U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
(7511C)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number: 69697-3

Date of Issuance: 9/20/02

Term of Issuance: Conditional

NOTICE OF PESTICIDE:

x Registration

___ Reregistration

(under FIFRA, as amended)

Name of Pesticide Product:

Sporodex L Biological Fungicide

Name and Address of Registrant (include ZIP Code):

Ms. Amy Roberts (U.S. Agent)
Technology Sciences Group Inc.
1101 17th Street, N.W.
Suite 500
Washington D.C. 20036-4704

FOR: Ms. Jennifer Hale
Plant Products Co.
Brampton, ON L6T 1G1
CANADA

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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. Submit production information for this product to Mr. Owen Beeder of Registration Division (7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.
3. This registration is registered under FIFRA § 3(c)(7)(C) because of the following outstanding data described below.

   A. A complete acute pulmonary toxicity / pathogenicity study (U.S. EPA OPPTS 885.3150) must be conducted using the technical grade active ingredient (TGAI) (*Pseudozyma flocculosa* strain PF-A22 UL) and the sterile filtrate of the production culture. The two acute pulmonary studies that were submitted did not have fully acceptable toxicity and pathogenicity results contained in a single study. Both of these studies were considered supplemental. However, taken together, parts of each study were acceptable for making a

Continued...

Signature of Approving Official: JLH see page 3

Date: 9/20/02

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regulatory decision. That is, the acute pulmonary toxicity/pathogenicity study had acceptable pathogenicity data, but not toxicity data and the acute pulmonary toxicity/pathogenicity range finding study had acceptable toxicity data, but did not address pathogenicity. In addition, the Agency decided that it would be prudent to test the sterile filtrate of the production batch to determine whether there were any toxic components of concern. Testing the sterile filtrate would not have been foreseeable by the registrant and a period reasonable sufficient for generation of the data has not elapsed. Thus, a confirmatory acute pulmonary toxicity / pathogenicity study using the TGAI and testing of the sterile filtrate from the production culture will be required to provide this additional information as a condition of registration. This study must be submitted to the EPA no later than October 3, 2003.

B) Certificates of analysis must be submitted to the Agency prior to the release of all production batches of SPORODEX L biological fungicide (U.S. EPA OPPTS 885-1100 through 885-1600). Bioassay results, conidial, total aerobic flora, enterobacteria, enterococci, fecal coliform, *E. coli*, *Staphylococci* and *Salmonella* counts must be determined for each production batch and be included in each certificate of analysis. Certificates of analysis must be submitted until sufficient consistency with regards to microbial contaminants has been established.

C) Additional storage stability data (OPPTS 830.6317) derived from at least five production-scale or pilot-scale batches are required to ensure product performance and safety during the shelf-life of the product. SPORODEX L Biological Fungicide should be tested over a period of time and in accordance with the desired storage and use conditions appearing on the product label. An interim expiration date of 3 months from the date of manufacture when SPORODEX L Biological Fungicide is stored at -20°C is required until additional data are submitted and approved by the Agency. For consideration of these data prior to the expiration date of the conditional registration, additional data should be submitted to the Agency no later than October 3, 2003.

D) Finally, although a skin sensitization study on the microbial active ingredient *Pseudozyma flocculosa* strain PF-A22 UL was not required by the Agency, the reporting of any incidents of hypersensitivity subsequent to registration is a standard practice for microbial products. The registrant will be expected to report any subsequent findings of hypersensitivity or other health Incident reports under FIFRA section 6(a)2 are to include details such as a description of the MPCA and formulation, frequency, duration and routes of exposure to the material, clinical observations, and any other relevant information. non-expiring unconditional registration under FIFRA section 3(c)5.

4. This registration will automatically expire on midnight September 30, 2004. EPA will reevaluate the data before deciding on whether to convert the conditional registration to a incidents to workers, applicators, or bystanders exposed to the MPCA (microbial pest control agent) as an ongoing condition of registration.

5. Submit five(5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling. A stamped copy of the label is enclosed for your records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Should you have any questions regarding submission of the data, please contact Dr. Sharlene Matten at telephone at 703-605-0514 or by e-mail at matten.sharlene@epa.gov.

cc: Encl.

Sincerely,

Janet L. Andersen, Ph.D.
Director
Biopesticides and Pollution
Prevention Division (7511C)

(Front Panel)

SPORODEX L BIOLOGICAL FUNGICIDE

For Control of Powdery Mildew on Greenhouse Roses and Cucumbers.

