

42519-34

03/07/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Luxembourg-Pamol, Inc.
c/o Frederick T. Smith
Senior Regulatory Specialist
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

MAR - 7 2013

Subject: Application for Pesticide Notification (PRN 98-10)
Submission date: 2/13/2013
Product Name: ProSoy PPT
EPA Reg. No.: 42519-34
EPA Decision Number: 475424

Dear Mr. Smith:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10.

The Agency acknowledges the update to the EPA Establishment Number and the site address.

The Confidential Statement of Formula (CSF) and label submitted with the application have been stamped "Notification" and will be placed in our records. If you have questions concerning this letter, please contact Heather Garvie at 703-308-0034 or me at 703-305-5410.

Sincerely,

A handwritten signature in black ink, appearing to read "Hope A. Johnson".

Hope A. Johnson
Acting Product Manager 21
Fungicide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42519-34	2. EPA Product Manager C. Giles-Parker	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ProSoy PPT	PM# 21	
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. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> 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:				2. Type of Container	
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		<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 <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph	<input type="checkbox"/> Paper glued	<input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____

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) 703/494-6500	
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 2/13/13			

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SciReg, Inc.
Science and Regulatory Consultants

February 13, 2013

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

Re: ProSoy PPT (EPA Reg. No. 42519-34):
Notification consistent with PR Notice 98-10

Dear Ms. Giles-Parker:

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

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A revised label and CSF are included.

Should you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

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NOTIFICATION
MAR 07 2013

Outer Label

(Front Panel)

ProSoy PPT

A systemic fungicide for the control of soybean diseases

Component A

Component B

ACTIVE INGREDIENT:	
Potassium Phosphite*	54.50%
OTHER INGREDIENTS:	45.50%
TOTAL	100.00%
*Phosphorous acid equivalent: 34.30% (4.2 lbs/gal).	

ACTIVE INGREDIENT:	
Tebuconazole*	38.70%
OTHER INGREDIENTS:	61.30%
TOTAL:	100.00%
Contains 3.6 pounds tebuconazole per gallon.	
* α -[2-(4-chlorophenyl)ethyl]- α -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol	

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID

If swallowed	<ul style="list-style-type: none"> • Call 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none"> • 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 on skin or clothing	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical information.

NOTE TO PHYSICIAN

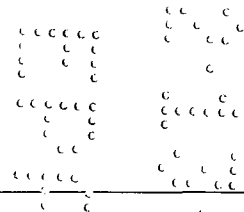
No specific antidote. Treat symptomatically. For additional information, call: 1-800-424-9300.

See side panel for additional precautionary statements.

EPA Reg. No.: 42519-34
EPA Est. No.: 42519-ISR-002

Net Contents: 3.75 Gallons Component A
30 Fl. Oz. Component B

Manufactured for:
LUXEMBOURG – PAMOL, INC.
3647 Willowbend Blvd., Suite 810
Houston, Texas 77054, U.S.A.
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

PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals: Caution: Harmful if swallowed or if absorbed through skin. Causes eye irritation. Avoid contact with skin, eyes or clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- Chemical-resistant gloves (such as nitrile, butyl, neoprene, and/or barrier laminate)
- shoes plus socks

Follow 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: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove clothing immediately if pesticide gets inside, 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 disposing of equipment washwater or rinsate.

Tebuconazole is toxic to mammals, fish, and aquatic invertebrates. Runoff may be hazardous to aquatic organisms in neighboring areas.

Ground Water Advisory: Tebuconazole is known to leach through soil into groundwater under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

Surface Water Advisory: Tebuconazole may contaminate water through drift of spray in wind. It has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to runoff that contains this product. A level, well-maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted within 48 hours.

DIRECTIONS FOR USE

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 State or tribal agency responsible for pesticide regulation. 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.

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 (REI) of 12 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
- chemical-resistant gloves (such as nitrile, butyl, neoprene, and/or barrier laminate)
- shoes plus socks

Chemigation: Do not apply this product through any type of irrigation system.

Requirements for ground applications:

For ground applications, adjust nozzle height and droplet size with wind speed according to the following table:

Wind speed	Nozzle height	Droplet size for standard nozzles (ASAE standard 572)
Less than 10 mph	Up to 2 feet	medium or coarser
	2-4 feet	coarse or coarser
	4-6 feet	very coarse or coarser
10 to 15 mph	0-2 feet	coarse or coarser
	2-4 feet	very coarse or coarser
	4-6 feet	extremely coarse

Do not apply only when the wind speed exceeds 15 mph. Do not apply at a nozzle height of greater than 6 feet above the ground or crop canopy. Apply as a medium or coarser spray (ASAE standard 572).

Requirements for aerial applications:

For aerial applications, apply only when the wind speed is less than or equal to 15 mph using a release height of no more than 10 feet above the ground or crop canopy. If the wind speed is less than 10 mph, apply as a medium or coarser spray (ASAE standard 572). If the wind speed is between 10 mph and 15 mph, apply as a coarse or coarser spray (ASAE standard 572). The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter. Do not make aerial applications into temperature inversions. When aerial applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.

