

TABLE 2.—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

| Company Number | Company Name and Address                                                         |
|----------------|----------------------------------------------------------------------------------|
| 100            | Syngenta Crop Protection, Inc.<br>P.O. Box 18300<br>Greensboro, NC<br>27419-8300 |
| 74530          | Helm Agro U.S., Inc.<br>Nordkanalstrasse 28<br>D-20097 Hamburg,<br>Germany       |

### III. Cancellation Order

Pursuant to section 6(f) of FIFRA, EPA hereby approves the requested cancellations of molinate product registrations identified in Table 1 of this notice. Accordingly, the Agency orders that the molinate product registrations identified in Table 1 are hereby canceled as of June 30, 2008.

### IV. Modification of the Terms and Conditions of the Molinate Registrations

The 2002 sales level of the molinate active ingredient will be the maximum amount that Syngenta and Helm will sell or distribute in 2004, 2005, and 2006. Syngenta and Helm may not sell or distribute any more than 75% of the 2002 sales levels in the year 2007, and sell or distribute more than 50% of the 2002 sales levels in the year 2008.

Syngenta and Helm will provide annual production/sales reports to the Agency beginning in the year 2004 through 2009. Syngenta and Helm will also provide inventory reports for the years 2007, 2008, and 2009. These reports will be submitted by September 30 of each year to the Agency's Chemical Review Manager for molinate.

Failure by either registrant to comply with the sale or distribution limits contained in the molinate registration constitutes grounds for immediate cancellation of the registration without opportunity for a hearing.

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

Section (6)(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registration be canceled. FIFRA further provides that before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

### VI. What Comments Did the Agency Receive?

EPA received two sets of comments on the voluntary cancellation requests for molinate products during the comment period. The commenters, Pesticide Action Network North America (PANNA) and Natural Resource and Defense Council (NRDC) strongly support the cancellation of molinate, but are concerned that the proposed phase-out is too long and will permit ongoing environmental and human health harm for many years. Further, they were concerned that the Agency is not requiring risk mitigation during the phase-out period to address exposure to molinate in ambient air.

EPA believes the voluntary agreement achieves more timely risk mitigation than would have been achieved through a regulatory process. In addition, under FIFRA, where the Agency must look at risks and benefits of a pesticide, it is not certain that the result of reregistration would have been cancellation. EPA's detailed responses to PANNA and NRDC comments may be found in the docket listed in Unit I.B1.

### VII. Provisions for Disposition of Existing Stocks

For purposes of this Cancellation Order, the term "existing stocks" is defined, pursuant to EPA's existing stocks policy (56 FR 29362, June 26, 1991), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled and released for shipment prior to the effective date of the cancellation order. The existing stocks provisions of this cancellation order are as follows:

The cancellation of these registrations has an effective date of June 30, 2008. After that date, Syngenta Crop Protection Inc., and Helm Agro U.S. Inc., may not sell or distribute any molinate products except as detailed in the cancellation order. Syngenta Crop Protection Inc., and Helm Agro U.S. Inc., will be permitted to distribute the molinate active ingredient in 2009 for the purposes of facilitating usage by August 31, 2009. No use of products containing molinate is permitted after the 2009 growing season (August 31, 2009).

### List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 26, 2004.

**Debra Edwards,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

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BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0058; FRL-7349-4]

### Muscodor albus Strain QST 20799; Notice of Filing a Pesticide Petition to Establish an Exemption from 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-2004-0058, must be received on or before May 7, 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:** Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: [bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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. *EPA Docket.* EPA has established an official public docket for this action under docket ID number OPP-2004-0058. 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-2004-0058. 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-2004-0058. 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-2004-0058.

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-2004-0058. 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: March 22, 2004.

**Janet L. Andersen,**

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

### **Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by AgraQuest, Inc. 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.

**AgraQuest, Inc.**

PP 3F6745

EPA has received a pesticide petition (PP 3F6745) from AgraQuest, Inc., 1530

Drew Avenue, Davis, CA 95616, 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 *Muscodor albus* strain QST 20799 in or on all food commodities.

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

*Muscodor albus* strain QST 20799 will be the active ingredient in end-use products for soil treatment to control root diseases in greenhouse and field crops, as well as a fumigant to control post harvest decay in fresh fruits, vegetables and cut flowers. When activated with moisture, *Muscodor albus* strain QST 20799 produces volatile compounds that are lethal to plant pathogenic organisms that cause diseases such as root rot, damping-off and wilt. End-use product will be mixed with the soil, applied to seeds, bulbs and/or tubers prior to planting, or used to treat enclosed containers of postharvest fruits, vegetables and cut flowers.

