

69592-5

06/20/2000

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511C) 401 M St., S.W.
Washington, D.C. 20460

EPA Reg.
Number:

69592-5

Date of Issuance:

JUN 20 2000

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional
Time-Limited

Name of Pesticide Product:

QST 713 Technical

Name and Address of Registrant (include ZIP Code):

AgraQuest, Inc.
1530 Drew Avenue
Davis, CA 95616-6320

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. The submitted manufacturing process did not have sufficient quality control required for all fermentation batches. Therefore, the Agency is requiring, as a term and condition of the registration, the following quality control procedure. Batches that do not meet the criteria below must not be used for commercial production.
After fermentation and prior to further processing, each batch must be tested for the following microbial contaminants and have levels below those listed:

E. coli/ Coliform Bacteria	< 10 cfu/g
Salmonella	0 cfu per 25 g
Shigella	0 cfu per 25 g
Staphylococci	< 10 cfu/g
Vibrio	0 cfu per 25 g
Yeast	< 10 cfu/g
Mold	< 10 cfu/g

Signature of Approving Official:

JZH see page 3

Date:

6-20-00

3. This registration will automatically expire on midnight July 1, 2002. EPA will reevaluate this registration before July 1, 2002 to determine whether to convert the registration to a non-expiring registration.

4. This registration is registered under FIFRA § 3(c)(7)(C) because of the outstanding product chemistry and ecotoxicity data. Submit the following data within the specified time frames:

TABLE 1: SUMMARY OF CONDITIONAL REGISTRATION DATA REQUIREMENTS

Product Chemistry Data Required			
Guideline	Title of Study	Data required	Date due
153-9 *885.2400	Storage Stability	Data for the 12 month storage stability of the end-use product has not been submitted. This data, along with clarification/justification of the plating technique description described in MRID# 4446517-03 and 446519-03 should be provided.	2 years from date of registration
151-11 *885.1200	Manufacturing Process	<p>Additional data described in the December 12, 1999 review and March 8, 2000 letter are required to upgrade submitted process, MRID# 446519-04 to acceptable. This includes:</p> <p>1) A formal submission that clearly describes new quality control steps taken to assure the consistent CFU/g values and limit microbial impurities in the Technical Powder.</p> <p>2) A 5 batch analysis of Technical Powder produced from cell cultures with latest QC</p> <p>3) Raw data for the above mentioned 5 batch analyses.</p>	1 year from date of registration
Ecological Effects Data Required			
154 19 *885-4200	Freshwater Fish toxicity/pathogenicity	MRID 448848-01 - did not meet guideline requirements. A new study must be submitted.	1 year from date of registration
154-20 *885-4240	Freshwater aquatic invertebrate toxicity/pathogenicity	A 21 day Freshwater Aquatic Invertebrate Study must be performed. Attenuated and filter sterilized controls should be used in the test. Test lab should attempt to determine cause of death and whether pathogenicity involved.	1 year from date of registration
154-21 *885-4280	30 Day Toxicity/Pathogenicity in <i>Paleomonetes vulgaris</i> (shrimp)	Required due to report of disease in terrestrial amphipod crustacean associated with <i>B. subtilis</i> infection. Protocol must be submitted before initiating study.	1 year from date of registration

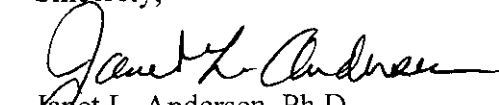
Guideline	Title of Study	Data required	Date due
154-23 *885-4340	Non-target insect-parasitic Hymenoptera	QST Technical was shown to cause mortality to parasitic Hymenoptera. MRID 446519-14 is graded supplemental. Potential pathogenicity was not investigated. A new 30 day study must be submitted.	1 year from date of registration
154-24 *885-4380	Honey bee Dietary toxicity/pathogenicity	All test concentrations showed treatment related mortality. MRID 4456519-17 is supplemental due to the short test duration and the lack of a determination as to whether mortality was due to toxicity only or whether pathogenicity contributed. A 30 day whole hive study is necessary to satisfy this guideline requirement.	1 year from date of registration

*885-xxxx = OPPTS Microbial Pesticide Test Guideline Numbers.

A stamped copy of the label is enclosed for your records.

5. Submit five(5) copies of the revised final printed labeling before you release the product for shipment

Sincerely,



Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

QST 713 Technical

For Use in Manufacturing or Formulating

ACTIVE INGREDIENT

QST 713 strain of dried *Bacillus subtilis* . . . 14.6%
Inert Ingredients 85.4%
Total 100 %

EPA Reg. No. 69592-5
EPA Est. No. 069592-CA-001

U.S. Patent # 6,060,051 on QST 713 strain of *Bacillus subtilis*

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Avoid contact with skin, eyes and clothing. Wash thoroughly with soap and water after handling. Get medical attention if any irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of EPA.

DIRECTIONS FOR USE – General Classification

This product can be used only for formulating end-use products for the control of various fungal plant pathogens. Formulators using this product are responsible for obtaining EPA registration for their formulated products. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STORAGE, DISPOSAL & SPILLS

STORAGE: Do not contaminate water, food or feed by storage or disposal. Do not store this product near fertilizers, seeds, or insecticides or fungicides. Do not store near heat or open flames. Store in a cool dry area above freezing. For safety and prevention of unauthorized use all pesticides should be stored in locked facilities, inaccessible to children.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Do not contaminate water when disposing of equipment wastewater.

CONTAINER DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

CONDITIONS OF SALE AND WARRANTY

AgraQuest warrants that the product conforms to its description on this label and is reasonably fit for the purpose stated on the label only when used in accordance with label directions under normal conditions of use. AGRAQUEST MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES EITHER OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE. Handling, storage and use of the product by Buyer or User are beyond the control of AgraQuest and Seller. Risks such as crop injury, ineffectiveness or other unintended consequences resulting from, but not limited to, weather or soil conditions, presence of other materials, disease, pests, drift to other crops or property or failure to follow label directions will be assumed by the Buyer or User. IN NO CASE WILL AGRAQUEST OR SELLER BE HELD LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE HANDLING, STORAGE OR USE OF THIS PRODUCT.

AgraQuest, Inc., 1538 Dew Avenue, Davis, CA 95616

JUN 20 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act, no pesticide may be sold or distributed in the United States unless it is registered under EPA Reg. No. 69592-5