SEP 1 1 2009

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

#### SEPA United States: Environmental Protection Office of Pesticide Programs

( 09-11-2009

Janssen PMP a Division of Janssen Pharmaceutical NV 1125 Trenton-Harbourton Road Titusville, N. J. 08560-0200

Attention: William R. Goodwine, Director Regulatory Affairs and Product Development

## Subject: ECONEA Technical EPA Registration No. 43813-27 Notification Dated August 10, 2009

This will acknowledge receipt of your notification of label change per PR Notice 2007-4 and PR Notice 83-3, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification dated November 4, 2008 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

arthe Larry / for

Marshall Swindell Product Manager (33) Regulatory Management Branch 1 Antimcrobials Division (7510P)

United States       Registration       OPP Identifier         Environmental Protection Agency	No. 2070-0060	n Approved. OMB No. 2070-			g form.	verse before completing	Tease read instructions on rev
Company/Product Number       2. EPA Product Manager       3. Proposed Classific         Adstall Swindell       X markall Swindell       X markall Swindell         Amstall Swindell       X markall Swindell       X mone         Company/Product Name       S. Expedited Review. In accordance with FIFRA Section folkil, my product is similar or identical in composition and to:       Section - II         Amson Market State       Product Name       EPA Reg. No.         Product Name       Product Name         Resubmission in response to Agency letter dated       Market Section - II         Monflament - Explain below.       Final printed lebies in response to Agency letter dated         Monflament - Explain below.       Other - Explain below.         Resubmission in response to Agency letter dated       Other - Explain below.         X Notification - Lebic Idance par PR Notice 2007-4. This notification is consistent with the quirements of Approver and to the labeling or the Confidential State Change par PR Notice 2007-4. This notification is consistent with the quirements of Augency letter section 1 and Section 11.         Notification of Idation of the Iso Chain of the Iso Chain or Hold Package and Iso Confidential State Chain of Hold Section 150.01.56.140, 156.144, 156.145.156.156.100. OCR 156.10, 156.144, 156.145.156.156.100. OCR 156.100, 156.144, 156.145.156.156.156.100. CR 156.100, 156.144, 156.145.145.156.156.156.100. CR 156.100.156.144, 156.145.156.156.100.01 and packaging         Yes       Yes       No.       Prestripa	fier Number	1	Amendment	· –	<b>Protection Age</b>	Environmental	₽PA
43813-27       Marshall Swindell       X       None       X         Company/Product (Namie)       PMe       33       X			tion I	esticide - Section	Application for		
CompanyProduct (Name)     Content Product (Name)     Product Name)     Section - II     Amendment - Explain below.     Content Enformation     Yes     Ye	Restricted	3. Proposed Classification					
Neme and Address of Applicent (include ZiP Code)         Janssen PMP, a Division of Janssen Pharmaceutica, N.V.         125 Trenton-Harbourton Road         Check if this is a new address         Check if this is a new address         Product Name         Besubmission in response to Agency latter dated         Yes         Notification - Explain below.         Resubmission in response to Agency latter dated         ''Me Tool" Application.         Other - Explain below.         Resubmission in response to Agency latter dated         ''Me Tool" Application.         Other - Explain below.         Conditional to the labeling or the	Nestricted	PM#					
Section - II         Amendment - Explain below.       Final printed labels in response to Agency letter dated         Resubmission in response to Agency letter dated       "Me Toe" Application.         Notification - Explain below.       Other - Explain below.         Xhotification - Explain below.       Other - Explain below.         Xhotification - Explain below.       Other - Explain below.         Xhotification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the require PA's regulations at 40 CPR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that if is a violation of 18 U.S.C. Sec. 1001 to willifully make any false states.         CPA's regulations at 40 CPR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Statement of Formula for this product. I understand that if is a violation of 18 U.S.C. Sec. 1001 to willifully make any false states.         PA's regulations at 40 CPR 156.10, 156.140, 156.140, 156.144, 156.146         State in the requirements of 40 CFR 156.10, 156.144, 156.146         State in the requirements of 40 CFR 156.10, 156.144, 156.146         Material This Product Will Be Packaged In:         Initial Assistant Packaging       Unit Packaging wgt. container         Yes       No         No       Yes"         No       Sizels) Retal Container	ind labeling	in composition and label	is similar or identical in coi	(b)(i), my product is to: EPA Reg. No	E.	n of Janssen Pharn on Road 00	Janssen PMP, a Division 1125 Trenton-Harbourto Titusville, NJ 08560-020
Amendment - Explain below.       Final printed liabels 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 pegeloi if necessary. (For section I and Section II.)         Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the require PA's regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that if is a violation of 18 U.S.C. Sec. 1001 to willifully make any false stateer.         EPA. Further understand that if the amended label is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.144         156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of Section - III         It may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of Section - III         It may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of Section - III         It may be additioned pegeloging       Yes         Yes       No         Package wgt       Soction - III         It design if Yes       No. per Package wgt         It may be submitted       A sizets) Restal Container					Sec		