#### *B. Product Identity/Chemistry*

1. *Identity of the pesticide and corresponding residues.* *Muscodor albus* strain QST 20799 is an endophytic fungus that was originally isolated from the bark of a cinnamon tree in Honduras. The strain grows as a white sterile mycelium and does not produce asexual or sexual spores, or other structures such as chlamydospores or sclerotia. *Muscodor albus* strain QST 20799 works to inhibit and kill microorganisms by production of a number of volatiles, mainly alcohols, acids, and esters. *Muscodor albus* strain QST 20799 will be the active ingredient in end-use products for soil treatment to control root diseases in greenhouse and field crops, as well as a biofumigant to control post harvest decay in fresh fruits, vegetables and cut flowers.

*Muscodor albus* strain QST 20799 works to inhibit and kill microorganisms by production of a number of volatiles, mainly alcohols, acids, and esters. Antifungal activity was found to be mainly associated with the production of 2-methyl-1-butanol, ethyl butyrate and isobutyric acid. Other compounds produced such as ethyl propionate, ethyl isobutyrate and methyl isobutyrate, although, less inhibitory, may also contribute to the antimicrobial activity. Many of these compounds are well known as natural constituents of fruit aromas, fresh leaves, wine and rum aromas, blue cheese aroma, other natural essential oils and olive and vegetable oil.

Volatiles produced by *Muscodor albus* strain QST 20799 have a fungicidal rather than a fungistatic action toward most fungi. Both vegetative hyphae and spores of plant pathogenic fungi are killed. The volatiles are also bactericidal against vegetative bacterial cells. Most *Muscodor albus* strain QST 20799 volatiles are non-polar and thus more likely to be absorbed or attach to the cell membrane, which is the first cellular component exposed after the cell wall. The disruption of cell membrane functions is a likely explanation for such a wide and unspecific activity. Damage to cell membrane components can cause loss of electrolytes, loss of osmotic balance and impair feeding functions. Damage to other cellular components is less likely, as they would require penetration of the cytoplasm and be more likely to have a more specific activity. Extensive work with crop plants has demonstrated that *Muscodor albus* strain QST 20799 will not establish on treated plants and does not represent a risk to non-target plants. The strain does not have spores or any other resting stage, and the volatiles it produces have been shown to dissipate rapidly in soil and water.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* Residues of the fungal active ingredient are not expected on food or feed items because the active ingredient will not be in direct contact with treated commodities. The volatile organic compounds produced by *Muscodor albus* strain QST 20799 were identified by GC-MS as follows: The most abundant compound was ethyl propionate followed by 3-methyl-1-butanol (or 2-methyl-1-butanol) and isobutyric acid, other compounds produced include ethyl butyrate, ethyl isobutyrate and methyl isobutyrate. Many of these compounds are well known as natural constituents of fruit aromas, fresh leaves, wine and rum

aromas, blue cheese aroma, other natural essential oils and olive and vegetable oil. A comprehensive data base search was carried out to assess the reported toxicities of these compounds. Data bases include the registry of toxic effects of chemical substances (RTECS) and the hazardous substance data bank (HSDB).

During postharvest testing with fruit in the box, levels of volatile organic compounds were measured using 10 grams (10g) product in an 11.4L box. Exposure from such treatment is at concentrations well below reported lethal dose (LD)<sub>50</sub> levels for these volatile compounds. Further, the volatile compounds rapidly dissipate in soil and water. They are not expected to accumulate on food/feed commodities, nor to be above the background levels of these naturally occurring compounds. A system was set up to determine levels of volatile organic compounds remaining on apples after treatment. This demonstrated that after a 48-hour exposure of 10g Arabesque to apples in a 11.4 L box, only two volatile compounds could be detected in the rinsate of the apple skins. All others were not detectable. These two were at very low concentrations (2-methyl-1-butanol, 8 ppb and isobutyl alcohol, 10 ppb). These levels diminish even further after 24-hours aeration. The LD<sub>50</sub> values reported for these compounds are 6 orders of magnitude higher than those observed right after exposure. Naturally occurring levels of the volatiles in foods are higher than those observed after treatment with Arabesque.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Residues of the fungal active ingredient are not expected on food or feed items because the active ingredient, *Muscodor albus* strain QST 20799, will not be in direct contact with treated commodities. As discussed immediately above, residue levels of the fungus will be zero because the microorganism has limited survivability once its carrier nutrient source is exhausted. The volatiles are already found naturally occurring in foods such as apples, mushrooms, bananas, apricots, grapes, wine and beer. Many of the volatile organic compounds produced by Arabesque are certified natural flavors and fragrances used in preparation of foods, cosmetics and perfumes. There are no fungal residues left in soil and the fungus never comes in contact with the postharvest produce. An analytical method for residues is not required for an exemption from tolerance because it is expected that, when used as proposed, *Muscodor albus* strain QST

20799 would not result in residues that are of toxicological concern. Volatile compounds produced by the active ingredient occur naturally, and dissipate rapidly in soil and water.

