

42519-24

5/23/2013

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 23, 2013

SciReg Inc.  
12733 Director's Loop  
Woodbridge, VA 22192  
Attn: Frederick T. Smith

Subject: Notification to change the EPA establishment Number and site consistent with the provisions of PR Notice 98-10. New establishment Number & site address to:

**Product name: VITAL.**  
**EPA Reg. No: 42519-24.**  
**EPA Est. No. 42519-ISR-002.**  
**Luxembourg Industries Ltd.**  
**Emek Sarah.**  
**Ramat Hovav, 8551600, ISRAEL.**

Your Submission dated April 18, 2013.

Dear Mr. Smith:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice (PRN) 98-10 dated above. A screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the action requested falls within the scope of this Notice. Our records have been duly noted, and the label submitted with this application has been stamped "Notification Accepted" and will be placed accordingly in our records.

If you have any questions regarding this action, you may contact Mr. Sylvester George at (703) 603-0688 or via e-mail at [george.sylvester@epa.gov](mailto:george.sylvester@epa.gov).

Sincerely,

*Linda A. Hollis*

Linda A. Hollis, Chief  
Biochemical Pesticide Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

2110



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 42519-24	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Vital	PM# 91	
5. Name and Address of Applicant (Include ZIP Code)  Luxembourg-Pamol, Inc. 3647 Willowbend Blvd., Suite 810 Houston, TX 77054  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ <b>Date:</b> <u>5/23/2013</u> Product Name _____ <b>Reviewer:</b> <u>S. George</u>	

**Notification Accepted**

**Section - II**

Amendment - Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_

Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application.

Notification - Explain below.  Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
**Notification consistent with PR Notice 98-10 to change address of producer.**  
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. Per Container	If "Yes" Package wgt. No. Per Container

3. Location of Net Contents Information  
 Label  Container

4. Size(s) Retail Container

5. Location of Label Directions  
 On label.  
 On label accompanying product.

6. Manner in Which Label is Affixed to Product  
 Lithograph  Other  
 Paper glued  
 Stenciled

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name Frederick T. Smith	Title Agent (SciReg, Inc.)	Telephone No. (Include Area Code) 703/434-6500
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**Certification**  
 I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete.  
 I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature 	3. Title Agent (SciReg, Inc.)
4. Typed Name Frederick T. Smith	5. Date 4/18/13

**SciReg, Inc.**  
Science and Regulatory Consultants

April 18, 2013

Ms. Linda Hollis  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Re: Vital (EPA Reg. No. 42519-24):  
Notification consistent with PR Notice 98-10

Dear Ms. Hollis:

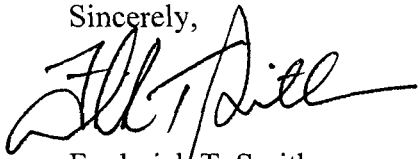
On behalf of Luxembourg-Pamol, Inc., SciReg, Inc. is submitting a notification consistent with PR Notice 98-10 to change the EPA Establishment Number and site address to:

EPA Est. No. 42519-ISR-002  
Luxembourg Industries Ltd.  
Emek Sarah  
Ramat Hovav, 8551600  
ISRAEL

A revised label and CSF are included.

Should you have any questions, please let me know.

Sincerely,



Frederick T. Smith  
Senior Regulatory Specialist

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Enclosures

Date: 5/21/2013

Reviewer: Seyhista Rango

(Front Panel)

# VITAL®

A systemic fungicide for the control of diseases caused by *Peronospora* spp., *Phytophthora* spp. and *Pythium* spp. on turf and ornamentals.

**ACTIVE INGREDIENT:**

Potassium Phosphite\* ..... 54.50%

**OTHER INGREDIENTS:** ..... 45.50%

**TOTAL** ..... 100.00%

\*Phosphorous acid equivalent: 34.30% (4.2 lbs/gal).

## KEEP OUT OF REACH OF CHILDREN CAUTION

### FIRST AID

<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15 – 20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

### HOTLINE NUMBER

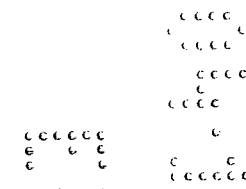
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call 1-800-424-9300.

