US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDE REGISTRATION ACTION DOCUMENT

MUSCODOR ALBUS QST 20799 (QST 20799® TECHNICAL)

(End-use Products ARABESQUE™, ANDANTE™, GLISSADE™)

PC Code 006503

Setember 25, 2005

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Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1801 Bell Street
Arlington, VA 22202

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(PC Code 006503)

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Office of Pesticide Programs:

Biopesticides and Pollution Prevention Division

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I. EXECUTIVE SUMMARY/FACT SHEET

Active Ingredient and Proposed Use

The active ingredient *Muscodor albus* Strain QST 20799, also known as *M. albus* NRRL 30547 (PC Code 006503), is a naturally-occurring endophytic fungus belonging to the family Xylariaceae (Ascomycetes). *M. albus* Strain QST 20799 was originally isolated from the bark of a cinnamon tree in Honduras. It was imported into the US with appropriate permits issued by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Services (APHIS). It grows as a white sterile mycelium and does not produce asexual or sexual spores or other reproductive structures such as chlamydospores or sclerotia. When hydrated, *M. albus* Strain QST 20799 produces a number of volatiles, mainly alcohols, acids, and esters, that are claimed to inhibit and kill plant pathogenic and other organisms, such as nematodes, that cause soil-borne and post harvest diseases.

The Technical Grade Active Ingredient (TGAI), *M. albus* Strain QST 20799, EPA Reg. No. 69592-RU (to be registered as 69592-14), will be manufactured in Mexico. It will be formulated into the End-use Products (EPs) named, Andante™, (EPA Reg. No. 69592-RT or 69592-17), Arabesque™, (EPA Reg. No. 69592-RL, or 69592-15), and Glissade™ (EPA Reg. No. 69592-RI, or 69592-18). Each of the EPs will contain 0.35% of the active ingredient. The EPs are proposed for use as a seed or propagule or soil treatment to control root diseases in greenhouse and field crops, as well as for control of post-harvest decay in fresh fruits and vegetables and cut flowers.

Proposed application rates for the 3 EPs range from 0.5 to 2 ounces per cubic foot of treated volume of the enclosed container for post harvest uses to 500 to 21000 pound per acre for soil treatment as discussed in Section II of this Biopesticide Registration Action Document (BRAD). Application of these maximum rates to the soil represent about 7.35 lb ai/acre applied to rows at a depth of 12 inches, so that the entire acre is not treated. All manufacturing regulations must be met to assure the quality and integrity of the product. Quality control measures, discussed in Section III.A. are in place to ascertain that human pathogens and unintentional ingredients are within regulatory levels.

Toxicology, Human Exposure and Risks

Technical Grade Active Ingredient

Summaries of the toxicological effects, from reviews of the submitted studies, are found in Table IIIb (Section III.B.2). No toxic, infective, or pathogenic effects were observed in two acute oral exposure tests in rodents. Based on the submitted studies, the TGAI is considered Toxicity Category IV for acute oral exposure. The results of the acute pulmonary exposure study indicated the TGAI was not toxic, infective, or pathogenic to rats. Results of an acute dermal toxicity study revealed no toxicity or dermal irritation in rabbits, and the TGAI was practically non-irritating in an acute eye irritation study with rabbits. The TGAI demonstrated low potential toxicity and cleared the tissues of treated rodents in the acute oral and pulmonary toxicology studies. It is not expected to survive at mammalian body temperatures. These rationales justified

granting the request to waive data requirements for acute intravenous or intraperitoneal or intracerebral toxicity/pathogenicity, and immune response studies for the TGAI. Cell culture studies are not required for fungal active ingredients. No incidents of hypersensitivity have been reported for the TGAI, but hypersensitivity incidents must be reported to comply with Section 6(a)(2). Volatiles, which are released on rehydration of the EPs, are characterized as naturally occurring fragrances, flavoring agents or as solvents. While they do not pose a dietary risk, they may be an inhalation hazard to workers. For the TGAI/MP, the acute pulmonary study supports waiving the acute inhalation study, but the Agency has required data to confirm this preliminary assessment.

End-use Products

Data waivers were granted for the EPs for acute oral, and dermal studies; primary dermal irritation; dermal sensitization; and a hypersensitivity study. The waivers were based on the lack of toxicity seen in the studies with the TGAI as test material, and low exposure scenarios. A request to waive data was also granted for primary eye irritation for the EPs based on (a) the minimal irritation seen in the TGAI study, (b) the lower concentration of active ingredient in the EPs compared to the TGAI, and (c) the non-infective or non-pathogenic effects in the studies reported. Furthermore, the inert ingredients in the EPs are considered to be of minimum risk, and are cleared for food use. The granular nature of the EP and the acute pulmonary study support waiving the acute inhalation toxicity study. However, volatiles are produced during rehydration of the EPs. They are known as naturally occurring fragrances and flavors of food commodities, and not likely to pose a dietary risk via inhalation. Nevertheless, the Agency is requiring data to confirm the preliminary assessment that they do not pose an inhalation risk to workers. In the meanwhile, the proposed EP labeling and PPE requirements are expected to mitigate any potential risk arising from use of the EPs. The request to waive the hypersensitivity study was waived, based on the rationale that no incidents of hypersensitivity have been reported for *Muscodor albus* QST 20799. Hypersensitivity incidents must be reported to comply with Section 6(a)(2).

Food Tolerances

This is the first proposed food/feed use of *M. albus* Strain QST 20799 for which an exemption from tolerance has been requested. The summaries of the reviewed studies, published literature, and scientific and exposure rationales in support of this exemption from tolerance are included in this BRAD. A final rule establishing the exemption from tolerance for residues of *M. albus* Strain QST 20799 on fruit and vegetable commodities will be published in the Federal Register concomitant with the issuance of the conditional registration of this pesticide.

FQPA Considerations

The Agency has considered *M. albus* Strain QST 20799 in light of the safety factors of the Food Quality Protection Act (FQPA) of 1996 and has made a determination of reasonable certainty of no harm to the U.S. population in general, and to infants and children in particular. Due to its incorporation into soil prior to planting, its lack of viability in soil once its food source

is exhausted, and the absence of direct contact with commodities treated postharvest, *M. albus* Strain QST 20799 is not expected to be present in/on food commodities (Section III.B.3).

The Agency also considered the potential for contamination of the pesticidal active ingredient, *M. albus* Strain QST 20799. Quality control and quality assurance methods are in place during the manufacturing process to ensure that the pesticide itself is free of contaminants. No unintentional ingredients are expected to be formed during the manufacturing process, which is conducted under aseptic conditions and includes sterilizing all media and equipment, as well as monitoring for human pathogens and microbial contamination. All batches with human pathogens or contaminants above regulatory levels must be destroyed.

As discussed in Section III.B., no toxicity endpoints were indicated to justify setting a numerical tolerance for *M. albus* Strain QST 20799. Based on the Toxicity Category IV classification for acute oral toxicity, a safety factor is not required for residues of *M. albus* Strain QST 20799 on fruits and vegetables. With regards to the proposed use of this active ingredient, no acute, subchronic, chronic, immune, endocrine, or nondietary exposures have been identified that may have incremental adverse effects on infants, children, or the general U.S. population.

The proposed food use pattern is not likely to result in dietary exposure or residues on food and feed, since *M. albus* Strain QST 20799 is incorporated into soil prior to planting and survives poorly in soil once the food supply is depleted. Postharvest treatment using *M. albus* Strain QST 20799 does not involve contact with the commodities being treated, therefore no residues are expected. Normal washing, peeling, cooking, or processing of treated fruits and vegetables would further reduce any possible residues of *Muscodor albus* QST 20799.

Occupational and Residential Exposure and Risk

Potential exposure of workers and pesticide handlers of *M. albus* Strain QST 20799 is expected to be minimal. The pesticide demonstrates low toxicity, infectivity, and pathogenicity potential by the acute oral or pulmonary routes. The pesticide is incorporated into the soil for pre-plant uses, and is used in enclosed containers for post-harvest uses. Mitigation of exposure of workers and pesticide handlers can be achieved by the use of personal protective equipment specified on the pesticide labels. There is a Restricted Entry Interval (REI) of zero (0) hour for end-use products containing *M. albus* Strain QST 20799 to be applied as seed, propagule or post harvest treatments, and a four (4) hour REI for soil treatments, pending resolution of the rodent inhalation study required as a condition of registration. Non-occupational exposure is mitigated by limiting the application of the pesticide to commercial and agricultural sites **(Section III.B.4)**.

Ecological and Environmental Exposure and Risks

Ecological and environmental exposure and risk are summarized in **Section III.C.** Evaluation of an acceptable avian oral exposure study with the TGAI indicated a lack of toxicity to nontarget avian species. Wild mammal testing of the TGAI was not required, since the submitted acute oral toxicity/pathogenicity study using rats was sufficient to make a “no apparent

hazard" finding for wild mammals. Data waivers were granted for non-target species testing for the EPs based on:

(a) the low survival of *M. albus* Strain QST 20799 in soil and soil runoff water;
(b) the low concentrations and rapid dissipation of the volatile compounds produced by the active ingredient;
(c) the low acute oral toxicity/pathogenicity of the TGAI in rats and birds;
(d) proposed labeling not to apply the EPs in estuarine or marine environments;
(e) the reported lack of phytotoxicity or colonization of plant materials during the registrant's nontarget testing; and
(f) a search of published literature that found no relevant adverse effects on organisms other than pathogenic fungi and bacteria.

Data Gaps and Requirements/Labeling

All deficiencies and labeling must meet Agency requirements **(Section V.C)**. Standard analyses of five production batches are required to establish that manufactured batches meet the nominal limits and quality control requirements **(Section VI)**.

The conditions of registration required for the EPs are::
(a) the storage stability data to support the claim that the EPs are stable for 1 year; and
(b) an acute inhalation study with a mixture of the volatiles to be administered for four (4) hours to rats through the nose at a concentration of 1000 times the expected exposure level.

If more extensive use patterns are sought for treatment of other non-agricultural or agricultural sites or crops, additional information and data will be required on a case-by-case basis in order to amend the relevant registrations.

II. OVERVIEW

A. Product Overview

Biological Name: *Muscodor albus* Strain QST 20799

ATCC Number: National Regional Research Laboratories (NRRL) 30547

Trade and Other Names: *Muscodor albus* Strain QST 20799 (TGAI)
QST 20799® Technical (Manufacturing Use Product or MP)
Andante™ (End Use Product or EP)
Arabesque™ (End Use Product or EP)
Glissade™ (End Use Product or EP)

OPP Chemical Code: 006503

Basic Manufacturer: AgraQuest, Inc.
1530 Drew Avenue
Davis, CA 95616

Manufacturing Establishment: Km. 6.5 Autopista
San Martin Texmelucan-Tlaxcala
Ixtacuixta, Tlax. C.P. 90122
Mexico

B. Use Profile

The following is information on the proposed uses with an overview of use sites and application methods.

Type of Pesticide: Fungicide, biofumigant

Manufacturing Use Product: QST 20799® Technical: TGAI. (69592-RU)
For manufacturing use only.

End-use Products: Andante™: fungicide/nematicide EP.
Arabesque™: fungicide/ EP.
Glissade™: fungicide/ EP.

