

annual maximums) and annual average concentrations across all use scenarios were 1.30 and 1.07 ppb for FL strawberries and 0.66, 0.35, 0.24, 0.07 and 0.05 ppb for Florida vegetables, respectively. EECs of spiromesifen enol were highest for Florida strawberries, with corresponding concentrations of 32, 30, 26, 17, 11, 3.9, and 1.7 ppb, respectively.

The highest acute and chronic concentrations (spiromesifen and enol in surface water combined) across all use scenarios were used to assess human health risk from drinking water. Potential risk was estimated by comparing estimated drinking water concentrations to the acute and chronic Population Adjusted Dose (PAD) values, while accounting for differences in body weight and drinking water consumption between adults and children. These calculations result in risk estimates in the form of percentages of the acute and chronic PAD values. Tier I acute risk for adults and children were estimated at 0.06 and 0.23%, respectively, while Tier II acute estimates were 0.05 and 0.17%, respectively. Maximum Tier I chronic risk was estimated at 2.5% for adults and 8.9% for children. Corresponding Tier II chronic risk was estimated at 0.52% for adults and 1.8% for children (0.81% for children using the mean of the annual average concentrations over the simulation period).

2. *Non-dietary exposure.* Exposure assessments were prepared for both mixer/loader-applicators and reentry workers based on use of spiromesifen on various field crops, vegetables and strawberries. Agricultural worker margins of exposure (MOE) estimates were conservatively based on a non-observable-effect level (NOEL) of 1.06 mg/kg/day, maximum label rates, and a dermal absorption value of 2.25%. An occupational exposure uncertainty factor of 100 was used in the assessment. All margins of exposure (total) exceeded 100, indicating that these uses of spiromesifen pose no significant risk to workers who mix, load and apply this product, or to those who reenter treated areas to perform post-application activities. These data support the use of a single layer of clothing for mixer/loaders and applicators, gloves for mixer/loaders, and a 12-hour REI for reentry workers.

Exposure assessments were also conducted for both applicators and reentry based on use of spiromesifen for ornamentals, greenhouse and nursery applications. There are no indoor residential uses for spiromesifen, and therefore no assessments were performed for indoor residential use. All margins of exposure (total) exceeded

100, indicating that these uses of spiromesifen pose no significant risk to workers who mix, load and apply this product, or to those who reenter treated areas to perform post-application activities. These data support the use of a single layer of clothing for mixer/loaders and applicators, gloves for mixer/loaders, and reentry activities to be performed immediately after the application spray dries.

#### D. Cumulative Effects

Spiromesifen represents a new class of chemistry, ketonoles. There are no known registered chemicals within this class. Bayer will submit information, if necessary, for EPA to consider concerning potential cumulative effects of spiromesifen consistent with the schedule established by EPA at 62 FR 42020 (Aug. 4, 1997) (FRL-5734-6) and other EPA publications pursuant to the Food Quality Protection Act.

#### E. Safety Determination

1. *U.S. population.* Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to spiromesifen from all label uses will utilize less than 10 percent of the RfD for chronic dietary exposures and that margins of exposure in excess of 100 exist for aggregate exposure to spiromesifen for non-occupational exposure. EPA generally has no concerns for exposures below 100 percent of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Margins of exposure of 100 or more also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to spiromesifen residues.

2. *Infants and children.* In assessing the potential for increased sensitivity of infants and children, data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity. None of these studies conducted with spiromesifen indicated developmental or reproductive effects. The toxicology

