenicity studies.

#### F. Safety Determination

1. *U.S. population.* Based on the low treating rate of seed treatment use, little evidence of toxicity or pathogenicity and limited exposure potential, Gustafson LLC believes there is a reasonable certainty of no harm to the U.S. population in general from aggregate exposure to *Bacillus pumilus* GB34 residue from all anticipated dietary and non-dietary exposures.

2. *Infants and children.* Based on the lack of toxicity and low exposure there is a reasonable certainty that no harm to infants, children or adults will result from aggregate exposure to *Bacillus pumilus* GB34.

#### G. Effects on the Immune and Endocrine Systems

Gustafson LLC had no information to suggest that *Bacillus pumilus* GB34 will have any effect on the immune and endocrine systems.

#### H. Existing Tolerances

There is an existing exemption from tolerance for *Bacillus pumilus* GB34 when used as a seed treatment in or on soybeans and soybeans after harvest 40 CFR 180.1224.

#### I. International Tolerances

Gustafson LLC is not aware of any international tolerances, exemptions from tolerance or maximum residue levels for *Bacillus pumilus* GB34.

[FR Doc. 04-4629 Filed 3-1-04; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0009; FRL-7344-5]

### Experimental Use Permit; Receipt of Application

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of an application 524-EUP-96 from Monsanto Company requesting to extend and amend an experimental use permit (EUP) for ZMIR39 x MON810 combined insecticidal trait stacked corn hybrids along with ZMIR39 and MON810 corn hybrids; *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector ZMIR39) in corn (ZMIR39) and *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production (vector PV-ZMCT01) in corn (MON810). The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

**DATES:** Comments, identified by docket ID number OPP-2004-0009, must be received on or before April 2, 2004.

**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:** Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8715; e-mail address: [mendelsohn.mike@epa.gov](mailto:mendelsohn.mike@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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-2004-0009. 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.

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