Table II: Use sites and application directions for EPs containing *Muscodor albus* QST 20799

	Arabesque™ (69592-RL)	**Andante (69592-RT)**	**Glissade™ (69592-RI)**
Formulation	**Granular**	**Granular**	**Granular**
Use sites	**Post harvest treatment** of fruits, cut flowers. **For post harvest use in packages of**: citrus, pome fruit, stone fruit, mango, papaya, avocado, caneberries, blueberry, strawberry, cranberry; fruiting vegetables, bulb vegetables, cucurbits, tubers/root vegetables, beans, cole crops; cut and potted flowers. **For seed or propagule treatment of**: vegetable, grain, and legume seeds; flower and vegetable seed bulbs; potato, sweet potato, yam, cocoyam, cassava, ginseng.	**As a soil biofumigant for**: vegetable seed or propagule and plant beds; fruit and nut trees; vine, caneberry and strawberry transplants, including orchard resets; ginseng seed beds, forest nurseries, seed or propagule or propagation beds for conifers and deciduous trees.	**For soil treatment of:** compost piles, potting soil, seed or propagule and propagating beds, soil media.
Target Pest	**For control of:** pre-plant seed or propagule, bulb, and tuber disease producing fungi and bacteria; post-harvest disease producing fungi and bacteria.	**For control of:** root rot-, damping off-, and wilt disease-producing fungi and bacteria. Nematodes.	**For control of:** root rot-, damping off-, and wilt disease-producing fungi and bacteria.
Application rates	Re-hydrate by adding 15 oz of water per pound of product at an ambient temperature of 68 to 85°F (20 to 30°C). For post-harvest treatment, add 0.5 to 2 oz of re-hydrated product per cubic foot of treated volume to enclosed container of treated commodity. Treat for 10 to 96 hrs at 40 to 85°F (5 to 30°C). For pre-plant treatment, add 0.5 to 2 oz of re-hydrated product per cubic foot of treated volume.	Ground application at 500 to 21000 lbs per acre. Apply uniformly to the soil surface using a fertilizer spreader or similar equipment. Incorporate into soil to a depth of 6 to 8 inches immediately after application. For small areas, uniformly mix 2 to 10 oz per cubic foot of soil by hand using gloves and appropriate PPE. Use higher rates in soils that contain high pathogen or nematode levels. Evenly distribute commodity to be treated in a layer no greater than 2 inches thick. Treat for 24 to 96 hrs at 55 to 85°F (13 to 30°C).	Uniformly blend 2 to 10 oz of product per cubic foot of soil.

Table II: Use sites and application directions for EPs containing *Muscodor albus* QST 20799

	Arabesque™ (69592-RL)	Andante (69592-RT)	Glissade™ (69592-RI)
Timing of applications	**Post harvest uses:** Treat for at least 10 hrs, but optimally for 24 - 96 hours at a temperature of 40°F to 85°F (5°C to 30°C). At storage temperatures of 32°F to 85°F (0°C to 5°C), treat for a period of 1-4 weeks. **Seed, bulb and propagules:** Treat for at least 24 hrs, but optimally 24-96 hrs at a temperature of 55°F to 85°F (13°C to 30°C)	**Soil uses:** Apply 5 - 7 days prior to direct seeding or 48 hrs before transplanting. Soil should be free of clods and plant residue. Soil temperature must be between 40°F and 85°F (5 to 30°C) during and at least 72 hrs after treatment. Soil must have sufficient moisture for seed or propagule germination or to sustain transplants (approximately 20%-50% field capacity).	**Greenhouse and nursery soil disease and nematode control:** Wait at last 5 to 7 days after treatment before seeding or transplanting.
Use Practice Limitations	For seed, propagule, post harvest treatments: Rehydrate by adding 15 ounces of water per pound of pesticide product at ambient temperature of 68°F to 85°F and use within 2 hours of rehydration. Do not store re-hydrated material for later use. For soil treatment, irrigate within 24 hrs of soil incorporation of dry product. Do not mix or apply with pesticides or other additives. Do not apply to dry soil or soil at field capacity moisture. Do not apply farmyard manure, peat, other organic fertilizers, burnt lime, or lime nitrogen just before or within 72 hrs after treatment. Do not apply to growing crops, use only as a pre-plant treatment. Excessive rainfall or irrigation within 48-72 hrs after treatment will negatively impact performance.		

C. Estimated Usage

This is the first conditional registration of the active ingredient, so estimated usage data are not available.

D. Data Requirements

The submissions to comply with Agency data requirements for granting this conditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). For *Muscodor albus* Strain QST 20799, the product identity and analysis data, as well as the data and information submitted for acute mammalian toxicology and ecological effects, are sufficient to allow the proposed use patterns. Based on evaluations of submitted data, as discussed in this document, the Agency foresees no unreasonable adverse effects on human health or the environment from the use of *Muscodor albus* Strain QST 20799, when it is used as labeled.

During production of the first five batches of this new active ingredient, the following standard confirmatory data are required to ascertain nominal limits and that adequate Quality Assurance and Quality Control procedures are in place. Analysis of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of unintentional ingredients and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. Submit results of batch analyses as each batch is produced. All batches containing human pathogens and unintentional ingredients above regulatory levels must be destroyed.

All pesticides containing the active ingredient *Muscodor albus* Strain QST 20799 that also contain unintentional ingredients, metabolites and contaminants above regulatory levels must be destroyed.

As conditions of registration, the following confirmatory data are required:
(i) an acute inhalation study in rodents is required at 1000 times the expected exposure level of a combination of the volatiles to confirm the preliminary assessment that the volatiles produced on rehydration of the pesticide do not pose an occupational inhalation risk;
(ii) storage stability data to confirm that the reports submitted in MRIDs 46039401 and 46038601demonstrate the claim that the product is EP is stable for 1 year.

E. Regulatory History

Experimental Use and Temporary Tolerance Exemption

Not applicable.

Section 3. Registration and Exemption from tolerance

Section 3(c) Registration

EPA received applications from AgraQuest, Inc., 1530 Drew Avenue, Davis, CA 95616 on July 15, 2003, to register *M. albus* Strain QST 20799 as a new active ingredient and Arabesque™ as a new end use product containing *M. albus* Strain QST 20799. Following consultation with the Agency, AgraQuest decided to split the original registration application into three separate End-use Product registration applications. The revised application for Arabesque™, Andante™ and Glissade™ as new end use products was submitted on January 13, 2004. When the application packages were deemed complete, notice of receipt of the applications for *M. albus* Strain QST 20799 as a new active ingredient and for Arabesque™, Andante™, and Glissade™ as new end use products containing *M. albus* Strain QST 20799 was published in the Federal Register (FR: April 14, 2004, Vol. 69, No. 72, page 19845-19847, FRL-7352-7). No comments were received on this notice of receipt of application to register *M. albus* Strain QST 20799 and Glissade™, Arabesque™, and Andante™ during the 30 day comment period. This BRAD summarizes data and information reviewed in support of the application and concludes that the

pesticide is eligible for a conditional registration. The conditions of registration to be submitted by the registrant within eighteen (18) months of registration are:

(i) an acute inhalation study in rodents is required at 1000 times the expected exposure level of a combination of the volatiles to confirm the preliminary assessment that the volatiles produced on rehydration of the pesticide do not pose an occupational inhalation risk;

(ii) storage stability data to confirm that the reports submitted in MRIDs 46039401 and 46038601demonstrate the claim that the product is EP is stable for 1 year.

Exemption from Tolerance

Concomitant with the application for the Section 3(c) registration, the registrant filed a petition (PP # 3F6745) requesting a permanent exemption from the requirement of a tolerance for the active ingredient, *Muscodor albus* Strain QST 20799, in or on all food commodities. A notice of filing of this petition was published in the Federal Register [FR: April 7, 2004, Vol. 69, No. 67, page 18370-18375, FRL-7349-4]. No comments were received during the 30 day comment period following this publication.

The remainder of this document and the Final Rule to be published simultaneously with this decision summarize the Agency's review and consideration of the tolerance exemption and registration requests. The low toxicity potential (as demonstrated in the acute oral studies) and the potential dietary exposure and risk are discussed below (Section III.B). The submitted data and information support an exemption from the requirement of a tolerance for residues of *M. albus* Strain QST 20799 and its end-use products, Andante™, Arabesque™, and Glissade™, on food commodities.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

The data submitted in support of product identity requirements for *M. albus* Strain QST 20799 are sufficient for the proposed use patterns of the microbial pesticide.

1. Product Identity and Mode of Action

Product Identity

Technical Grade Active Ingredient

Muscodor albus Strain QST 20799 is a naturally-occurring endophytic fungus that was originally isolated from the bark of a cinnamon tree in Honduras. It was identified as a new genus and species taxonomically related to the *Xylariaceae*, based on similarity of the 18S rDNA sequences. *M. albus* QST 20799 is in the class *Pyrenomycetes* (*Ascomycetes*) and on deposit at the National Regional Research Laboratory as NRRL 30547. It grows as a white sterile mycelium and does not produce asexual or sexual spores or other structures such as chlamydospores or sclerotia. *M. albus* Strain QST 20799 will be the active ingredient in a manufacturing use product used to produce:

a) end-use products for soil or seed or propagule treatment to control root diseases in greenhouse and field crops,

and b) an end-use product to control post-harvest decay in fresh fruits and vegetables and cut flowers.

The TGAI is manufactured under aseptic conditions. Microbial contamination is monitored by human pathogen tests and contaminant analysis. Additionally, the well water used to manufacture the TGAI is to be tested on a regular basis for human pathogens and other contaminants. Results of analysis of five batches of the manufacturing use product for *Streptococcus* spp., *Staphylococcus aureus*, *Salmonella* spp., *Shigella* spp., *Vibrio cholerae*, yeast, *E. coli*, and coliforms were within the maximum allowable levels (either negative or <10 cfu/g) (MRID 46039401, BPPD DER dated 04/28/04, cover memo from Ibrahm Barsoum, USEPA to Shanaz Bacchus, USEPA dated 10/14/04).

End Use Products

The end use products contain *M. albus* Strain QST 20799 along with inert ingredients which provide a solid carrier/nutrient source. The inerts are exempt from the requirement of a tolerance under 40 CFR 180.950(a). Tables IIIa and IIIb summarize the product characterization studies evaluated in support of this conditional registration decision. Studies to characterize the end use products (MRIDs 46038601, 46173101, 46173301, and 46173401) reviewed in 2004 were considered unacceptable but upgradable pending submission of additional information regarding the active and inert ingredient contents, preliminary analysis, unintentional impurities, storage stability, and corrosion characteristics (BPPD DER 04/28/04). Subsequent submissions

upgraded these data requirements to acceptable (BPPD DER 06/ /05). Manufacture of the EPs must meet the requirements of Occupational Safety and Health Administration (OSHA) and all other relevant manufacturing regulations.

Mode of Action

When it is hydrated, *M. albus* Strain QST 20799 produces a number of volatiles, mainly alcohols, acids, and esters, that inhibit and kill plant pathogenic organisms that cause diseases such as root rot, damping off, and wilt. The antifungal activity is associated with the production of ethyl propionate, isobutyl alcohol , 2-methylbutyl acetate , isoamyl isobutyrate , 2-methyl-1-butanol, isobutyric acid, phenethyl alcohol. The volatiles produced by *M. albus* Strain QST 20799 have a fungicidal rather than fungistatic action. Both vegetative hyphae and spores of plant pathogenic fungi are killed. The volatiles are also bactericidal against vegetative bacterial cells. The activity is believed to be due to disruption of cell membrane functions.

2. Physical and Chemical Properties Assessment

The physical and chemical properties of the Technical Grade Active Ingredient are summarized in Tables IIIa and IIIb. The TGAI or MP is maufactured by a liquid fermentation process. The inert is added to manufacture the EP, which is subsequently dried and shipped. At this time the three EPs use the same inert, but are labeled with different names and use directions to fit with different market segments and use sites.

TABLE IIIa: Product Identity & Manufacturing Process for *M. albus* Strain QST 20799 (TGAI/MP)*, Andante™ (EP), Arabesque™ (EP), and Glissade™ (EP).**

Guideline	Study	Result	MRID #
151-10 ***885.1100	Product Identity	Acceptable for *M. albus* Strain QST 20799*, Arabesque™, Andante™ and Glissade™**.	46039401 46038601 46173401
151-11 ***885.1200	Manufacturing Process	Acceptable for *M. albus* Strain QST 20799*. Acceptable for Arabesque™, Andante™ and Glissade™**	46039401 46038601
151-12 ***885.1300	Discussion of Formation of Unintentional Ingredients	Acceptable for *M. albus* Strain QST 20799. Acceptable for Arabesque™, Andante™, and Glissade™	46039401 46038601 Add new MRID
151-13 *885.1400	Analysis of Samples	Acceptable for *M. albus* Strain QST 20799*. Not required for commodities treated with Arabesque™, Andante™, or Glissade™, because of exemption from the requirement of a tolerance**.	46039402 46038601
151-15 *885.1500	Certification of limits	Acceptable for *M. albus* Strain QST 20799*, Arabesque™, Andante™, and Glissade™**.	46172701 46173301 46173401
151-16	Analytical Method	Acceptable for *M. albus* Strain QST 20799*, Arabesque™, Andante™, and Glissade™**.	46039401 46039402 46038601

***M. albus* Strain QST 20799 (TGAI/MP),** ** Arabesque™, Andante™, and Glissade™ (EPs)
***OPPTS Harmonized Guidelines

TABLE IIIb: Physical & Chemical Properties of *M. albus* Strain QST 20799 (TGAI) and Arabesque™ (EP)					
Physical/Chemical Properties**					
Guideline	**Property**	***M. albus* Strain QST 20799 TGAI/MP**	**MRID #**	**Arabesque™ EP Andante Glissade**	**MRID # for 3 EPs**
63-2 *830.6302	Color	Cream	46039401	Light brown	46038601
63-3 *830.6303	Physical state	Liquid	46039401	Solid granules	46038601
63-4 *830.6304	Odor	Mild, earthy	46039401	Mild, earthy	46038601
63-13 *830.6313	Stability	Stable for approximately 2 weeks at normal temperature; unstable at elevated temperature; no reaction to metals or metal ions.	46039401	Stable one year. Data supporting this claim required.	46038601
63-17 *830.6317	Storage Stability	See stability above. TGAI is not stored, but used immediately for manufacture of EP.	46039401	Stable one year. Data supporting this claim required.	46038601
63-20 *830.6320	Corrosion characteristics	See Stability and storage stability above for manufacture. Not shipped.		Not corrosive in original packaging	46038601
63-12 *830.7000	pH	3.7 (Not shipped)	46039401	Not applicable	
63-2 *830.7100	Viscosity	100 cP	46039401	Not applicable	
63-6 *8307300	Boiling point	100°C	46039401	Not required	
63-7 *830.7300	Density/specific gravity	8.4 lbs/gal	46039401	28 lbs/ft^3	46038601
*830.7370	Dissociation Constant in water		46039401?		46173401? 46173101 46038601?
*830.7520	Particle size	Not applicable		8-200 mesh	46038601
*830.7840 *830.7840	Water solubility (shake flask & generator column method)		46039401 46173101	NA**	46173101 46038601
830.7950	Vapor pressure	NA	46039401 46173101	NA**	46173401 46173101
	Solubility	NA	46039401 46173101	NA**	46173401 46173101
830.7550-830.7570	Partition Coefficient	NA		NA**	46173401 46173101

*OPPTS Harmonized Test Guidelines

**Guideline data requirements (40 CFR §158.740(a)) for melting point, boiling point, solubility, *vapor pressure, dissociation constant, octanol/water partition coefficient, oxidizing or reducing potential, flammability/flash point, explodability, miscibility, and dielectric breakdown voltage were not required because of the nature of the microbial pesticide.*

B. Human Health Assessment

1. Food Clearances/Tolerances

An exemption from tolerance for *M. albus* Strain QST 20799 is being established with this eligibility for a conditional registration of the pesticide for use on all food commodities.

There is reasonable certainty that no harm will result from dietary exposure to products treated with *M. albus* QST Strain 20799. This includes all anticipated dietary exposures and all other exposures for which there is reliable information, as long as the pesticide is used according to label directions. Below is the toxicology assessment (Section III.B.2) and discussion of other factors which led to this conclusion (Sections III.B.3-IIIB.9).

2. Toxicology Assessment

Summaries of the acute toxicological studies (Table 2a) and the rationales for certain data waiver requests (Table 2b) are discussed below.

a. Acute Oral Toxicity/Pathogenicity (MRID 46106401, OPPTS 870.1100; MRID 46039404, OPPTS 885.3050)

Two studies were submitted. In an acute oral toxicity study (MRID 4616401), young adult rats (3/sex) were fasted overnight and received a single gavage dose of 5000 mg/kg CP011 (QST 20799) in distilled water. Body weight was recorded prior to dosing, shortly after dosing, and weekly thereafter. Animals were observed for mortality and clinical signs of toxicity twice daily for 14 days after treatment. There were no mortalities or gross abnormalities at necropsy. With the exception of one male that had soft feces at one and four hours after dosing, no clinical signs of toxicity were noted during the study. The male and female oral LD_{50} was >5000 mg/kg (Toxicity Category IV). This study was considered **ACCEPTABLE**.

An acute oral toxicity/pathogenicity study was conducted with *Muscodor albus* QST 20799 (MRID 46039404). Young adult rats (22/sex) were divided into the following groups:
Groups 1-4 = Treated groups, all received total treatment of 0.1 g dry weight (1×10^8 cfu/rat).
Group 5 = Controls treated with autoclaved test material
Group 6 = Untreated shelf control held in same room as the treated groups
Group 7 = Untreated non-shelf control held in a separate room.

All groups were fasted overnight. The test material was administered by oral gavage in two doses approximately two hours apart. Body weight was recorded prior to dosing and on days 4, 8, 15, and 22. The rats were observed for clinical signs of toxicity hourly after dosing and twice on subsequent days. Fecal samples from group 4 rats were collected on days 4, 8, 15, and 22. Animals were sacrificed at specific intervals and necropsied in the order of non-shelf then shelf controls followed by the treated groups. Recovery of viable *M. albus* Strain QST 20799 from the blood, organs, intestinal contents, and feces was determined by serial ten-fold dilutions with

sterile phosphate buffered saline and plating on potato dextrose agar, followed by incubation at 27±2 °C for five to seven days.

All animals gained weight during the study and there were no unscheduled deaths. No clinical signs of toxicity were observed, and no abnormal findings were noted at any necropsy interval. *M. albus* Strain QST 20799 was not detected in any organ or blood sample. The test organisms in the intestinal contents and feces were less than 1000 cfu/g, the detection limit. Based on the presented/submitted data, the test organism was not toxic, infective, or pathogenic to rats by oral administration. However, there was no confirmation of the dosing effect since the TGAI was not recovered from any organs at all. The study was classified as **ACCEPTABLE**. No further study is required for this data requirement at this time.

TABLE IIIc: Tier I Studies Evaluated - Acute Mammalian Toxicity of *Muscodor albus* QST 20799

Guideline	Study	Toxicity Category	Results	MRID #
81-1 *870.1100	Acute oral toxicity	IV	LD_{50} >5000 mg/kg. No mortality. One male had soft feces at one and four hours post-dose. **Acceptable for TGAI or MP.**	46106401
152-10 *885.3050	Acute oral toxicity/ pathogenicity	IV	No mortality or adverse clinical signs were observed, and no abnormal findings were noted at any necropsy interval in test with 22 male and 22 female rats treated with 1 x 10^8 cfu/rat. No test organisms were found in any organ or blood. Test organisms in the intestinal contents and feces were <1000 cfu/g, the detection limit. **Acceptable for TGAI or MP.**	46039404
152-32 *885.3150	Acute pulmonary toxicity	NA	No treatment-related mortality or evidence of pathogenicity in rats in the 22-day study. No test organisms were detected in blood, organs, intestinal contents, or feces. **Acceptable for TGAI or MP.**	46039406
152-11 *870.1200	Acute dermal toxicity	IV	No mortality or adverse clinical signs were observed, and no dermal irritation was seen. The LD_{50} was >2 mg/kg. **Acceptable for TGAI or MP.**	46106402
*870.2400	Acute eye irritation	IV	No mortality, corneal opacity, iritis, or positive conjunctival irritation were noted. **Acceptable for TGAI or MP.**	46039407

* OPPTS Guideline Numbers.

b. Acute Pulmonary Toxicity/Pathogenicity (MRID 46039406; OPPTS 885.3150)

In a 22-day acute pulmonary toxicity/pathogenicity study, young adult rats (29/sex) were divided into the following groups:

Groups 1-5 = Treated groups, each received total treatment of 1.9 x 10^3 to 2.4 x 10^3 cfu/rat.
Group 6 = Controls treated with autoclaved test material
Group 7 = Untreated shelf control held in same room as the treated groups

A suspension of *Muscodor albus* QST 20799 was administered in a single dose by intratracheal instillation. Body weights were recorded on days 1,4, 8, 15, and 22 or at death. The rats were observed for clinical signs of toxicity hourly after dosing and twice/day on subsequent days. Fecal samples from group 5 rats were collected on days 4, 8, 15, and 22. Animals were sacrificed at specific intervals and necropsied. Recovery of viable *Muscodor albus* QST 20799 from the blood, organs, intestinal contents, and feces was determined by serial ten-fold dilutions with sterile phosphate buffered saline and plating on potato dextrose agar, followed by incubation at 27±2°C for five to seven days.

All animals gained weight during the study. One group 4 female died two hours after dosing, one group 5 female was found dead on day 2, and one group 5 male was sacrificed on day 4 due to severity of clinical signs. These deaths were likely due to the dosing procedure. All other rats survived to scheduled sacrifice. There were no test organism-related body weight changes. Clinical signs in a few animals were related to the dosing method. No mortality or clinical signs were seen in the control group that was inoculated with the killed organisms. *Muscodor albus* QST 20799 was not found in any of the samples. Based on the data, the test organism was not toxic, infective, or pathogenic to rats. This study was considered **ACCEPTABLE**. No further study is required for this data requirement at this time.

c. Acute Dermal Toxicity (MRID 46106402; OPPTS 870.1200)

Muscodor albus QST 20799 (2 ml/kg) was applied to the clipped dorsal-lumbar region of rabbits (5/sex) and the application sites were covered for 24 hours, after which the dressings and any excess test substance were removed. Rabbits were checked for clinical signs hourly post-treatment and for survival and clinical signs twice daily thereafter for 14 days. Body weight was recorded on days 1, 8, and 15. The Draize method was used to rate skin irritation. On day 15, the rabbits were euthanized and gross necropsies were performed.

No rabbits died during the study, and all animals gained weight overall. No clinical signs of toxicity were observed during the study, and no dermal irritation was noted on any animal. No treatment-related findings were seen at gross necropsy. The acute lethal dose (LD_{50}) was >2 ml/kg equivalent to 2g/kg body weight. The TGAI is considered Toxicity Category IV for acute dermal effects. Pathogenicity was not addressed in this study. This study was considered **ACCEPTABLE**. No further study is required for this data requirement at this time.

d. Acute Eye Irritation (MRID 46039407; OPPTS 870.2400)

QST 20799 (0.1 ml/eye) was instilled into the conjunctival sac of one eye of three female rabbits; the other eye served as a control. Eyes were examined and scored 1, 24, 48, and 72 hours after test material instillation. No animals died during the study. No corneal opacity, iritis, or positive conjunctival irritation was noted on any rabbit during the study. One rabbit had slight conjunctival irritation (score 1) one hour after dosing with recovery by 24 hours. The maximum average score was 2.0 one hour after test material instillation. The test material was practically non-irritating and the TGAI considered Toxicity Category IV for acute ocular effects . The study

was considered **ACCEPTABLE**. No further study is required for this data requirement at this time.

e. Data Waiver Requests: Health Effects

1. Requests to waive data for the TGAI/MP:

The results of the preceding acute toxicology tests and other rationales were submitted in the registrant's requests to waive data for the following tests for the TGAI/MP:

i. Acute Inhalation (Guideline 152-32; OPPTS 870.1300)
ii. Acute Intravenous (IV), Intracerebral (IC), Intraperitoneal (IP) injection Toxicity/Pathogenicity (Guideline 152-33; OPPTS 885.3200)
iii. Cell Culture (Guideline 152.39; OPPTS 885.3500)
iv. Hypersensitivity Study (Guideline 152-36)
v. Hypersensitivity Incidents (Guideline 152-37; OPPTS 870.3400)
vi. Immune Response (Guideline 152-38; OPPTS 885.3800)

(i) Acute Inhalation Toxicity/Pathogenicity (Guideline 152-32; OPPTS 870.1300)

The registrant cited the acute pulmonary toxicity/pathogenicity study (see Unit III.3, above) to justify waiving the acute inhalation study. In that study the active ingredient cleared tissues and was not toxic, infective, or pathogenic to rats when instilled intratracheally. In addition, the registrant's argument that the exposure during formulations of the granular EPs from the MP justifies granting this request to waive acute inhalation data requirements for the MP.

Nevertheless, because of the fungal nature of the active ingredient, to mitigate against potential worker inhalation risk, the Agency is requiring labeling to include a dust/mist filtering respirator with a NIOSH prefix N-95, R-95 or P-95 for workers who manufacture EPs from the MP. Manufacture of the EPs must meet the requirements of Occupational Safety and Health Administration (OSHA) and all other relevant manufacturing regulations.

Volatiles, produced on rehydration of the EPs, are well-known, naturally occurring food fragrances, flavors or solvents. For a discussion of these volatiles, see **Acute inhalation** in the section below for the EPs. The Agency has decided that they do not pose a dietary risk via inhalation, and has required labeling to protect against potential worker exposure. An acute inhalation rodent test is required as a condition of registration to confirm this preliminary assessment regarding occupational exposure.

(ii) Acute IV/IP/IC study (Guideline 152-33; OPPTS 885.3200)

As discussed above, in an acute oral toxicity/pathogenicity study with the TGAI, no clinical signs of toxicity were observed in rats and no viable *M. albus* Strain QST 20799 was recovered from blood, organs, or intestinal contents. Data from the registrant's in-house study show that *M. albus* is not viable at temperatures of 34°C and above, and, therefore, would not be expected to survive at mammalian body temperatures. Based on low toxicity potential indicated by these observations, **the Agency granted the request to waive the acute IP study.**

(iii) Cell culture (Guideline 152.39; OPPTS 885.3500)

This study is required for viruses and is not required for a fungal active ingredient such as *M. albus* Strain QST 20799. **The request to waive this data requirement is granted**.

(iv) Hypersensitivity Study (Guideline 152-36)

No incidents of hypersensitivity have occurred during the research, development, or testing of *M. albus* QST 20799 or the Arabesque™ end product. A hypersensitivity study is not required at this time, but may be required in the future if there are reports of hypersensitivity incidents associated with this active ingredient used in pesticides.

(v) Hypersensitivity Incidents (Guideline 152-37; OPPTS 870.3400)

The registrant requested to waive reports of hypersensitivity incidents, because no incidents of hypersensitivity associated with the TGAI or proposed components of the EP have been reported to date. However, the registrant agreed to report hypersensitivity incidents, should they occur in the future. This guideline requirement is satisfied at this time. In order to comply with FIFRA requirements under Section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency. **This data requirement is not waived.**

(vi) Immune response (Guideline 152-38; OPPTS 885.3800)

The lack of pathogenicity seen in the acute oral toxicity/pathogenicity study with the TGAI indicates the immune system was not adversely affected by *M. albus* QST 20799. Based on these considerations, **the justifications to support the request to waive data requirements for the immune response studies for the TGAI/MP are acceptable.**

Table IIId. Data waiver requests for *Muscodor albus* QST 20799 (TGAI/MP)

Guideline	Study	Toxicity Category	Results	MRID #
*870-1300	Acute inhalation	IV	Acute pulmonary supports waiver. However, need confirmatory data on inhalation effects of volatiles as a condition of registration for EPs.	46039406 46552603
152-32 *885.3200	Acute IV/IP/IC	NA	Acute oral, dermal and pulmonary studies with active ingredient indicate no toxicity/pathogenicity; and clearance from blood, organs and intestinal contents. **Waived for TGAI/MP**	46106401 46039404
152-39 *885.3500	Cell culture	NA	Not required for fungal active ingredient	NA
152-36 *885.3400	Hypersensitivity Study	NA	No reports of hypersensitivity incidents. **Waived for TGAI/MP**	NA
152-37 *885.3400	Hypersensitivity Incidents	NA	No reports of hypersensitivity incidents. Reports are required to comply with FIFRA Section 6(a)(2). **Not waived for TGAI/MP**	NA
152-38 *885.3800	Immune Response	NA	Acute oral, dermal and pulmonary studies with active ingredient indicate no toxicity/pathogenicity; and clearance from blood, organs and intestinal contents. Immune system not adversely affected. **Waived for TGAI/MP**	46106401 46039404 46039406 46106402

*OPPTS Harmonized Guideline Numbers.

2. Requests to waive data for the EPS:

Based on the submissions for the acute toxicology for the TGAI/MP, the registrant also requested that the Agency waive the studies for the following data requirements for the **EPS**:

i. Acute Oral Toxicity (OPPTS 870.100)
ii. Acute Inhalation (Guideline 152-32; OPPTS 870.1300)
iii. Acute Dermal Toxicity (OPPTS 870.1200)
iv. Primary Dermal Irritation (OPPTS 870.2500)
v. Dermal Sensitization (OPPTS 870.2600)
vi. Primary Eye Irritation (OPPTS 870.2400)
iii. Hypersensitivity Study (Guideline 152-36)
vi. Hypersensitivity Incidents (Guideline 152-37; OPPTS 885.3400)

(i) Acute Oral (OPPTS 870.100)

In an acute oral toxicity/pathogenicity study (see Section III.B.2.a), the active ingredient was not toxic, infective, or pathogenic to rats. The Arabesque™ EP contains a lower concentration of the active ingredient (0.35% w/w) than does the MP (2.1%), and all the inert ingredients are commonly-consumed food grade commodities on List 4A that are exempt from the requirement of a tolerance under 40 CFR 180.950(a).

When the EPs containing *Muscodor albus* QST 20799 are rehydrated, it produces volatiles. Generally, an acute oral test is not required when the test material is volatile. Nevertheless, the Agency considered the patterns of use, and the nature of the volatiles produced under these conditions. *M. albus* QST 20799 and its volatiles are not expected to be present in/on treated food commodities as a result of these proposed uses. The pesticide is incorporated into soil prior to planting, is not viable in soil once its food source is exhausted, and is not in direct contact with treated seed or propagules or food or feed commodities treated post harvest. It is not a systemic pesticide and, thus, will not be translocated in seed or propagules or other treated food and feed commodities. The volatiles are well-known fragrances and flavors of food and beverages, are short-lived, and are not expected to remain on treated food or feed commodities. Thus, acute oral tests, as conducted with the aqueous suspension of the TGAI, *Muscodor albus* QST 20799, are sufficient to support the request to waive data for this guideline for the EP. **This data waiver request is granted.**

ii. Acute Inhalation (Guideline 152-32; OPPTS 870.1300)

An acute pulmonary toxicity/pathogenicity study (see Section III.B.2.b) found the active ingredient was not toxic, infective, or pathogenic to rats. However, the Agency did consider that exposure to all the volatiles produced during rehydration of the pesticide was not fully addressed.

For product characterization, and to establish that pesticide residues do not accumulate on treated commodities, the registrant provided data to the Agency about potential volatiles produced during rehydration of the active ingredient in a pesticide EP, Arabesque™. These volatiles occur naturally in food products, and are used as fragrances, flavoring agents or as solvents (BPPD DER 06/ / 05). In the chromatograms, the volatiles were identified as seven (7) peaks (pk) 1, 2, 3, 4, 6, 10 and 11:

(Pk 1) Ethyl propionate in wine, white grapes and, cocoa;
(Pk 2) Isobutyl alcohol in food and beverages;

(Pk 3) 2-Methylbutyl acetate in apples;

(Pk 4) Isoamyl isobutyrate in honey, hop oil and whiskey;

(Pk 6) 2-Methyl-1-butanol in wine, kiwi, apples and alcoholic beverages. It is a volatile component of blue cheese aroma, concord grape juice essence, nectarines, apples, papaya fruit, oranges, tomatoes and is released in the volatile emissions from poultry manure.

(Pk 10) Isobutyric acid in cheese, fruits, vinegar and alcoholic beverages;

(Pk 11) Phenethyl alcohol in foods such as olive oil, grapes, tea, apple juice, coffee, and alcoholic beverages (BPPD DER 06/ /05).

At room temperature a 10 gram sample of the EP, Arabesque, rehydrated 1:1 with water, produced low concentrations of the volatiles ranging from 0.15 ppb for 2-Methylbutyl acetate and Isoamyl isobutyrate to 20.5 ppb for Isobutyric acid. The inhalation LC_{50} was reported from published literature for most of the volatiles and found to be within acceptable threshold levels. Volatiles dissipating from the rehydrated pesticide are well below those reported inhalation LC_{50} values. All the volatiles are reported as naturally occurring in foods as fragrances and flavors, and they dissipate shortly after rehydration, without compromising efficacy in the time required for storage or other treatments related to proposed agricultural practices. However, the inhalation LC_{50} was not reported for ethyl propionate, 2-methylbutyl acetate, and isoamyl isobutyrate. The Agency has decided that the exposure to these substances will not pose a dietary risk via inhalation, because they are short-lived, well-characterized flavors and fragrances which occur naturally in consumed food and feed commodities.

However, to confirm the preliminary assessment that the volatiles produced on rehydration do not pose a worker inhalation exposure risk, the Agency is requiring an acute inhalation test in rats. The rodents are to be exposed through the nose to a mixture of all the volatiles produced on pesticide rehydration. The test material is to be administered at 1000 times the concentration of the expected exposure level.

In the meanwhile, to mitigate against potential worker inhalation risk, the Agency required labeling to include a dust/mist filtering respirator with a NIOSH prefix N-95, R-95 or P-95 for all applicators and handlers.

iii. Acute Dermal Toxicity (OPPTS 870.1200)*
iv. Primary Dermal Irritation (OPPTS 870.2500)
v. Dermal Sensitization (OPPTS 870.2600)

*An acceptable acute dermal study (LD_{50} >2 ml/kg equivalent to 2g/kg body weight) was conducted for the TGAI/MP. The acute dermal LD_{50} is >2g/kg, and the pesticide is considered Toxicity Category IV for acute dermal effects. The proposed EP label has the corresponding dermal First Aid, Precautionary Statements, and PPE for a Toxicity Category IV product.

vi. Primary Eye Irritation (OPPTS 870.2400)

A primary eye irritation study (see Section III.B.2.d) showed that the active ingredient produced minimal irritation that cleared in 24 hours (Toxicity Category IV). This placed the TGAI in Toxicity Category IV for acute ocular effects. The EPs contain a lower concentration of the active ingredient (0.35%) than does the TGAI/MP (2.1%). The inert ingredients in the EPs are

commonly consumed food commodities considered to be of minimum risk (List 4A) and are exempt from the requirement of a tolerance.

The EP is to be applied as a soil mix or post-harvest additive, not as a foliar spray. Nevertheless, because of the granular nature of the pesticide goggles are required for eye protection. Based on these considerations, the justifications to support the request to waive data requirements for primary eye irritation are acceptable.

TABLE IIId: Tier I - Data Waivers for Acute Mammalian Toxicity for EPs Arabesque™, Andante™ and Glissade™ containing *M. albus* Strain QST 20799

Guideline	Study	Comments	MRID No.	Status**
*870.11	Acute oral toxicity	Acute oral toxicity study with *M. albus* QST 20799 found LD_{50} >5000 mg/kg bw. **Acceptable for TGAI or MP**. **Justifiable rationale to waive study for EP.**	46106401	**Waived**
		In acute oral study **Acceptable for TGAI or MP**, no mortality or adverse clinical signs were observed, and no abnormal findings were noted at any necropsy interval. Study was conducted with 22 male and 22 female rats treated with 1 x 10^8 cfu/rat. No test organisms were found in any organ or blood. Test organisms in the intestinal contents and feces were <1000 cfu/g, the detection limit. **Waived for EPs for proposed uses.**	46039404	
*870.13	Acute inhalation toxicity	Acute pulmonary toxicity/pathogenicity study with active ingredient found no toxicity, infectivity, or pathogenicity. EP label requires dist/mist respirator for handlers/applicators. **Confirmatory data required for inhalation effects of volatiles from rehydrated EPs.**	46039406	**Waived**
152-31 *885.3100 **152-34** *870.2500 **152-36** *870.2600	Acute dermal toxicity Primary dermal irritation Dermal sensitization	Acute dermal toxicity/pathogenicity study with active ingredient found no clinical toxicity (LD_{50} > 2 ml/kg equivalent to 2g/kg bw) or dermal irritation. EP label has dermal first aid, precautionary statements and PPE for Toxicity Category IV product. **Waived for EPs**.	46106402	**Waived**
152-35 *870.2400	Primary eye irritation	Primary eye irritation study with active ingredient found minimal irritation which cleared within 24 hrs. **Waived for EPs.**	46039407	**Waived**
152-36 *885.3400	Hypersensitivity Study	Acceptable report of no hypersensitivity incidents. **Waived for TGAI/MP, EPs**.		**Waived**
152-37 *885.3400	Hypersensitivity Incidents	EPA requires reports of adverse effects and hypersensitivity incidents to comply with 6(a)(2) 40 CFR 159.152. **This data requirement is not waived.**		**Must be submitted if incidents occur**

**OPPTS Harmonized Guideline Numbers.
** Status for EPs, Arabesque™, Andante™ and Glissade™. Inerts of other EPs will be reassessed on case-by-case basis.

vi. Hypersensitivity Incidents (Guideline 152-37; OPPTS 885.3400)
No incidents of hypersensitivity have occurred during the research, development, or testing of *M. albus* Strain QST 20799 or the Arabesque™ end product. However, in the future and in order to comply with FIFRA requirements under Section 6(a)(2), any incident of hypersensitivity associated with the use of this pesticide must be reported to the Agency.

Summary

Based on these considerations, the justifications to support the request to waive data requirements for the EPs, Arabesque™, Andante™ and Glissade™ were acceptable**.** for acute oral toxicity (OPPTS 870.100), acute dermal toxicity (OPPTS 870.1200), acute inhalation toxicity (OPPTS 870.1300), primary dermal irritation (OPPTS 870.2500), dermal sensitization (OPPTS 870.2600), and a hypersensitivity study (OPPTS 885.3400)**. The request to waive data requirements for hypersensitivity incident reports is not granted.** All hypersensitivity incidents must be reported as required to comply with FIFRA Section 6(a)(2). Requests to amend registration for other EPs will be reassessed on case-by-case basis to consider the toxicological effects of the inerts.

g. Subchronic, Chronic Toxicity and Oncogenicity

Based on the data generated in accordance with the Tier I data requirements (40 CFR §158.740(c)), Tier II tests (Guidelines 152B-40 through 152B-49) involving acute oral, acute inhalation, subchronic oral, acute intraperitoneal or intracerebral or intravenous, primary dermal, primary eye, immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity were not required. As a result, Tier III tests (Guidelines 152-50 through 53) involving chronic testing, oncogenicity testing, mutagenicity, and teratogenicity also were not required.

h. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of this active ingredient, *Muscodor albus* Strain QST 20799, at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine

effects. There is no known metabolite that acts as an "endocrine disrupter" produced by this microorganism. The submitted toxicity/pathogenicity studies in the rodent (required for microbial pesticides) indicate that following acute oral, dermal, and pulmonary toxicity/pathogenicity studies, the immune system is still intact and able to process and clear the active ingredient. In addition, based on the low potential exposure level associated with the proposed use of this pesticide, the Agency expects no incremental adverse effects to the endocrine or immune systems.

3. Dietary Exposure and Risk Characterization (includes drinking water)

Dietary Exposure

The proposed food use pattern is not likely to result in dietary exposure or residues on food and feed. *M. albus* Strain QST 20799 is to be used as a pre-plant biofumigant incorporated into soil prior to planting or as a postharvest biofumigant in enclosed containers. Due to the poor survivability of the fungus in soil, dietary exposure from pre-harvest agricultural applications is not anticipated. The postharvest treatment does not involve contact between the fungus and the fruits or vegetables being treated, therefore no residues are expected. Furthermore, the active ingredient is not a systemic pesticide. Thus, detectable residues of *Muscodor albus* QST 20799, the microbe, are not expected in/on treated seed or propagules or food or feed commodities.

The volatile compounds produced by the active ingredient dissipate rapidly in soil and water. Furthermore, these volatile compounds occur naturally in several food commodities as flavors and fragrances. Hence, they are not expected to be present on treated seed or propagules, food or feed, solely as a result of treatment with this pesticide. Since they dissipate rapidly and do not adhere to treated commodities, detectable residues are not expected when food or feed commodities are treated. In addition, should any possible residue occur on treated commodities, it can be easily removed by washing, peeling, cooking, or processing.

Finally, as discussed in the Toxicology Assessment above, the acute oral tests demonstrate low toxicity potential via dietary exposure to this Toxicity Category IV pesticide. Hence, even if the pesticide was present in/on food commodities, exposure via the dietary route is not expected to cause any harm. Because of its low acute toxicity and no reported cases of disease or injury in the literature, the dietary risk posed by *Muscodor albus* QST 20799 and its volatiles to adults, infants, and children is anticipated to be minimal. Dietary exposure via drinking water, as presented below (see Section 5), is not likely to have any adverse effects on adult humans, infant and children.

Therefore, the Agency has determined that dietary exposure (including consumption of drinking water) to *Muscodor albus* Strain QST 20799 and its volatiles is not likely to cause harm to US adult humans, infant and children.

4. Occupational and Residential Exposure and Risk Characterization

a. Non-occupational Residential, School and Day Care Exposure and Risk Characterization

Non-occupational dermal and inhalation exposure is not likely, since the use sites are commercial and agricultural. Pesticide drift is expected to be minimal, since the EP is

incorporated into the soil for pre-planting treatment, or is used in enclosed containers for post-harvest treatment. Soil survivability of *M. albus* Strain QST 20799 is poor, and it has no spores or resting structure. The volatile compounds produced by *M. albus* Strain QST 20799 dissipate rapidly in the environment. The acute pulmonary toxicity study demonstrated no treatment-related adverse effects when the active ingredient was instilled into rats intratracheally. No hypersensitivity incidents have been reported for either the TGAI/MP or EP.

b. Occupational Exposure and Risk

Occupational exposure should be minimal if the end use product is used as labeled. Pesticide drift is expected to be minimal, since the EP is incorporated into the soil for pre-planting treatment, or is used in enclosed containers for post-harvest treatment. Dermal exposure via the skin would be the primary route of exposure for mixer/loader applicators, but this can be minimized by use of the appropriate PPE. PPE for pesticide handlers and applicators includes a long-sleeved shirt, long pants, waterproof gloves, and shoes plus socks. Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting the NIOSH standards of at least –95, R-95, or P-95. There is a restricted entry interval of zero (0) hours for incorporation into growing media when used in enclosed environments. No hypersensitivity incidents have been reported for either the TGAI/MP or EP.

5. Drinking Water Exposure and Risk Characterization

Exposure to *M. albus* Strain QST 20799 via drinking water is unlikely. Since *M. albus* Strain QST 20799 occurs as a sterile mycelium and has no spores or resting structure, it is unlikely to be capable of substantial growth in soil after its food base in the product has been exhausted. Thus, transfer of *M. albus* Strain QST 20799 from soil to groundwater is unlikely. Even if such a transfer were to occur, the fungus would not tolerate the conditions drinking water treatment would provide, e.g., chlorination, pH adjustments, high temperatures, and/or other water treatment conditions. Thus, exposure from the proposed use of *M. albus* Strain QST 20799 and its volatiles is not likely to adversely affect adult humans, infants or children via drinking water.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

Results from Tier I studies did not trigger Tier II subchronic or Tier III chronic dietary exposure studies. Based on the submitted studies, the TGAI demonstrates low acute oral toxicity potential, and was classified as Toxicity Category IV for acute oral effects. Residues of the active ingredient are not expected on food or feed items because the active ingredient will not be in direct contact with the treated commodities. Standard practices of washing, peeling, cooking, or processing treated fruits and vegetables would further reduce any possible active ingredient residues. The volatile organic compounds produced by the active ingredient have been shown to dissipate rapidly in soil and water, and occur naturally as flavors and fragrances in certain foods and beverages. The Agency has decided that the acute and chronic risks posed by dietary exposure to the pesticide via the proposed use on fruits and vegetables are likely to be minimal to non-existent to infants and children.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Dermal

Potential non-occupational dermal exposure to *M. albus* Strain QST 20799 is unlikely because the use sites are commercial and agricultural and the granular nature of the end-use products, minimizes pesticide drift. A lack of hypersensitivity incidents and the poor survivability of the fungus in soil or lack of persistence on food commodities indicate that *M. albus* Strain QST 20799 poses minimal risk to populations via non-occupational dermal exposure (see Sections III.B.2 and III.B.4a).

Oral

Sections III.B.2 (Toxicology), III.B.3 (Dietary exposure and risk), III.B.5 (Drinking water), and III.B.6 (Dietary risks for sensitive subpopulations) discuss the rationales behind the Agency's determination that consumption of fruits or vegetables treated with *M. albus* Strain QST 20799 is not likely to pose a dietary risk because of the low toxicity potential observed in the acute oral toxicology submissions.

Inhalation

As discussed in Section III.B.4, non-occupational inhalation exposure is expected to pose no adverse effects to human adults, infants, or children when the pesticide is used as labeled. This determination was made based on the incorporation of the pesticide into the soil and minimal expected pesticide drift, due to its granular nature. In post-harvest applications, the pesticide is used in enclosed containers. The volatiles produced on rehydration of the EPs are common fragrances, flavors and solvents naturally occurring in food and beverages. Thus, non-occupational inhalation exposure is not likely to harm human health.

Summary Aggregate Exposure

In summary, the potential aggregate exposure via treatment of soil, seed or propagules, fruits and vegetables, and cut flowers with *M. albus* Strain QST 20799 is not likely to pose any adverse effects *Muscodor* strains via aggregate exposure. This includes hazards derived from (a) dietary exposure from the treated food/feed commodities, (b) drinking water potentially exposed secondary to treatment of sites with this pesticide; and (c) dermal and inhalation non-occupational and occupational exposure of populations exposed to *M. albus* Strain QST 20799.

8. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to *M. albus* Strain QST 20799 and to other substances that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Based on tests in mammalian systems, *M. albus* Strain QST 20799 does not appear to be toxic or pathogenic to humans. Thus, there is no indication that *M. albus* Strain QST 20799 shares any common mechanisms of toxicity with other registered pesticides. There are no other registered products containing *M. albus* Strain QST 20799, and the volatiles produced on rehydration dissipate rapidly from the soil and treated commodities. Based on the low toxicity potential of *M. albus* Strain QST 20799, its limited survival time in soil once the carrier nutrient source is exhausted, and the lack of contact between the fungus and the

commodities being treated post-harvest, no cumulative effect is expected from the use of *M. albus* Strain QST 20799 on fruits and vegetables or cut flowers.

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

There is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposures to residues of *M. albus* Strain QST 20799 as a result of its use as a soil or seed or propagule treatment to control root diseases in greenhouse and field crops, or as a fumigant to control post-harvest decay in fruits and vegetables and cut flowers. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm from this fungus via dietary, non-occupational inhalation or dermal exposure since the organism is non-toxic and non-pathogenic to animals and humans. The Agency has arrived at this conclusion based on the lack of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (see Section III.B.2 and Section III.B.4.a).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of exposure will be safe for infants and children. Margins of exposure are often referred to as uncertainty factors. In this instance, based on all the available information, the Agency concludes that *M. albus* Strain QST 20799 is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children, and adults when *M. albus* Strain QST 20799 is used as labeled, the Agency has determined that the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure approach to assess the safety of *M. albus* Strain QST 20799.

