LUXEMBOURG

December 12, 2017 By E-Mail and by courier service

Document Processing Desk (DCI/PRD)
Attn: Brian Kettl
US EPA (7508P)
One Potomac Yard (South Building)
2777 S. Crystal Drive
Arlington VA 22202-3553

Re: Luxembourg-Pamol, Inc. Response to Tebuconazole Data-Call-In

Dear Mr. Kettl:

This letter responds to the Data Call-In of the US Environmental Protection Agency (US EPA) for the active ingredient tebuconazole. Luxembourg-Pamol, Inc. (Luxembourg) will comply with the requirements listed in EPA Form 6300-3, except for those requirements that are relevant to support antimicrobial uses. Luxembourg's label does not included antimicrobial uses (see attached label).

Luxembourg has agreed to share the cost of the studies with other registrants. A cost sharing agreement is currently being prepared.

If you have any questions, please do not hesitate to contact me at (212) 495-9717 or by e-mail at meldan@luxpam.com.

Sincerely,

M. Eldan

Michal Eldan, PhD
VP, Health and Environment
Tel: (212) 495-9717
Email: meldan@luxpam.com

Attachments

CC. David Luxembourg
Sheryl Dolan, B&C

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LUXEMBOURG-PAMOL, INC. ~~12733 DIRECTORS LOOP~~ ~~WOODBRIDGE, VA 22192~~ 3641 Willowbend Blvd., Suite 810 Houston, TX 77054	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data Requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirement on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirement on the attached form entitled "Requirements Status and Registrant's Response."
42519-27			V	N/A	N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative M. Eldefrawi VP Health & Environment

9. Date 12/12/2017

10. Name of Company Luxembourg-Pamol, Inc.

11. Phone Number 212-495-9717

ED_002206_00005421-00003

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LUXEMBOURG-PAMOL, INC. ~~12733 DIRECTOR'S LOOP~~ ~~WOODBRIDGE, VA 22192~~ 3647 Willowbend Blvd, Suite 810 Houston, TX 77054	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Applicator Exposure Data Requirements (Conventional Chemical)									
875.1200	Dermal exposure--Indoor	(15, 19, 41)	Y				A,C,Q,X,BB	TEP	12	9
875.1400	Inhalation exposure--indoor	(15, 19, 41)	Y				A,C,Q,X,BB	TEP	12	4
875.1700	Product Use Information	(15, 22)	N				A,C,Q,X,BB	TEP	12	9
	Nontarget Plant Protection Data Requirements (Conventional Chemical)									
850.4100	Seedling Emergence and Seedling Growth	(6, 14)	N				A,C,Q,X,BB	TEP	12	2
850.4150	Vegetative Vigor	(7, 14)	N				A,C,Q,X,BB	TEP	12	2
	Post-Application Exposure Data Requirements (Conventional Chemical)									
875.2100	Foliar dislodgeable residue dissipation	(14, 28)	N				A,C,Q,X,BB	TEP	12	2
875.2300	Indoor surface residue dissipation	(15, 17, 39, 41)	Y				A,C,Q,X,BB	TEP	12	9

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Washington, D.C. 20460

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LUXEMBOURG-PAMOL, INC. ~~12733 DIRECTOR'S LOOP~~ ~~WOODBRIDGE, VA 22192~~ 3647 Willowend Blvd, Suite 810 Houston, TX 77054	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)									
850.2100	Avian acute oral toxicity test	(14, 23)	N				A,C,Q,X,BB	TGAI	12	2
850.3020	Honey bee acute contact toxicity	(8, 14, 21)	N				A,C,Q,X,BB	TGAI	12	2
850.3030	Honey bee toxicity of residues on foliage	(2, 9, 14, 41)	Y				A,C,Q,X,BB	TEP	12	2
850.3040	Field testing for pollinators	(1, 3, 14, 20, 41)	Y				A,C,Q,X,BB	TEP	24	2
835.1110	Activated sludge sorption isotherm	(15, 34)	N				A,C,Q,X,BB	TGAI	12	9
835.3110	Ready biodegradability	(15, 33)	N				A,C,Q,X,BB	TGAI	12	9
835.3220	Porous pot test	(15, 32)	N				A,C,Q,X,BB	TGAI	12	9
835.3240	Simulation Test-Aerobic Sewage Treatment-Activated Sludge	(15, 31)	N				A,C,Q,X,BB	TGAI	12	9

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Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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EPA FORM 6300-3

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1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LUXEMBOURG-PAMOL, INC. ~~12733 DIRECTOR'S LOOP~~ ~~WOODBRIDGE, VA 22192~~ 3647 Willowbend Blvd., Suite 810 Houston, TX 77054	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1598