Material This Product Will Be Packaging     Unit Packaging     Yes     Yes     No     Yes     Yes     No     Yes     Yes     No     Yes     Yes     No     Yes     Yes     No     Yes     Yes     No     Yes     Yes     Yes     No     Yes     Yes	the statement to 5.146, and	e to the labeling or the ully make any false stateme .140, 156.144, 156.146, an	uidance in PR Notice 2007-4 anges have been made to the S.C. Sec. 1001 to willfully ma of 40 CFR 156.10, 156.140, 1	Other - Explain tion II.) consistent with the guid i6.156. No other changes a violation of 18 U.S.C h the requirements of 4	<ul> <li><b>For section I and Set</b></li> <li><b>This notification is</b></li> <li>144, 156.146, and 1</li> <li>I understand that it below is not consistent w</li> </ul>	below. al page(s) if necessary a per PR Notice 2007- R 156.10, 156.140, 15 ormula for this produc hat if the amended lat	X Notification - Explain X Notification - Explain X Notification: Use addition Notification of label change EPA's regulations at 40 CFI Confidential Statement of FI EPA. I further understand to
Child Resistant Packaging       Unit Packaging       Water Soluble Packaging       2. Type of Container         Yes       No       Yes       No       Plastic         Certification must       If "Yes" Unit Packaging wgt.       No. per container       No. per container       No. per container       No. per container       Paper Paper         A Location of Net Contents Information       4. Size(s) Retail Container       5. Location of Label Directions       Other (Specify) Plastic if Other         X       Lobel       Container       110 lbs (50 kg)       Other       Other         Manner in Which Label is Affixed to Product       Withograph Stencifed       Other       Section - IV         . Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this explication.)       Telephone No. (Include A (609) 730-2607         Iame       Title       Senior Director, Regulatory Affairs & Product Development       6. Date Applic RecUrve RecUrv				ion - III	Sec		
Yes       Yes       Yes       Motei         No       No       No       No       No       Pession         Certification must       If "Yes"       No. per       Container       No. per       Container         No       If "Yes"       No. per       Container       No. per       Container       Peper         A costion of Net Contents Information       4. Size(s) Retail Conteiner       5. Location of Label Directions         X       Label       Container       110 lbs (50 kg)       Container         Manner in Which Label is Affixed to Product       Withograph       Other       Other         Section - IV       . Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)       Telephone No. (Include A (609) 730-2607         Iame       Title       Senior Director, Regulatory Affairs & Product Development       (609) 730-2607         Kertification       Leartify that the statements I have made on this form and all attachments thereto are true, accurate and complexitors of RecCives on this form and all attachments thereto are true, accurate and complexitors of the Applic RecCives on this form and all attachments thereto are true, accurate and complexitors of the Applic RecCives on this form and all attachments thereto are true, accurate and complexitors of the Applic RecCives on the complexitors of the Applic Recives on the complexitors on this form and all attachments thereto are tr				· · · · ·		Be Packaged In:	. Material This Product Will
. Location of Net Contents Information       4. Size(s) Retail Container       5. Location of Label Directions         X       Lebel       Container       110 lbs (50 kg)       Image: Container         Manner in Which Label is Affixed to Product       Image: Container       Other       Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this epplication.)         . Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this epplication.)         Iame       Title         William R. Goodwine       Title         Lecrify that the statements I have made on this form and all attachments thereto are true, accurate and complete: or operation.	tic lined fier drum	latel lastic lass eper	Metal Plastic Glass Paper	Yes No No. per	No. per If "Ye	X No	Yes No
Kanner in Which Label is Affixed to Product     Manner in Which Label is Affixed to Product     Section - IV     Section - IV     Section - IV     Manner     Milliam R. Goodwine     Title     Senior Director, Regulatory Affairs & Product Development     (609) 730-2607     Certification     Leertify that the statements I have made on this form and all attachments thereto are true, accurate and completers of	<u></u>	Directions	lr ı	vor 5			Location of Net Contents I
Section - IV . Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Iame William R. Goodwine L certify that the statements I have made on this form and all attachments thereto are true, accurate and completers of RecCived of Certification			in the second sec	Other	Lithograph		
I. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)         Iame       Title         Villiam R. Goodwine       Senior Director, Regulatory Affairs & Product Development       (609) 730-2607         Certification       6. Date Applic         I certify that the statements I have made on this form and all attachments thereto are true, accurate and completers of the statements I have made on this form and all attachments thereto are true, accurate and completers of the statements I have made on this form and all attachments thereto are true, accurate and completers of the statements I have made on this form and all attachments thereto are true, accurate and completers of the statements I have made on the statements I have made on the statements I have made on the form and all attachments thereto are true, accurate and completers of the statements I have made on the form and all attachments thereto are true.				on - IV			
lame Title Senior Director, Regulatory Affairs & Product Development (609) 730-2607 Certification L.certify that the statements I have made on this form and all attachments therato are true, accurate and completers of RecCived of		ss this application 1	if nacessary, to process this			items directly halow f	Contect Point Complete
Certification Leartify that the statements I have made on this form and all attachments thereto are true, accurate and complaters of Received of		ephone No. (Include Area C	Telephone		Title		lame
l acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment of the starms both under applicable law.	្ត្រីប	6. Date Application Recived o	e, accurate and complateso o	ments thereto are true,	Certification this form and all attact	nents I have made on y knowlinglly false or r	I certify that the staten I scknowledge that any
2. Signature Milliam R. Loodwine Senior Director, Regulatory Affairs & Product Development	ບ ບຸບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ ບ	provent (), v j č	fairs & Product Development	rector, Regulatory Affair		11	
J. Typed Name     5. Date     دینین اللہ اللہ اللہ اللہ اللہ اللہ اللہ الل	ς. υ		00000	uet 10 200	5. Date	·	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Yellow Applicant Copy