### C. Mammalian Toxicological Profile

Studies to evaluate the safety to mammals were conducted on the technical grade active ingredient (TGAi) are summarized as follows:

1. *Acute oral toxicity (OPPTS Harmonized Guideline 870.1100).* In a non-GLP acute oral toxicity study on rats (three male/three female) using the limit dose, no effects were seen in test animals and an LD<sub>50</sub> >5,000 milligrams/kilogram (mg/kg) is proposed. All six rats gained weight during the course of the study. There were no mortalities during the study. At necropsy all tissues appeared grossly normal in all six rats. Clearance was not measured in this study.

2. *Acute oral toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3050).* In an acute oral toxicity/pathogenicity study a dose of 0.1 gram dry weight of mycelium (equivalent to  $1 \times 10^8$  cfu/g) was administered to rats (15 male/15 female) via oral gavage. There were no adverse effects, mortalities, clinical signs or abnormal macroscopic findings at post-mortem. No viable *Muscodor albus* strain QST 20799 were recovered from the organs, blood, intestinal contents or feces from any of the treated animals during the study, and the test material was rated as non-toxic and non-pathogenic.

3. *Acute dermal toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3100).* In an acute dermal toxicity/pathogenicity study on rabbits (five male/five female) using a dose of 2.0 mL/kg body weight applied topically, there were no dermal reactions, mortalities, significant clinical signs or abnormal macroscopic findings at post-mortem. An LD<sub>50</sub> >2,000 mg/kg was established.

4. *Acute pulmonary toxicity/pathogenicity (OPPTS Harmonized Guideline 885.3150).* In an acute pulmonary toxicity/pathogenicity study on rats (23 male/23 female) using a dose of 0.3 grams/100 grams (or 3.0 grams/kg) body weight (highest possible dose) administered by a single intratracheal instillation, there were three unscheduled deaths. Deaths were attributed to the dosing procedure and viscous nature of the test material. No toxicity or clinical signs related to treatment with the active ingredient were observed. No viable *Muscodor albus* strain QST 20799 were recovered from the organs, blood, intestinal contents or feces from any of the treated

animals during the study, and the test material was rated as non-toxic and non-pathogenic.

5. *Primary eye irritation (OPPTS Harmonized Guideline 870.2400)*. In a primary eye irritation study on rabbits (three female) using a dose of 0.1 mL per eye administered topically, there was minimal irritation at 1 hour post dosing, but all effects cleared by 24-hours. No corneal opacity or iridal effects were observed. *Muscodor albus* strain QST 20799 was rated "minimally irritating" to eyes.

6. *Hypersensitivity incidents (OPPTS Harmonized Guideline 885.3400)*. The registrant has noted that no incidents of hypersensitivity or any other adverse effects have occurred through the research, development or testing of the active ingredient and its related end-use product. Should any hypersensitivity incidents occur, they will be reported per FIFRA section 6(a)(2). The above studies show the active ingredient is not toxic, pathogenic, infective or irritating to mammals. In addition, growth temperature analysis has shown that *Muscodor albus* strain QST 20799 does not grow below 5 °C or above 34 °C, which would indicate that the active ingredient would be unlikely to infect humans or other mammals with normal body temperatures above 37 °C.

7. *Data waiver requests*. For the technical grade active ingredient (TGAI) and the end-use products, Arabesque, Andante and Glissade, a waiver has been requested for the acute intravenous injection toxicity/pathogenicity, acute oral toxicity (limit dose), acute dermal toxicity (limit dose), acute inhalation toxicity (limit dose), dermal irritation, dermal sensitization and the conditionally required Tier 1 data for cell culture and immune response. Rationale for waiver of these data requirements is based on the lack of exposure, demonstrated safety to mammals, in the toxicity/pathogenicity and irritation tests, and the known growth temperature range of the organism. A temperature growth study was conducted at temperatures from 5 °C to 34 °C. Growth was observed from 10 °C to 30 °C; no growth occurred at 5 °C or at 34 °C. Therefore, it can be concluded that the organism will grow above 5 °C and below 34 °C. Since this is lower than the body temperature of the mammalian test animals, it is unlikely that the organism would survive in these studies.

*Muscodor albus* strain QST 20799 produces volatile organic compounds that inhibit or kill several plant pathogens. The volatile compounds produced by the active ingredient have been evaluated in a risk assessment

conducted by the registrant. None of these compounds are endotoxins and they are not toxic to humans.