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals	(15, 30)	N				A,C,Q,X,BB	TGAI	12	9
850.3300	Modified Activated Sludge, Respiration Inhibition Test	(15, 18, 24, 29)	N				A,C,Q,X,BB	TGAI	12	9
850.4500	Algal Toxicity	(16, 25, 38)	N				A,C,Q,X,BB	TGAI, TEP	12	2
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity	(16, 25)	N				A,C,Q,X,BB	TGAI, TEP	12	2
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation	(14, 35)	N				A,C,Q,X,BB	TGAI	12	2
SS-1196	Whole Sediment: Chronic toxicity to saltwater invertebrates	(16, 37, 41)	Y				A,C,Q,X,BB	TGAI	24	2
SS-1197	Whole Sediment: Chronic toxicity to freshwater invertebrates	(16, 36, 41)	Y				A,C,Q,X,BB	TGAI	24	2
SS-1311	Honey bee adult acute oral toxicity	(10, 14)	N				A,C,Q,X,BB	TGAI	12	2
SS-1312	Honey bee larvae acute oral toxicity	(13, 14)	N				A,C,Q,X,BB	TGAI	12	2

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Washington, D.C. 20460

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LUXEMBOURG-PAMOL, INC. ~~12733 DIRECTOR'S LOOP~~ ~~WOODBRIDGE, VA 22192~~ 3692 Willowbend Blvd, Suite 810 Houston, TX 77054	N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	14-Sep-2017 GENERIC ID # GDCI-128997-1596

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6 Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
SS-1313	Honey bee adult chronic oral toxicity	(11, 14, 41)	Y				A,C,Q,X,BB	TGAI	12	2
SS-1314	Honey bee larvae chronic oral toxicity	(12, 14, 41)	Y				A,C,Q,X,BB	TGAI	12	2
SS-1315	Semi-field testing for pollinators	(5, 14, 26, 27, 41)	Y				A,C,Q,X,BB	TGAI, TEP	24	2
SS-1316	Field trial of residues in pollen and nectar	(4, 14, 40)	Y				A,C,Q,X,BB	TEP	24	2

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Tegrol® Technical

For manufacturing or formulating use only

ACTIVE INGREDIENT:

Tebuconazole:

α -[2-(4-chlorophenyl)-ethyl]- α -(1,1-dimethylethyl)-1*H*-1,2,4-triazole-1-ethanol ..... 98.1 %

OTHER INGREDIENTS: ..... 1.9 %

TOTAL: ..... 100.0 %

STOP - Read The Label Before Use

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

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 swallowed: Call a poison control center or doctor immediately for treatment advice. Have a 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 to an unconscious person.

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.
Call a poison control center or doctor for treatment advice.

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.

In case of medical emergency, also call toll free 1-800-424-9300.
NOTE TO PHYSICIAN: No specific antidote is available. Treat symptomatically.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND FOR DIRECTIONS FOR USE

EPA Reg. No. 42519-27

EPA Est. No. 81092-CHN-001

Net contents: **500 kg** (1102.3 lbs)

Made in China

Manufactured for
LUXEMBOURG-PAMOL, INC.
3647 Willowbend Boulevard, Suite 810
Houston, TX 77054, Tel. 877-343-4239
Customer Service: 713-661-8800

LUXEMBOURG

00032-7/160510_1/1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING

May be fatal if inhaled. Harmful if swallowed. Causes moderate eye irritation. Do not breathe dust and avoid contact with eyes and clothing. Wear a NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number prefix TC-84A, or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to estuarine invertebrates.
Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into 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

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

For manufacturing and formulating only into end-use fungicides for the following uses: almonds, apples, asparagus, barley (foliar treatment only), beans, garden beets, corn, cucurbit vegetables group, grapes, dry and green bulb onion groups, hops, leafy brassica vegetables group, lychee, okra, peanuts, pecans, pistachios, soybeans, stone fruit (crop group 12), sunflowers, turf (golf course only), turnips, walnuts, wheat (foliar treatment only), and grasses grown for seed.
Detailed information on chemical and physical properties and other formulating recommendations for Tegrol® Technical are available upon request from Luxembourg-Pamol. Obtain and read this information before undertaking the formulation of Tegrol® Technical in order to avoid formulation hazards and insure a satisfactory finished product.
Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency.
For specific information on federally registered uses, contact Luxembourg-Pamol. Any variance from the federally registered labeling for products containing Tegrol® Technical will have to be supported by data provided by the formulator.

This product may be used to formulate products for any additional uses not listed on the MP label if the formulator, user group, or grower has complied with EPA data submission requirements regarding the support of such use(s).

RESTRICTIONS

DO NOT PACKAGE TEGROL® TECHNICAL IN METAL CONTAINERS.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food and feed.
Store in original container and out of reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away.
You may contact 1-800-424-9300 for assistance.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law.
If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste Representative at the nearest U.S. EPA Regional Office for guidance.

Container Handling: Nonrefillable Container: Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.
Empty the remaining contents into 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 or reconditioning, 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

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 fullest extent permitted by 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.

Tegrol® is a trademark of Luxembourg Industries Ltd.

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