**See back panel for additional precautionary statements.**

EPA Reg. No.: 42519-24  
EPA Est. No.: 42519-ISR-002

Net Contents: 1, 2.5, or 250 gallons

**Manufactured for:**  
LUXEMBOURG-PAMOL, INC.  
3647 Willowbend Blvd., Suite 810  
Houston, Texas 77054  
**Customer Service (713) 661-8800**  
Batch No. XXXX-XX



**FOR CHEMICAL SPILL, LEAK,  
FIRE OR EXPOSURE CALL  
TOLL FREE: 1-800-424-9300**

**AGRICULTURAL CHEMICAL  
DO NOT SHIP OR STORE WITH  
FOODS, FEEDS, DRUGS OR CLOTHING**

(Back Panel)

**PRECAUTIONARY STATEMENTS**  
**Hazards to humans and domestic animals**

**CAUTION** Harmful if swallowed or if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**Personal Protective Equipment (PPE)**

Applicators and other handlers must wear:

- long-sleeved shirt and long pants,
- waterproof gloves,
- shoes plus socks.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

**User Safety Recommendations**

Users should:

- Remove clothing/PPE immediately after handling this product. Then wash thoroughly and put on clean clothing.
- 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.

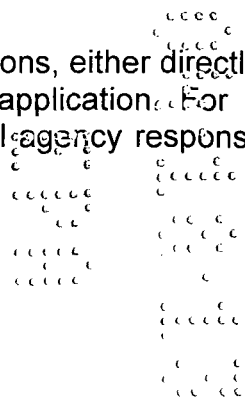
**Environmental Hazards**

For terrestrial uses: 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 when cleaning equipment or disposing of equipment wash water or rinsate.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.



**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 interval. 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 (REI) of 4 hours.

**EXCEPTION:** if the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

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,
- shoes plus socks.

**Non-Agricultural Use Requirements**

The requirements in this box apply to uses of this product that are NOT within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

**General Information:**

VITAL® is a systemic product, which contains potassium phosphite (phosphonate). The phosphonic anion is effective in prevention and control of diseases caused by *Peronospora*, *Phytophthora* and *Pythium*, by fungicidal activity and activation of the plants' natural resistance mechanism. VITAL® is intended for use as part of an Integrated Pest Management (IPM) system. When used in conjunction with good cultural management practices and as part of a complete disease control program, VITAL® will control downy mildew, *Phytophthora*, *Pythium* and *Xanthomonas campestris*. In order to achieve maximum results in controlling the disease, carry out spraying before the appearance of the disease or when disease is first observed. Initiate applications when environmental conditions are favorable for disease development.

**Mixing and Application Instructions:**

Apply in sufficient water to ensure thorough coverage. Fill spray tank halfway with clean water. Add the required amount of VITAL® to the tank as indicated in the table below. While agitating, add the remaining amount of water. Apply solution directly to turfgrass or ornamental foliage, unless directed otherwise in the **DIRECTIONS FOR USE**. For optimum control, thorough coverage is required. Do not apply this product through any type of irrigation system.

**Compatibility:**

VITAL® is believed to be compatible with most commonly used pesticides. Consult specific product labels for additional information. Conduct a tank spray compatibility test when you plan to mix this product with other products. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, and then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding products to the spray tank.

Test the tank-mix combinations on a small number of plants before treating large areas, as the sensitivity of plants to these mixtures may vary.

VITAL® has been evaluated for phytotoxicity on a large variety of plants under various normal field conditions. However, testing all plant species, in all mixtures and combinations is not feasible. Where feasible, test for phytotoxicity a small portion of the area to be treated, prior to treating the entire area.

**Application Rate:**

Begin spraying when environmental conditions are favorable for the development of disease or as indicated below. Do not apply above the recommended rates.

Use Site	Disease	Rate	Application Interval	Remarks
Turf <sup>2</sup>	<i>Pythium</i>	3-4 fl. oz. per 1000 sq. ft.	7-14 days	Use the low rate program when applications are started early in the season or when tank mixing multiple products under high temperatures (>90°F)

		4-6 fl. oz. per 1000 sq. ft.	14 days	Begin preventative applications when conditions first favor blight. As disease pressure increases, increase the rate of VITAL®.
	Yellow Tuft	12 fl. oz. per 1000 sq. ft.	21 days	Repeat at recommended interval. Do not mow or water treated areas until foliage is completely dry.
<b>Bedding Plants</b> FOLIAR APPLICATION	<i>Downy Mildew</i>	4 pints/100 gallons of water	7 days	Plants such as Begonia, Geranium, Impatiens, Marigold, Pansy, Petunia, Phlox, Salvia, Snapdragon, Verbena, Vinca and Zinnia. Spray to wet.
	<i>Phytophthora</i> <i>Pythium</i> spp.	2-4 pints <sup>1</sup> /100 gallons of water	14 days	
<b>Conifers in Nurseries</b> DIP at Transplanting	<i>Phytophthora</i> <i>Pythium</i> spp.	4 pints/100 gallons of water	14 days	Plants such as Douglas fir, spruce and pines. Thoroughly wet plant and root mass.  Spray to wet using no more than 400 gallons per acre.
FOLIAR APPLICATION		2-4 pints <sup>1</sup> /100 gallons of water		
<b>Ornamentals</b> FOLIAR APPLICATION	Downy Mildew	4 pints/100 gallons of water	7 days	Plants such as Aglaonema, Aphelandra, Azalea, Bougainvillea, Boxwood, <i>Cattelya skinneri</i> , Cissus, Dieffenbachia, Hibiscus, Juniper, Leather Leaf Fern, Pittosporum, Philodendron, Pothos, Rhododendron, Spathiphyllum, and <i>Taxus media</i> , English Ivy, Schefflera athurium, Syngonium fills.  Plants such as Aphelandra, Azalea, Boxwood, Cissus, Dieffenbachia, Japanese Holly, Monterey Pine, Philodendron, Pieris, Pittosporum, Rhododendron, Schefflera, Spathiphyllum, and <i>Taxus media</i> .  Plants such as Rhododendron, Azalea, or Pieris. Apply immediately prior to potting. Follow this with FOLIAR APPLICATION (ORNAMENTALS) as needed.
	<i>Phytophthora</i> <i>Pythium</i> spp. <i>Xanthomonas campestris</i>	2-4 pints <sup>1</sup> /100 gallons of water	14 days	
	DRENCH APPLICATION	<i>Phytophthora</i> <i>Pythium</i> spp.	0.65 to 1.25 pints <sup>1</sup> /100 gallons of water per 400 sq. ft.	
SOIL INCORPORATION	<i>Phytophthora</i>	0.80 to 1.25 pints <sup>1</sup> per cubic yard of soil mix	30 days	
<b>Roses</b> FOLIAR APPLICATION	Downy Mildew	4 pints/100 gallons of water	7 days	In field, container, or landscape in conjunction with disease sanitation. Spray to wet using no more than 400 gallons per acre.



<p><b>Oak<sup>3</sup></b> TREE INJECTION</p>	<p><i>Phytophthora ramorum</i></p>	<p>Measure the area under the tree canopy. Apply 0.034 fl. oz. (1ml.) of Vital® in 0.68 fl. oz. (20ml.) water for each 10 square feet of area under the canopy. Divide the total amount needed per tree by the number of syringes or injections to be used.</p>	<p>Not more than one application per year</p>	<p>Tree Preparation:</p> <ol style="list-style-type: none"> <li>1. Carefully remove 2-4 inches of soil from the base of the tree to uncover the top of the root flares.</li> <li>2. Drill holes through the bark into the sapwood under the root flares. Drill-hole diameter (typically 3/16-5/16 inch) must be adequate to allow insertion of syringe or injection tee and formation of airtight contact between active xylem and delivery point of the injection. The key is to deliver the product to the active xylem. Space holes 3-6 inches apart around the base of the tree with a slight downward angle into only healthy tissue.</li> <li>3. Disinfect the drill bit with Lysol® or 20% Clorox® between trees. Inject only Vital® and water.</li> </ol>
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**Notes:**

- 1 Use the higher rate when conditions favor disease development and/or with increased disease pressure.
- 2
  - Do not apply to turf under stress or during severe weather conditions, such as very high temperatures.
  - Do not mow or apply water to treated areas until the foliage is completely dry.
  - Do not apply above the recommended rates.
  - Use a shorter spray interval and a higher rate under high disease pressure.
  - When Vital® is applied to stressed turf, in combination with several products in the same spray tank, there is a risk of causing tip burn. This tip burn is temporary and usually disappears after 3-5 days. Use the following strategies to mitigate tip burn when using multiple product applications: 1) not mowing immediately before application, 2) spraying early in the day, 3) lightly watering before application, and 4) watering 2-4 hours after product application.
  - Application made during periods of extreme stress (temperature, water or other environmental factors) may cause temporary discoloration. Discoloration is short term, and will be removed in 1-4 mowings.
- 3 Not for use in New York State.

**Important:**

Do not apply on plants when they are under water stress, or during severe weather conditions such as high or very low temperatures.

**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Store in a dry, cool place.

**Pesticide Disposal:** To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

**Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.

Container sizes of 5 gallons or less: Triple rinse as follows: Empty the remaining contents into the application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Container sizes greater than 5 gallons: Triple rinse as follows: Empty the remaining contents into the application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Then offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**Warranty Limitations and Disclaimer**

To the extent consistent with applicable law, Luxembourg warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. To the extent consistent with applicable law, Luxembourg EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer assumes all risk of use of this material when such use is contrary to label instructions. Read and follow the label directions carefully.

Vital® is a registered trademark of Luxembourg Industries Ltd.

Clorox® is a registered trademark of The Clorox Co.

Lysol® is a registered trademark of Reckitt Benckiser Inc.