The results of toxicity testing indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. This product will be a viable alternative to the use of soil fumigants and postharvest fungicides that have been demonstrated to be harmful to the environment and human health (e.g., methyl bromide and 1,3 dichloropropane). There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced are not of toxicological concern and dissipate rapidly in the environment. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* strain QST 20799 are low.

#### D. Aggregate Exposure

1. *Dietary exposure—i. Food*. Dietary exposure from use of *Muscodor albus* strain QST 20799, as proposed, is minimal. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. For soil treatment the poor survivability of the active ingredient will limit any dietary exposure. For post-harvest treatment there is no contact between the fungus and the postharvest commodity. The fungus will be in a container or sachet which will allow volatiles to contact the food commodity. The fungus itself will not be in contact with the food commodity. Preliminary studies showed that no residue levels of concern of either the fungus or the volatiles were found on apples exposed to the active ingredient. As discussed above, the active ingredient will not be in direct contact with treated food/feed commodities, and naturally occurring levels of the volatiles in foods are higher

than those observed after treatment with Arabesque.

The results of acute oral, dermal and pulmonary toxicity/pathogenicity testing with the TGAI, indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* strain QST 20799 are low.

During commercial and regular use of treated food materials, standard practices of washing, peeling, cooking or processing fruits and vegetable would further reduce any possible residue of the active ingredient. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern, and dissipate rapidly in the environment.

ii. *Drinking water*. Similarly, exposure to humans from residues of *Muscodor albus* strain QST 20799 unconsumed drinking water would be unlikely. *Muscodor albus* strain QST 20799 is not known to grow or thrive in aquatic environments. Potential exposure to surface water would be negligible and exposure to drinking water (well water or ground water) would be impossible to distinguish from the naturally occurring exposure. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. The risk of the microorganism passing through the soil to ground water is minimal to unlikely. Additionally the fungus would not tolerate the treatment conditions water is subjected to in a municipal drinking water facility (including: chlorination, pH adjustments, high temperatures and/or anaerobic conditions). Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment.

The results of toxicity testing indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799.

There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the potential hazard and the dietary exposure to human adults, infants and children associated with the use of *Muscodor albus* strain QST 20799 are low.

2. *Non-dietary exposure.* The potential for non-dietary inhalation and dermal exposure to the general population, including infants and children, is unlikely as the pesticide is proposed for agricultural or postharvest use sites. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment. Personal protective equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings.

The results of toxicity testing indicate there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* strain QST 20799 are low. Non-dietary exposures would not be expected to pose any quantifiable risk because there are no detectable residues of toxicological concern.

#### E. Cumulative Exposure

It is expected that, when used as proposed, *Muscodor albus* strain QST 20799 would not result in residues that are of toxicological concern. The major

intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment. The results of toxicity testing indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* Strain QST 20799 are low.

#### F. Safety Determination

1. *U.S. population.* Acute toxicity studies have shown that *Muscodor albus* strain QST 20799 is not toxic, pathogenic, infective or irritating to mammals. The major intended use of *Muscodor albus* strain QST 20799 is to fumigate soil and harvested crops for the purposes of disease control. *Muscodor albus* strain QST 20799 has limited survivability once its carrier nutrient source is exhausted. Volatile compounds produced by *Muscodor albus* strain QST 20799 are not of toxicological concern and dissipate rapidly in the environment. The results of toxicity testing indicates there is no risk to human health or the environment from *Muscodor albus* strain QST 20799. There are no reports of ecological or human health hazards caused by *Muscodor albus* strain QST 20799. It does not produce recognized toxins, enzymes, or virulence factors normally associated with mammalian invasiveness or toxicity. The absence of acute toxicity or pathogenicity in laboratory animals demonstrates the benign nature of this strain. The limited survival of *Muscodor albus* strain QST 20799, the rapid dissipation of the volatile compounds produced, and lack of acute toxicity indicate that both the hazard and the exposure associated with the use of *Muscodor albus* strain QST 20799 are low. There is a reasonable

population from exposure to this active ingredient.

2. *Infants and children.* As mentioned above, it is expected that, when used as proposed, *Muscodor albus* strain QST 20799 would not result in residues that are of toxicological concern. There is a reasonable certainty of no harm for infants and children from exposure to *Muscodor albus* strain QST 20799 from the proposed uses.

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

To date there is no evidence to suggest that *Muscodor albus* strain QST 20799 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

#### H. Existing Tolerances

There is no EPA tolerance for *Muscodor albus* strain QST 20799.

#### I. International Tolerances

There is no Codex alimentarius commission maximum residue level (MRL) for *Muscodor albus* strain QST 20799.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0073; FRL-7349-9]

### Forchlorfenuron; Notice of Filing a Pesticide Petition to Establish an Extension of a Time-Limited 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-2004-0073, must be received on or before May 7, 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:** Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone