

BIOPESTICIDE REGISTRATION ACTION DOCUMENT

***MUSCODOR ALBUS* QST 20799
(QST 20799® TECHNICAL)
(End-use Products ARABESQUE™, ANDANTE™, GLISSADE™)**

PC Code 006503

**Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
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Muscodor albus Strain QST 20799
(PC Code 006503)

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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

II. OVERVIEW

A. Product Overview

Biological Name:	<i>Muscodor albus</i> Strain QST 20799
ATCC Number:	National Regional Research Laboratories (NRRL) 30547
Trade and Other Names:	<i>Muscodor albus</i> 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.

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 Ibrahim 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