data which support these uses of spiromesifen include the following: An oral developmental toxicity study in rat that did not reveal any evidence of teratogenic potential. Maternal and developmental NOAELs were 10 mg/kg bw/day. An oral developmental toxicity study in rabbits demonstrated a maternal NOAEL of 5 mg/kg bw/day, a developmental NOAEL of 35 mg/kg bw/day and did not reveal any teratogenic potential. A two-generation study in rats, with a parental toxicity NOAEL of 2.2 mg/kg bw/day, did not reveal evidence of a primary reproductive toxicity potential. The reproductive NOAEL was 14.2 mg/kg bw/day. FFDCA Section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when prenatal and postnatal threshold effects were observed in studies or to account for incompleteness of the toxicity database. Based on the toxicological data requirements, the data relative to prenatal and postnatal effects in children is complete. No indication of increased susceptibility of younger animals was observed in any of the above studies. For the population with the highest exposure, children 1-6 years old, the acute dietary exposure at the 95th percentile was 0.4% of the aPAD, equivalent to an MOE of 24845. Acute exposure of the overall US population was equivalent to 0.3% of the aPAD. For the chronic dietary analysis, the most highly exposed population subgroup was children 1-6 years old, with an exposure equal to 1.2% of the cPAD. Chronic exposure for the overall U.S. population equated to 0.4% of the cPAD.

#### F. International Tolerances

Codex maximum residue levels (MRLs) are not yet established for spiromesifen.

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0221; FRL-7371-5]

### Experimental Use Permit; Receipt of Application

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

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of an application 67979-EUP-L from Syngenta Seeds, Inc. - Field Crops - NAFTA requesting an experimental use permit (EUP) for the plant-incorporated

protectant *Bacillus thuringiensis* VIP3A insect control protein as expressed in events COT202 and COT203 cotton plants. 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 identification (ID) number OPP-2004-0221, must be received on or before August 27, 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:**

Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5412; e-mail address: [cole.leonard@epa.gov](mailto:cole.leonard@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 interested in agricultural biotechnology 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-2004-0221. 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, 1801 South Bell St., 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. 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-2004-0221. 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-2004-0221. 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-2004-0221.

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, 1801 South Bell St., Arlington, VA, Attention: Docket ID Number OPP-2004-0221. 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. Offer alternative ways to improve the notice.
7. Make sure to submit your comments by the deadline in this document.
8. 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. Background

Syngenta Seeds is proposing to test 245 acres of the plant-incorporated protectant *Bacillus thuringiensis* VIP3A insect control protein as expressed in events COT202 and COT203 cotton plants from March 2005 to March 2006 in the States of Alabama, Arizona, Arkansas, California, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Texas. Testing is to include insect efficacy, agronomic performance, and breeding and observation in field trials.

#### III. What Action is the Agency Taking?

Following the review of the Syngenta Seeds, Inc. - Field Crops - NAFTA application and any comments and data received in response to this notice, EPA will decide whether to issue or deny the EUP request for this EUP program, and if issued, the conditions under which it is to be conducted. Any issuance of an EUP will be announced in the **Federal Register**.

#### IV. What is the Agency's Authority for Taking this Action?

The specific legal authority for EPA to take this action is under FIFRA section 5.

#### List of Subjects

Environmental protection,  
Experimental use permits.

Dated: July 19, 2004.

**Janet L. Andersen,**

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

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#### ENVIRONMENTAL PROTECTION AGENCY

[OPPT-2004-0092; FRL7363-5]

#### Draft Federal Guide for Green Construction Specs; Notice of Availability

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

**ACTION:** Notice.

**SUMMARY:** Under Executive Order 13101, EPA's Office of Prevention, Pesticides, and Toxic Substances is responsible for providing information to Federal agencies to assist them in practicing environmentally preferable purchasing (EPP). Because construction and renovation of buildings constitute a large share of Federal expenditures and may involve significant environmental impact, EPA has a special interest in providing tools to promote environmentally preferable purchasing during these activities. The draft Federal Guide for Green Construction Specs is being developed by EPA with our partners, the Office of the Federal Environmental Executive and the members of the multiagency-sponsored Whole Building Design Guide, to help Federal building project managers meet various mandates as established by statute and Executive Orders, as well as EPA and the Department of Energy (DOE) program recommendations. Following an advance review with