Spray Drift Management:

Aerial applications: The spray boom should be mounted on the aircraft so as to minimize drift caused by wing tip vortices. The minimum practical boom length should be used, and must not exceed 75 percent of the wingspan or rotor diameter. Use the largest droplet size consistent with pest control. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible and by avoiding excessive spray boom pressure. Apply in a minimum of 5 gallons of spray solution per acre by aircraft spray equipment. Spray should be released at the lowest possible height consistent with good pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided. Make aerial and ground applications when wind velocity favors on-target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 15 mph (miles per hour). Avoid applications when wind gusts approach 15 mph. Risk of exposure to sensitive aquatic areas can be reduced by avoiding applications when wind direction is toward the aquatic area. Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of spray drift to aquatic areas. Avoid spraying during conditions of low humidity and/or high temperature. Do not make aerial or ground applications during temperature inversions. Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface.

OBSERVE THE FOLLOWING PRECAUTIONS WHEN SPRAYING IN THE VICINITY OF AQUATIC AREAS SUCH AS LAKES, RESERVOIRS, RIVERS, PERMANENT STREAMS, MARSHES OR NATURAL PONDS, AND ESTUARIES.

- Apply only during alternate years in fields adjacent to aquatic areas listed above.
- Do not apply by ground or air within 100 feet of aquatic areas listed above.
- Do not cultivate within 10 feet of an aquatic area to allow growth of a vegetative filter strip.

Rotational Crop Restrictions:

Treated areas may be replanted with peanuts, soybeans, sunflowers, wheat, and barley as soon as practical after last application. Any other crop may be planted into treated areas 120 days after last application.

General Information:

ProSoy PPT is a systemic product. When used in conjunction with good cultural management practices and as part of a complete disease control program, ProSoy PPT will control soybean downy mildew and rust. In order to achieve maximum results in controlling the diseases, spraying should be carried out before the appearance of the diseases or when diseases are first observed. Begin applications when environmental conditions are favorable for disease development.

Mixing and Application Instructions:

Apply the finished spray solution in a minimum of 20 gallons per acre by ground sprayer or in a minimum of 10 gallons of spray solution per acre by aircraft spray equipment. Check equipment calibration frequently. Complete coverage and uniform application are essential for the most effective results, especially when lower spray volumes are applied. If necessary, increase the spray volume per acre for complete crop coverage.

Fill spray tank halfway with clean water. Add the required amount of Component A and B to the tank as indicated in the Application Instructions. While agitating, add the remaining amount of water. Apply solution directly to foliage. For optimum control, thorough coverage is required.

Compatibility:

Consult specific product labels for additional information on compatibility. It is always advisable to 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. Follow the more restrictive requirements of any tank mix partner. Do not tank mix with any product which contains a prohibition on tank mixing.

Phytotoxicity indications:

The components of this product have been evaluated for phytotoxicity on a large variety of crops under various normal field conditions. However, testing all soybean varieties, in all mixtures and combinations is not feasible. Test a small portion of the area to be treated for phytotoxicity, before treating the entire area. Test tank-mix combinations on a small number of plants before treating large areas, as crop sensitivity to these mixtures may vary. Do not apply to plants under stress.

DISEASE CONTROL AND APPLICATION INSTRUCTIONS

This combination product is only for use on soybeans to control soybean rust (*Phakopsora pachyrizi*), downy mildew (*Peronospora manshurica*) and powdery mildew (*Microspheera diffusa*). One box will treat up to 15 acres (1 quart of Component A plus 2 fl. oz. of Component B per acre). Individual use of either component alone is prohibited. Start applications at flowering. Repeat on a 10 - 21 day interval. Under severe disease pressure, use one box to treat 7.5 acres.

Do not make more than 2 applications of a tebuconazole-containing product to soybeans per season. A maximum of 8 fl. oz. of ProSoy PPT Component B (0.225 lb tebuconazole ai) may be applied per acre per crop year. Do not apply more than 0.225 pounds of the active ingredient tebuconazole per acre per year. Do not apply within 30 days of harvest. Do not feed soybean forage or hay to livestock.

STORAGE AND DISPOSAL

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

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

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

Container Handling: Nonrefillable containers. Do not reuse or refill these containers. Triple rinse (or equivalent) promptly after emptying. 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 1/4 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. Then offer for recycling, if available, or puncture or dispose of in a sanitary landfill, or by incineration. Do not burn unless allowed by state and local ordinances. Outer box may be disposed of in a sanitary landfill or recycled.

Warranty Limitations and Disclaimer

To the extent consistent with applicable law, Luxembourg warrants 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. 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. To the extent consistent with applicable law, Buyer assumes all risk of use of this material when such use is contrary to label instructions. Read and follow the label directions carefully.