C. Environmental Assessment

1. Ecological Effects Hazard Assessment

Below is a summary of the ecological effects database evaluated in support of this action. The data waiver justifications and the database of studies and information on toxicity of *M. albus* Strain QST 20799 to non-target organisms are sufficient to allow its conditional registration as a microbial pesticide for use on seed and propagules and to control root diseases of greenhouse and field crops or as a fumigant to control post-harvest decay in fruits and vegetables and cut flowers. The registrant conducted an avian oral toxicity/pathogenicity study for the TGAI, and requested that all other studies to support ecological data requirements for the proposed manufacturing use, postharvest, seed, propagule and soil treatments of *M. albus* Strain QST 20799 be waived. These requests, and their scientific justifications are discussed after the summary of the submitted avian oral study.

a. Toxicity to Terrestrial Animals

(i) Avian Oral Toxicity/Pathogenicity (MRID 46172702, OPPTS 885.4050)

Young bobwhite quail (*Colinus virginianus*) received an oral gavage of QST 20799® Technical whole broth (reported purity of 2.5%, dry weight) at a mean daily dose of 1% of their

body weight for five consecutive days, followed by a 26-day observation period. Birds were observed once a day for mortality and clinical signs of toxicity. Body weight was recorded on days 0, 1, 2, 3, 4, 11, 18, 25, and 30. Mean estimated food consumption was determined for days 0-4, 5-11, 12-18, 19-25, and 26-30. At study end, all birds were necropsied.

No treatment-related mortality or adverse clinical signs occurred during the study, and no treatment-related changes were seen at necropsy. Body weight and feed consumption were unaffected by treatment. This study is acceptable and no further study is required for the proposed uses of *Muscodor albus* QST 20799.

TABLE IIIe: Eco-Toxicology Summary/Studies Evaluated- *Muscodor albus* QST 20799

Guideline No.	Study	Status, Classification & Comments	MRID No.
154-16 *885.4050	Avian oral toxicity	The no-observed-effect dosage of *M. albus* Strain QST 20799 to bobwhite quail was 1% of body weight for 5 consecutive days with a 30-day observation period.	46172702

*885 series = OPPTS Microbial Pesticide Test Guideline Numbers.

b. Data waiver requests for ecological effects of *Muscodor albus* strain QST 20799

Scientific justifications were submitted to waive data in support of the following Tier I studies:

(i) Avian Injection Toxicity (OPPTS 885.4100; Guideline 154-17)
(ii) Wild Mammal Testing (OPPTS 885.4150; Guideline 154A-18)
(iii) Freshwater Fish Toxicity/Pathogenicity (OPPTS 885.4200; Guideline 154-19)
(iv) Freshwater Aquatic Invertebrate Testing (OPPTS 885.4240; Guideline 154-20)
(v) Estuarine and Marine Animal Testing (OPPTS 885.4280; Guideline 154-21)
(vi) Non-target Insect Studies (OPPTS 885.4340; Guideline 154-23)
(vii) Honeybee Testing (OPPTS 885.4380; Guideline 154-24)

Justifications for Data Waivers Ecotoxicity testing of *Muscodor albus* QST 20799

Rationales for these data waiver requests are found in Volume 10 of the submissions and are summarized below.

(i) Avian Injection Test (OPPTS 885.4100; Guideline 154-17)

This study isn not required by the current testing guidelines on microorganisms not related to avian pathogens. In addition, the active ingredient occurs as a plant endophyte and has not been found capable of colonizing soil. The population of active ingredient outside its host plant has been found to decrease to zero within a few days. The volatile acids and esters produced by the active ingredient are in the parts per billion range, three to four orders of magnitude below any reported ecotoxicological effects of the compounds, and dissipate within 24 to 48 hours. A search of published literature on *M. albus* and other *Muscodor* species found no evidence of adverse biological effects to organisms other than pathogenic fungi and bacteria. Further, in-house studies by the registrant have shown that *M. albus* Strain QST 20799 does not survive at temperatures of 34°C or higher, indicating it would not survive at avian body temperature (typically 40 to 44°C).

No further data are required at this time for the avian injection for the proposed uses of *Muscodor albus* QST 20799.

(ii) Wild Mammal Testing (OPPTS 885.4150; Guideline 154A-18)

These data are required only when the acute oral rodent toxicity/pathogenicity study (OPPTS 885.3050) is not sufficient for wild mammal hazard assessment. The acute oral rat study submitted in support of the registration (MRID 46039404) is sufficient to make a "no apparent hazard" finding to wild mammals. In that study, viable *M. albus* Strain QST 20799 demonstrated no toxicity or pathogenicity when administered to rats at an oral dose of 1×10^8 cfu/animal. Similarly, the acute pulmonary study in rodents demonstrated no toxicity or pathogenicity when *M. albus* Strain QST 20799 was administered intratracheally at a dose of 1.9×10^3 to 2.4×10^3 cfu/animal, although dosing procedure-related deaths occurred.

Based on the low mammalian toxicity/pathogenicity observed effects, the Agency has determined that the use of this microbial pesticide is not likely to pose incremental hazards to wild mammals at the proposed label use rates. No additional testing at higher tiers is ordinarily required, since no pathogenic or toxic effects were observed in the Tier I mammalian maximum hazard dose studies. The request to waive data for wild mammal testing is granted for the proposed uses of *M. albus* Strain QST 20799. No further data are required at this time for the wild mammal testing for the proposed manufacturing and soil and postharvest uses of *Muscodor albus* QST 20799.

(iii) Freshwater Fish Toxicity/Pathogenicity (OPPTS 885.4200; Guideline 154-19)

(iv) Freshwater Aquatic Invertebrate Testing (OPPTS 885.4240; Guideline 154-20)

An in-house study provided by the registrant showed that the concentration of active ingredient in the water runoff of Arabesque™ in soil dropped four logs (from 9.3×10^4 to 7.7 cfu/ml) at time zero. Additionally, sterile mycelia in the water wash do not have the nutrients required to continue metabolism and would not be expected to propagate. The volatile acids and esters produced by the active ingredient are in the parts per billion range, three to four orders of magnitude below any reported ecotoxicological effects of the compounds, and dissipate within 24 to 48 hours in soil, and would not be found in the run-off to aquatic environments. A search of published literature on *M. albus* found no evidence of any adverse biological effects to organisms other than pathogenic fungi and bacteria. The justifications are **acceptable** to waive these data requirements for the proposed uses of *Muscodor albus* QST 20799. No further data are required at this time for aquatic animal testing for the proposed manufacturing and soil and postharvest uses of *Muscodor albus* QST 20799.

(v) Estuarine and Marine Animal Testing (OPPTS 885.4280; Guideline 154-21)

Data for this guideline are conditionally required only when the product is intended for direct application to the estuarine or marine environment, or is expected to enter those environments in significant concentrations due to the intended use or mobility pattern. End use products containing *M. albus* Strain QST 20799 are not intended for direct application into estuarine or marine environments and are not expected to enter those environments in significant concentrations. The end use products are granular formulations that are to be incorporated into the soil or used in enclosed environments such as greenhouses or enclosed containers. The volatile acids and esters produced by the active ingredient are in the parts per billion range and dissipate within 24 to 48

hours. The justifications are **acceptable** to waive these data requirements for the proposed uses of *M. albus* QST 20799.

(vi) Non-target Plant studies (OPPTS 885.4300; Guideline 154-22)

The registrant has performed a number of greenhouse trials to evaluate efficacy of *M. albus* Strain QST 20799. No indications of phytotoxicity or colonization of plant materials were observed for a variety of nontarget plant species. Furthermore, deliberate attempts to establish colonies of *M. albus* on plants, including tomato, pepper, eggplant, and crabapple, have failed. The active ingredient is an endophyte and does not perpetuate in soil, where it will be applied. A search of published literature on *M. albus* found no evidence of adverse effects on plants. The justifications are **acceptable** to waive this data requirement for the proposed use of *M. albus* QST 20799. No further data are required at this time for aquatic or terrestrial plant testing for the proposed manufacturing and soil and postharvest uses of *Muscodor albus* QST 20799.

(viii) Non-target Insect Studies (OPPTS 885.4340; Guideline 154-23)
(ix) Honeybee Testing (OPPTS 885.4380)

M. albus Strain QST 20799 occurs as a plant endophyte and has not been found to be capable of colonizing soil, where the population of active ingredient outside its host plant has been found to decrease to zero within a few days. The volatile acids and esters produced by the active ingredient are in the parts per billion range, three to four orders of magnitude below any reported ecotoxicological effects of the compounds, and dissipate within 24 to 48 hours from enclosed spaces. A search of published literature on *M. albus* found no evidence of adverse biological effects to organisms other than pathogenic fungi and bacteria. An in-house earthworm study by the registrant found no negative effects after 7 or 14 days. The justifications are **acceptable** to waive these data requirements for the proposed uses of *Muscodor albus* QST 20799. No further data are required at this time for insect testing for the proposed manufacturing and soil and postharvest uses of *Muscodor albus* QST 20799.

Rationales for the data waiver requests discussed above are summarized in the Table below.

TABLE IIIf: Eco-Toxicology Summary: Data Waivers for *Muscodor albus* QST 20799

Guideline No.	Study	Status, Classification & Comments	Status
154-17 *885.4100	Avian injection test	No hazards from *M. albus* Strain QST 20799 to avian species are anticipated from the intended use. No significant exposure of *M. albus* Strain QST 20799 to avian species is expected from the intended use. An acceptable waiver rationale supports these findings.	**Waived**
154A-18 *885.4150	Wild mammal testing	Acute toxicity tests indicate *M. albus* Strain QST 20799 is not toxic, infective, or pathogenic to mammals. There is no indication of variable sensitivity among mammalian species, and no significant exposure is expected from the intended use. An acceptable waiver rationale supports these findings.	**Waived**
154-19 *885.4200	Fresh water fish testing	No significant exposure of *M. albus* Strain QST 20799 to aquatic animals is expected from the proposed use patterns. No hazards from *M. albus* Strain QST 20799 to freshwater fish, freshwater aquatic invertebrates, or estuarine and marine animals are anticipated from the intended use. An acceptable waiver rationale supports these findings.	**Waived**
154-20 *885.4240	Fresh water aquatic invertebrate testing		
154-20 *885.4280	Estuarine and marine animal testing		
154-22 *885.4300	Non-target plant studies, Tier 1	No hazards from *M. albus* Strain QST 20799 to non-target plant species are anticipated from the intended use. No adverse effects were seen in greenhouse trials, and attempts to establish colonies on different plant hosts failed. The rationale for this data waiver request is acceptable.	**Waived**
154-23 *885.4340	Non-target insect studies, Tier 1	No hazards from *M. albus* Strain QST 20799 to non-target insect species are anticipated from the intended use. The rationale for this data waiver request is acceptable.	**Waived**
154-24 *885.4380	Honey bee testing, Tier 1		

*885 series = OPPTS Microbial Pesticide Test Guideline Numbers.

2. Environmental Assessment

Based on the studies and rationales for the data waivers discussed above, exposure and risk from the proposed use of *M. albus* Strain QST 20799 and its end-use products, Andante™, Arabesque™, and Glissade™, on fruits and vegetables and cut flowers are expected to be minimal to non-existent to non-target organisms, including birds, wild mammals, honey bees and other insects, freshwater fish and invertebrates, estuarine and marine animals, and non-target terrestrial and aquatic plants.

Based on the results of the submitted acute toxicity studies, and a maximum growth temperature of approximately 34°C, risk from *M. albus* Strain QST 20799 to wild mammals and avian wildlife is not anticipated. The poor survival of *M. albus* Strain QST 20799 in soil and its

lack of toxicity indicate that the exposure and hazard potentials are low, as are risks to the human health and the environment.

No reports of toxicological or pathogenic effects produced by *M. albus* were found in the public literature. *M. albus* is not known to produce recognized toxins, enzymes, or virulence factors normally associated with invasiveness or toxicity in animals Since it is an endophyte, *M. albus* Strain QST 20799 is not expected to survive in surface water. The large size of *M. albus* Strain QST 20799 mycelium prohibits the generation of aerosols, and no spores are produced, so wild animal inhalation exposure is also unlikely.

Hazards to Insects and Animals

In *in vitro* bioassays, high concentrations of the volatiles produced by *M. albus* Strain QST 20799 inhibited growth and development of beet armyworm (*Spodoptera exigua*), corn rootworm (*Diabrotica undecimpunctata*), and house fly (*Musca domestica*) eggs and/or larvae. Adult lady beetles (*Hippodamia convergens*) showed sluggish behavior and mortality after a seven-day exposure. After 14 days of exposure, most of the nematodes *(Caenorhabditis elegans)* in the test plates were dead. However, studies where *M. albus* Strain QST 20799 was incorporated into the soil showed no comparable adverse effects on corn rootworm *(D. undecimpunctata)* larvae or root knot nematodes (*Meloidogyne incognita*) (MRID 46039408).