# **ECONEA<sup>®</sup>** Technical

Anti-fouling Preservative

# For Formulating Use Only

ACTIVE INGREDIENT: Tralopyril*	93.2%
INERT INGREDIENTS:	6.8%
TOTAL:	100.0%

TOTAL:

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. . . .

\* CAS# 122454-29-9

# **KEEP OUT OF REACH OF CHILDREN**



DANGER

POISON

See side panel for first aid and additional precautionary statements

EPA Reg. No.: 43813-27

# EPA Est. No.: 241-MO-001

Manufactured for: **JANSSEN PMP** a Division of Janssen Pharmaceutica NV 1125 Trenton-Harbourton Road Titusville, NJ 08560

® Registered Trademark of Janssen Pharmaceutica

Rev. 08/09

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# PRECAUTIONARY STATEMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

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

Handler Personal Protective Equipment (PPE):

- Wear long-sleeved shirt, long pants, socks, shoes, and chemical resistant natural rubber gloves.
- Wear protective eyewear such as goggles, face shield or safety glasses.
- Wear dust filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P, or HE filter.

Pesticide User Safety Requirements:

Discard clothing and other absorbent materials that have been heavily contaminated with this product. Do not reuse them. 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.

	FIRST AID
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 a poison control center
	or doctor.
	-Do not give anything by mouth to an unconscious person.
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
lf 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.
lf on skin or	-Take off contaminated clothing.
clothing	-Rinse skin immediately with plenty of water for 15-20 minutes.
	-Call a poison control center or doctor for treatment advice.
	HOT LINE NUMBER:
	on this pesticide product (including health concerns, medical
	r pesticide incidents) call the National Pesticide Telecommunications
Information Cer	nter at 1-800-858-7378.
	()(()
	mergency assistance (spill, leak, fire, or accident), call Chem Trectat
1-800-424-930	).
	ct container with you when calling a poison control center or doctor, or
going for treatm	
	NOTE TO PHYSICIAN COCCO
Probal	ble mucosal damage may contraindicate the use of gastric lavage.

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# DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product is intended for use only during industrial formulation processes producing antifouling products for control of hard fouling organisms. Formulators using ECONEA are responsible for providing additional data to support registration of their end-use product(s).

## STORAGE AND DISPOSAL

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

**STORAGE:** DO NOT mix or store this product or solutions of this product in a manner inconsistent with its labeling.

**PESTICIDE DISPOSAL:** Pesticide wastes may be acutely hazardous. Improper disposal is a violation of Federal Law. Pesticide, mixtures, or equipment rinse waters that cannot be chemically reprocessed must be disposed of according to applicable federal, state or local procedures. Contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by State and local authorities. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner.

#### **ENVIRONMENTAL HAZARDS**

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 to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### NOTICE OF WARRANTY

Janssen PMP, a Division of Janssen Pharmaceutica NV warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. It is impossible to eliminate all risks inherently associated with the use of this product. Ineffectiveness or other unintended consequences may result description, all of which are beyond the control of Janssen PMP. To the extent permitted by law, Janssen PMP disclaims any liability for consequential, special or indirect damages resulting from the use, handling, application, storage or disposal of this product or for damages. To the extent consistent with applicable law, Janssen PMP makes no warranties of merchantability or of fitness for a particular purpose or any other express or implied warranty except as stated above.