COMMERCIAL

READ THE LABEL BEFORE USING

POTENTIAL SENSITIZER

ACTIVE INGREDIENT/GUARANTEE: *Pseudozyma flocculosa* strain PF-A22 UL 1.3%
OTHER INGREDIENTS: 98.7%
TOTAL: 100.0%
(Contains a minimum of 3×10^8 colony forming units/mL)

KEEP OUT OF REACH OF CHILDREN
CAUTION

U.S. EPA Registration No.: 69697-3
U.S. EPA Establishment: 69697-CAN-001

REGISTRATION NUMBER 27161 PEST CONTROL PRODUCTS ACT

Net Contents: 1 L (32 U.S. fl oz)

Manufactured by: Plant Products Co. Ltd.
314 Orenda Road
Brampton, Ontario L6T 1G1, Canada
(905) 793-7000

Distributed by: Plant Products Co. Ltd.
6160 Riverside Drive
Suite 103
Dublin, OH 43017

Lot Number: [XXX]

Date of manufacture: [XXX]
Use within 3 months of the date of manufacture

KEEP FROZEN UNTIL USE

ACCEPTED
[redacted]
In EPA Letter Dated
SEP 20 2002
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.
69697-3

(Back Panel)

PRECAUTIONS / PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. May cause sensitization. Avoid contact with skin, eyes or clothing. Avoid breathing mist. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Applicators and other handlers must wear long-sleeved shirt and long pants, waterproof gloves and shoes plus socks. All mixers/loaders and applicators must wear a dust/mist-filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products. Remove contaminated clothing and follow manufacturer's instructions for cleaning / maintaining PPE before reuse. If no such instructions are available use clothing detergent and hot water for cleaning all washable PPE. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS: Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean highwater mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

FIRST AID	
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • 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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
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 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 do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.

Seek medical attention IMMEDIATELY if irritation occurs and persists or is severe. Have container, label or product name and product registration number with you when calling a poison control center or doctor, or when seeking medical attention.

TOXICOLOGICAL INFORMATION / NOTE TO PHYSICIAN

No specific antidote is available. Treat the patient symptomatically.

DIRECTIONS FOR USE

In the U.S. - It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or thorough drift. Only protected handlers may be in the area during application.

In Canada - NOTICE TO USER: This control product is to be use only in accordance with the directions on this label. It is an offence under the PEST CONTROL PRODUCTS ACT to use a control product under unsafe conditions.

In the U.S. -

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval of 4 hours.

PPE requirement for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is coveralls, waterproof gloves and shoes plus socks.

In Canada -

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. Workers can enter treated areas during the REI if appropriate PPE is worn, including a long sleeved shirt, long pants, shoes plus socks and waterproof gloves as well as a NIOSH approved respirator with any N-95, R-95, P-95 or HE filter for biological products.

GENERAL INFORMATION

SPORODEX L is a naturally occurring fungus which is an antagonist to the powdery mildew disease organism. SPORODEX L is an aqueous liquid formulation of *Pseudozyma flocculosa* formulated to control powdery mildew disease on the listed crops.

APPLICATION RATES

CROP	DISEASE	RATE
Greenhouse roses Greenhouse cucumbers	Powdery mildew disease	**In U.S. and Canada:** 500 mL per 100 L of water. Add 20 mL of an appropriate wetting agent per 100 L of spray mixture. or 64 U.S. fl oz per 100 U.S. gallons of water. Add 3 U.S. fl oz of an appropriate wetting agent per 100 U.S. gallons of spray mixture.

Add SPORODEX L to water. Spray foliage to run-off at weekly intervals, beginning when environmental conditions favor development of powdery mildew, or at first sign of disease.

Apply up to 1500 L of spray mixture per hectare (150 U.S. gallons of spray mixture per acre) for cut roses, cucumbers or about 1000 L per hectare (100 U.S. gallons per acre) for potted roses.

Maintain relative humidity above 70% for 12 hours after application, for example, by using shade curtain or by applying SPORODEX L late in the day or during prolonged cloudy conditions.

NOTE: Use of chemicals at the same time as SPORODEX L may inhibit this product's activity against powdery mildew. Do not tank mix SPORODEX L with chemical pesticides.

SPORODEX L has not been tested for compatibility with all chemical and biological products (including biological control insects and arthropods) used in greenhouse production. For details on compatibility contact the distributor or manufacturer, or test effectiveness on a small number of plants prior to commercial scale use.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store frozen at -20°C (-4°F) or less and keep away from food or feed. Keep product in original container during storage and keep container lid tightly closed when not in use. This product should be used within 3 months of the date of manufacture when stored at -20°C (-4°F). Thaw at room temperature prior to using.

In the U.S.-

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Completely empty package into application equipment. Then dispose of empty package in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. Do not reuse container.

In Canada-
DISPOSAL

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray to the spray mixture in the tank.
2. Follow provincial instruction for any required additional cleaning of the container prior to its disposal.
3. Make the container unsuitable for further use.
4. Dispose of the container in accordance with provincial requirements.
5. For information on the disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

In the U.S. - NOTICE TO USER: Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than indicated on the label. User assumes all risks of use, storage, or handling not in strict accordance with label instructions.

In Canada - NOTICE TO BUYER: Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition.

SPORODEX L is a trademark of Plant Products Co. Ltd.