A search of the public literature found no information on toxic or pathogenic effects of the volatile compounds produced by *M. albus* or any other member of the Xylariaceae group of fungi to any animal. Based on the result of the submitted acute rodent and avian oral toxicity studies, a maximum growth temperature of approximately 34°C (MRID 46039408), and the fact that the product is incorporated into soil or confined in post harvest application, no risk to wild mammals and other terrestrial animals, fish, other aquatic wildlife, and honeybees is anticipated.

Hazards to Plants

Muscodor albus is an endophytic deuteromycetous species adapted for growth in cinnamon trees bearing molecular relatedness to the ascomycetous group Xylaria. Relatively few Xylariaceae have been found to be pathogenic to plants. In these cases they are usually unspecialized pathogens living as saprophytes or weak pathogens until their host is weakened by environmental stresses such as drought or insect damage that allow the Xylariaceae to then cause damage. There are no reports of *M. albus* plant infections.

When used as a pre-plant treatment, *M. albus* Strain QST 20799 could come into contact with plant roots. However, in-house testing by the registrant found no signs of pathogenicity to bell pepper, lettuce, tomato, sunflower, corn, cosmos, eggplant, or squash plants grown in soil treated with *M. albus* Strain QST 20799. Similar results were seen in tests done at Montana State University with canola, wheat, barley, corn, chickpea, potato, tomato, sugar beet, chrysanthemum, and cucumber. Deliberate attempts by the registrant to infect crabapple, tomato, pepper, and eggplant with *M. albus* Strain QST 20799 were unsuccessful (MRID 46039408)

In post-harvest use, the likelihood of *M. albus* Strain QST 20799 coming in contact with the treated commodity is minimal, since the fumigation treatment does not involve physical contact

with the fungus and the fungus does not produce airborne propagules. Residues of the volatile compounds produced by *M. albus* Strain QST 20799 on treated commodities are not expected to be of environmental concern.

Hazards to Other Microorganisms

M. albus Strain QST 20799 has been tested against oomycetes, true fungi, and bacteria. Three days of exposure to the volatiles produced by *M. albus* Strain QST 20799 on PDA inhibited growth of *Fusarium solani*, *F. oxysporum*, *Cercospora beticola*, *Bacillus subtilis*, and *Xylaria* (Strobel et al, 2001, appended to MRID 46039408). The exposure was lethal to *Pythium ultimum*, *Phytophthora cinniamoni*, *Rhizoctonia solani*, *Ustilago hordei*, *Stagonospora nodorum*, *Sclerotinia sclerotiorum*, *Aspergillus fumigatus*, *Verticillium dahliae*, *Tapesia yallundae*, *Escherichia coli*, *Staphylococcus aureus*, *Micrococcus luteus*, and *Candida albicans*.

The registrant's in-house studies found that *M. albus* Strain QST 20799 volatiles inhibited and killed the soil-borne pathogens *Fusarium aveneaceum*, *Sclerotinia minor*, and *Phytophthora capsici*. Similar effects were seen for the post-harvest pathogens *Penicillium expansum*, *P. digitatum*, *Monilinia fructicola*, *Botrytis cinerea*, and *Colletotrichum acutatum*. The volatiles did not inhibit growth of *M. albus* Strain QST 20799 itself or the saprophytic soil fungus *Trichoderma* (MRID 46039408). Exposure to agricultural soil microorganisms is expected to be transient and of short duration. Therefore no risk to beneficial soil microorganisms is anticipated. No exposure, and therefore no risk to forest mycorrhizal fungi is expected from the proposed commercial uses of *M. albus* Strain QST 20799.

Endangered Species Considertions

M. albus Strain QST 20799 is an endophyte adapted for growth in cinnamon trees as sterile mycelium (spore production has not been detected) and functions to inhibit growth of undesirable microbial species. Searches of the published literature show no reports of adverse effects on wildlife, including plants. For pre-plant use, *M. albus* Strain QST 20799 will be incorporated into the soil, where viability is limited once the carrier food supply in the end product is exhausted. For post-harvest use, the product is used in enclosed containers where there is no exposure to non-target wildlife. Based on results of the submitted toxicity studies and a maximum growth temperature of approximately 34°C, the risk of *M. albus* Strain QST 20799 to wild mammals, birds, other terrestrial animals including insects, fish and other aquatic wildlife is not expected. As a result the Agency has made a no effect finding to listed species from the proposed uses of *M. albus* Strain QST 20799. Therefore, no adverse effects are expected to endangered species from the proposed uses of pesticides containing *M. albus* QST 20799.

3. Conclusions

The intended use for *M. albus* Strain QST 20799 is fumigation of soil and harvested crops, seed and propagules for disease control. If approved, its use could potentially replace soil fumigants and post-harvest fungicides that have been demonstrated to be harmful to the environment, e.g., methyl bromide and 1,3-dichloropropane. There are no reports of environmental health hazards caused by *M. albus* Strain QST 20799. The organism is not known to be a plant or animal pathogen, and it does not produce recognized toxins, enzymes, or virulence

factors normally associated with invasiveness or toxicity. The lack of acute toxicity and pathogenicity of *M. albus* in laboratory animals, insects of plants indicates the strain is benign. The volatile compounds produced by *M. albus* Strain QST 20799 at field use concentrations well below LD_{50} levels for several insects tested. The poor survival of *M. albus* Strain QST 20799 in soil and the lack of toxicity indicate that the exposure and the hazard potential for *M. albus* Strain QST 20799 are extremely low, as are the risks to human health and the environment.

4. Ecological Exposure and Environmental Expression Risk Characterization

As discussed above, *Muscodor albus* QST 20799 and the volatiles produced from its rehydrated end-use products, Andante™, Arabesque™, and Glissade™ are not likely to persist in the environment. Since it is an endophyte, *M. albus* QST 20799 is not expected to survive in surface water. The granular nature of the EPs indicate that the likelihood of spray drift is minimal to non-existent from pesticides containing this active ingredient. The large size of *M. albus* QST 20799 prohibits the generation of aerosols.

Since *M. albus* Strain QST 20799 is a tree endophyte that exists as a sterile mycelium, it is unlikely to persist in soil once the carrier nutrient source is exhausted. There is no evidence that it grows well in other environments, except for artificial media. In a study by the registrant, grain colonized by *M. albus* was incorporated into soil and later recovered to determine if the fungus could be re-isolated. All grain recovered on day 0 had viable *M. albus*, but re-isolation frequency dropped to 30% after 4 days and 0% after 7 days. The substrate for *M. albus* Strain QST 20799 appears to be taken over rapidly by a number of soil-borne fungi such as *Trichoderma* (volume 10 of the submission).

The ecological test and environmental expression data support a conclusion of reasonable certainty that no incremental hazards to non-target organisms or to the environment are anticipated as a result of the intended use of *M. albus* Strain QST 20799, or its end-use products, Andante™, Arabesque™, and Glissade™ on seed and propagules, fruits and vegetables and cut flowers, and no further testing is required at this time.

D. Efficacy Data

Efficacy data are not required, since the target pests, plant pathogenic bacteria, fungi, and nematodes, have not been identified as a public health hazard (PR Notice 2002-1).

IV. PUBLIC INTEREST FINDING

The Agency believes that the use of *M. albus* Strain QST 20799 under this conditional registration would be in the public interest. The criteria for Agency evaluation of public interest findings are outlined in 51 FR No. 43, Wednesday March 5, 1986. Under part IV.A, the proposed product may qualify for an automatic presumptive finding that the proposed conditional registration is in the public interest if it is for a minor use, is a unique replacement for pesticides of concern, or is for use against a public health pest.

The most effective treatment of soil and postharvest crops to protect against pathogens has been methyl bromide. Since the approval of the Montreal treaty, there has been a great effort to find viable alternatives to methyl bromide. While many of the alternatives do not deplete the ozone layer, most are still very toxic. For example, many towns in California have limited the use of 1,3-dichloropropene and Metam due to air quality and environmental concerns. A highly toxic rating was given to chloropicrin and propargyl bromide (methyl bromide alternatives for soil treatment) by OSHA, and thiabendazole (used for postharvest commodities) is a known carcinogen. Growers and packers are faced with resistant strains of postharvest plant pathogens, and the need for viable resistance management alternatives is strong. Furthermore, the use of low toxicity, low risk biopesticides based on *M. albus* QST 20799 will allow growers to expand their export markets, as many countries do not allow chemical residues on fruits and vegetables.

Based on these rationales, the Agency has determined that *M. albus* Strain QST 20799 is likely to provide a cost-effective biocontrol agent for treatment of soil and postharvest crop pathogens in fruits and vegetables and cut flowers, and that availability of pesticides containing this active ingredient to growers is in the public interest.

V. RISK MANAGEMENT AND REGISTRATION DECISION

A. Determination of Eligibility

Section 3(c)(7)(C) of FIFRA provides for the conditional registration of a pesticide containing a new active ingredient (*i.e.,* not contained in any currently registered pesticide) "for a period reasonably sufficient for the generation and submission of required data . . . on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria" identified in regulations issued under FIFRA "and on such other conditions as the Administrator may prescribe." Such a conditional registration will be granted "only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest."

M. albus Strain QST 20799 (TGAI/MP) and its end-use products, Andante™, Arabesque™, and Glissade™, are eligible for a conditional registration because the proposed uses of this active ingredient on fruits and vegetables and cut flowers is in the public interest. *M. albus* QST 20799, when used as labeled, is not likely to pose an unreasonable risk to health or the environment as discussed in this document. Certain conditions apply to this eligibility and the applicant must take certain actions (e.g., generate and provide certain data) within the time frames outlined in Section VI of this document.

B. Regulatory Position

1. Conditional Registration Eligible use

Data submitted are sufficient for a conditional registration of *M. albus* Strain QST 20799 (TGAI/MP) and its end-use products, Andante™, Arabesque™, and Glissade™, for use on fruits and vegetables and cut flowers in accordance with label directions, if the applicant takes the actions listed in Section VI of this document.

2. Tolerance Reassessment

This is the first food use of this pesticide. No tolerance reassessment is required.

3. Ineligible Uses

Any other application of this pesticide, not in compliance with Agency requirements, will constitute a misuse.

4. CODEX Harmonization

There are no Codex harmonization considerations since there are no Codex Maximum Residue Limits set for food use of this active ingredient.

5. Non-food Re/Registrations

This is a new active ingredient and, therefore, not the subject of reregistration at this time. The pesticide is proposed for use on ornamentals, forestry, cut flowers and a number of non-food propagules.

6. Risk Mitigation

There is minimal or negligible potential risk to non-target organisms (plants and wildlife) and to ground and surface water contamination through the proposed use of products containing *M. albus* Strain QST 20799 as discussed in this document, provided the label directions are followed. No mitigation measures are required at this time for dietary risk, including risk due to exposure via drinking water. Appropriate PPE is required for pesticide handlers. This includes a long sleeved shirt, long pants, waterproof gloves, shoes, socks, and an appropriate dust/mist-filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. The product label will also bear Environmental Hazards text to mitigate any potential risk as determined by reviewed data and use sites.

7. Endangered Species Statement

The Agency has made a no effect finding for endangered and threatened species from *M. albus* QST 20799 in microbial pesticides used for seed or propagule treatments, or on root diseases of greenhouse and field crops, or as a fumigant to control post-harvest decay in fruits and vegetables and cut flowers. No adverse effects are expected to endangered species from the proposed uses of pesticides containing *M. albus* QST 20799. No labeling is required for endangered species at this time.

C. LABELING RATIONALE

It is the Agency's position that the labeling for manufacturing products containing *Muscodor albus* Strain QST 20799 must comply with the pesticide labeling requirements in existence when such products are registered.

1. Manufacturing Use Product Labeling

The label must include appropriate statements to indicate that the registered product is a MP if the intent is to use the product to formulate EPs. The label must indicate the PPE required when handling or formulating the MP into the EP.

The following NPDES statement must be placed on the manufacturing use product for the active ingredient, *Muscodor albus* Strain QST 20799, at this time.

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without

previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

2. End-use Product Labeling

It is the Agency's position that the labeling for End-use Product products containing *Muscodor albus* Strain QST 20799 must comply with the pesticide labeling requirements in existence when such products are registered.

a. Human Health Hazard

(i) Worker Protection Standard

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with PR Notice 93-7, "Labeling Revisions required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7", which reflect the WPS (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170). Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices, such as, and including the WPS labeling.

PPE for pesticide handlers and applicators include: long-sleeved shirt, long pants, waterproof gloves, and shoes plus socks. Mixer/loaders and applicators must wear a dust/mist filtering respirator meeting the NIOSH standards of at least N-95, R-95, or P-95. There is a Restricted Entry Interval of zero (0) hours for post harvest, seed or propagule treatments, and four (4) hour REI for soil treatments and for incorporation into growing media when used in enclosed environments.

(ii) Other Precautionary Labeling

The Agency has examined the toxicological data base for *M. albus* Strain QST 20799 and concluded that the precautionary labeling required during this conditional registration process (i.e. Signal Word, First Aid Statements, WPS statements for pesticide handlers, and other label statements) adequately mitigates the risks associated with the proposed uses. Additional labeling may be required for other uses of products containing *M. albus* Strain QST 20799 on a case-by-case basis.

b. Environmental Hazards Labeling

Standard Environmental Hazards labeling statements are required for this agricultural application.

Provided the following statements are placed in the environmental hazards statement, the risk of exposure to *M. albus* Strain QST 20799 is minimal to nonexistent to non-target organisms including endangered species:

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of rinsate or equipment washwaters."

3. Application Rate

It is the Agency's position that the labeling for the pesticide products containing *M. albus* Strain QST 20799 must comply with the current pesticide labeling requirements. The Andante™ end-use product is to be applied as a granular formulation at the rate of 500 to 21000 pounds per acre, or for small treatment areas, at the rate of 2 to 10 ounces per cubic foot of soil, and then incorporated into the soil. The Glissade™ end-use product is to be applied as a granular formulation at the rate of 2 to 10 ounces per cubic foot of soil, and then incorporated into the soil. The Arabesque™ end-use product is to be applied as a re-hydrated (15 ounces of water per pound of product) granular formulation at the rate of 0.5 to 2 ounces of re-hydrated product per cubic foot of treated volume of the enclosed container.

D. LABELING

a. TGAI or Manufacturing Use Product

There is a separate technical grade of the active ingredient (TGAI) proposed to be registered at this time for use as a manufacturing use product (MP). It must clearly state "For formulation into End-Use Products only."

Manufacturing Use Product Name: QST 20799® Technical

Ingredient Statement:	w/w
Muscodor albus strain QST 20799*	2.1%
(consists of fungal cell mass and residual fermentation media)	
Other Ingredients	97.9%
Total	100%

*Contains a minimum of 2 x 10^6 cfu/g

Based on the evaluation of the acute oral and pulmonary toxicity/infectivity exposure studies submitted to support registration of products containing *Muscodor albus* Strain QST 20799, the signal word is "CAUTION." Signal words for other products containing this active ingredient will vary depending on toxicity/pathogenicity evaluations of those products.

b. End-use Products

At this time the EPs Andante™, Arabesque™, Glissade™ are similar.

End-use Product Names: Andante™, Arabesque™, Glissade™

Ingredient Statement:	w/w
Muscodor albus Strain QST 20799.....	0.35%
Inert Ingredients	99.65%
Total 100.00%*	

* viability of End-use Product: minimum of 1 x 10^5 cfu/g

Based on the evaluation of the acute oral and acute pulmonary toxicity/infectivity studies submitted for the active ingredient, the signal word is "CAUTION" for the End-Use Products Andante™, Arabesque™, Glissade™ , containing 0.35% *Muscodor albus* Strain QST 20799. Signal words for these and other end-use products containing this active ingredient will vary depending on formulation changes and the toxicity/pathogenicity evaluations of those products.

VI. WHAT REGISTRANTS MUST DO

A. Reports of incidents of adverse effects to humans or domestic animals are required under FIFRA, Section 6(a)(2) and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the **reregistration** of the end-use products since the products are being registered after November 1984 and are, therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time. Before releasing these products for shipment, the registrant is required to provide appropriate labels and other Agency requirements as discussed in this BRAD.

The following are standard data requirements for any registered microbial pesticide product. The registrant must provide the following data to ascertain that Quality Assurance and Quality Control and nominal limits of the pesticide are maintained during manufacture.

Analysis of 5 batches is required at production and must include data relevant to certification of limits, detection, identification, enumeration and rejection limits of unintentional ingredients and potential human pathogens (bacterial and fungal) using routine quality control and assurance methods to be implemented for large scale production. Batch analysis must also include viability and storage stability data. Submit results of batch analyses as each batch is produced. All batches containing unintentional ingredients and human pathogens above regulatory levels must be destroyed. The data from production batches are required as confirmatory data.

All batches containing metabolites or unintentional ingredients or human pathogens of toxicological concern and above regulatory levels, must be appropriately destroyed.

TABLE 6a: Data required during five production batches of *Muscodor albus* QST 20799			
Guideline	**Title of Study**	**Data required**	**Date due**
*885.1300 151-12	Discussion of Formation of Unintentional Ingredients	Five batch analysis to include identification and enumeration of bacterial and fungal contaminants, unintentional ingredients, viability and storage stability data.	As batches are produced.
*885.1500 151-15	Certification of limits	Standard data requirement for production batches.	As batches are produced.

*OPPTS Harmonized Guidelines

B. As conditions of registration, the registrant must submit the following:

TABLE 6b: Data required as conditions of registration for *Muscodor albus* QST 20799			
Guideline	**Study**	**Data Required**	**Time to submit data**
63-17 *830.6317	Storage Stability	Stable one year. Data supporting the claims for storage stability in submissions made to the Agency as MRIDs 46039401 and 46038601	Within 18 months of conditional registration.
*870-1300	Acute inhalation	Confirmatory data on inhalation effects of volatiles as a condition of registration.	Within 18 months of conditional registration

*OPPTS Harmonized Guidelines

C. If more extensive use patterns are sought for treatment of other agricultural terrestrial sites or crops, additional information and data will be required on a case-by-case basis.

VII. APPENDICES

APPENDIX A - Use sites

Table 5 lists the use sites for the product. The registrant must comply with the appropriate labeling requirements before releasing products containing *M. albus* Strain QST 20799 as the active ingredient for shipment.

TABLE 5: Use Site Conditional Registration - *Muscodor albus* QST 20799	
QST 20799® Technical: for manufacturing use only. **Andante™:** vegetable seed or propagule and plant beds; fruit and nut trees; vine, caneberry and strawberry transplants, including orchard resets; ginseng seedbeds, forest nurseries, seed or propagule or propagation beds for conifers and deciduous trees. **Arabesque™:** citrus, pome fruit, stone fruit, mango, papaya, avocado, caneberries, blueberry, strawberry, cranberry; fruiting vegetables, bulb vegetables, cucurbits, tubers/root vegetables, beans, cole crops; cut and potted flowers; vegetable, grain, and legume seeds; flower and vegetable seed or propagule bulbs; potato, sweet potato, yam, cocoyam, cassava, ginseng. **Glissade™:** compost piles, potting soils, seed or propagule and propagating beds, soil media.	**Official date registered:**

APPENDIX B - BIBLIOGRAPHY

BPPD Technical Support Documents
References: Biopesticides and Pollution Prevention Division Memoranda and Reviews

April 28, 2004 Review of Data for the Registration of a New Microbial TGAI: *Muscodor albus* Strain QST 20799. Memorandum from Ibrahim Barsoum and John Kough to Shanaz Bacchus. US EPA/OPP/BPPD

October 14, 2004 Cover memorandum from Ibrahim Barsoum, BPPD/USEPA to Shanaz Bacchus, BPPD/USEPA. Summary of acute toxicology studies for *M. albus* QST 20799, TGAI.

October 14, 2004 Cover memorandum from Ibrahim Barsoum, BPPD/USEPA to Shanaz Bacchus, BPPD/USEPA. Summary of acute toxicology studies for *M. albus* QST 20799, EP.

October 21, 2004 Cover memorandum from Ibrahim Barsoum, BPPD/USEPA to Shanaz Bacchus, BPPD/USEPA. Review of data for the registration of a new microbial EPs: Arabesque, Andante, Arabesque from a new TGAI: *Muscodor albus* QST 20799.

CITATIONS/BIBLIOGRAPHY

Studies submitted in support of this registration action and Pesticide Petition # 3F6745

MRID	Citation Reference
46038601	Lin, J., J. Mercier, and J. Thurston (2003) Product Chemistry of Arabesque, Volume 2. Unpublished study prepared by AgraQuest, Inc.
46039401	Lin, J., J. Mercier, and J. Thurston. (2003) Product Chemistry of QST 20799 Technical. Unpublished study prepared by AgraQuest, Inc.
46039402	Carter, J.N. (2003) QST 20799 - Five Batch Analysis. Unpublished study prepared by AgraQuest, Inc.
46039404	Moore, E.L. (2003) QST 20799 - Acute Oral Toxicity and Pathogenicity to the Rat. Unpublished study prepared by Huntingdon Life Sciences Ltd.
46039406	Moore, E.L. (2003) QST 20799 - Acute Pulmonary Toxicity and Pathogenicity to the Rat. Unpublished study prepared by Huntingdon Life Sciences, Ltd.
46039407	Freeman, D.L. and M. Watson. (2003) Acute Eye Irritation Study in New Zealand White Rabbits with QST 20799. Unpublished study prepared by Ricera Biosciences, LLC.
46039408	Heins, S., J. Jimenez, and J. Mercier. (2003) Risk Assessment for *Muscodor albus* Strain QST 20799. Unpublished study prepared by AgraQuest, Inc.
46106401	Freeman, D.L. (2002) An Acute Oral Toxicity Study with Albino Rats with CP011. Unpublished study prepared by Ricera LLC.
46106402	Rees, P.B. (2003) QST 20799 - Acute Dermal Toxicity and Pathogenicity to the Rabbit. Unpublished study prepared by Huntingdon Life Sciences, Ltd.
46172701	Manker, D. (2003) Supplement to MRID No. 46038601, QST 20799 Technical: Certification of Limits. Unpublished study prepared by AgraQuest, Inc.
46172702	Gallagher, S.P., L.R. Mitchell, and J.B. Beavers. (2003) QST 20799 Technical: An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite. Unpublished study prepared by Wildlife International Ltd.
46173101	Manker, D. (2003) Supplement to MRID No. 46038601, Glissade™: Certification of Limits, Dissociation Constant, Partition Coefficient, Solubility, and Vapor Pressure, Volume 2. Unpublished study prepared by AgraQuest, Inc.

46173301 Manker, D. (2003) Supplement to MRID No. 46038601, Arabesque™: Certification of Limits, Dissociation Constant, Partition Coefficient, Solubility, and Vapor Pressure, Volume 2. Unpublished study prepared by AgraQuest, Inc.

46173401 Manker, D. (2002) Supplement to MRID No. 46038601, Andante™: Certification of Limits, Dissociation Constant, Partition Coefficient, Solubility, and Vapor Pressure, Volume 2. Unpublished study prepared by AgraQuest, Inc.

None Manker, D. (2002) Rationale for Waiver of Certain Data Requirements for QST 20799® Technical (TGAI) and Arabesque™ (EP). Unpublished study prepared by AgraQuest, Inc.

None Edgecomb, D.E. (2004) Proposal for Testing of Batches of Serenade Garden Disease Control Ready to Use (EPA Reg. No. 69592-16) and Periodic Testing of Well Water from AgraQuest's Tlaxcala, Mexico Plant. Unpublished study prepared by AgraQuest, Inc.

None Manker, D.M. (2003) Requests for Waivers of Toxicity/Pathogenicity and Product Chemistry Studies for *Muscodor albus* (QST 20799 Technical). Unpublished study prepared by AgraQuest, Inc.