



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Mary McKinney Hunt **Product Registration** Bayer Environmental Science 2T Alexander Drive Research Triangle Park, NC 27709 SEP 2 5 2008

SUBJECT:

Application for Pesticide Notification (PRN 98-10 and 97-5)

Request General Label Changes(s)

EPA Reg. No. 11556-136

Application Dated July 25, 2008

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 07/25/08 for the above product(s). The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and 97-5 and finds that the action(s) requested fall within the scope of PRN 98-10 and 97-5. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely.

Linda Arrington

Notifications & Minor Formulations Team Leader Registration Division (7505P)

Office of Pesticide Programs

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ication for	Pesticide - Sec		
	2. EPA Product Ma George LaRocc	-	3. Proposed Classification  None Restricted
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	Product Name		20200
Se	ction - II		
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Please read instructions on I	reverse before completing form.	Form Ar	proves. OMB No.	2070-0060	). Approvel expires 2-28-9
<b>\$EPA</b>	United States Environmental Protection Washington, DC 2046	•	Registr Amend  Other	,	OPP Identifier Number
	Application	for Pesticide - Sec	tion I	*	
1. Company/Product Numbe 11556-1		2. EPA Product Mar George LaRocca	•	3. Pro	posed Classification
4. Company/Product (Name) Tempo 1% Dust Insecticide		<b>PM#</b> 13	PM#		
5. Name and Address of App	olicant (Include ZIP Code)				FIFRA Section 3(c)(3)
Bayer HealthCare LL0 P.O. Box 390	C, Animal Health Division	(b)(i), my product to: EPA Reg. No		TIFICA	nposition and labeling TION
Shawnee Mission, KS	66201-0390	EFA Reg. No	S	EP 252	008
Check if this	is a new address	Product Name			
		Section - II			
Amendment - Explain  Resubmission in resp  Notification - Explain	onse to Agency letter dated	Agency let	ed labels in repson ter dated Application. plain below.	se to	
been made as permitted by N	nce are five (5) copies of the proposed of lotification per PR Notice 98-10 Notificatents statement to delete chemical name.  I. NON-PRIA 2 ACTION	ions, Non-Notifications and Mir	nsecticide, EPA Re nor Formulation Am	g. No. 11556 endments. A	i-136. Minor revisions have Also, per PR Notice 97-5,
		Section - III	****		
1. Material This Product Will	Be Packaged In:		· 		
Child-Resistant Packaging Yes No	Unit Packaging Yes No	Water Soluble Packaging Yes No	2. Type of	f Container  Metal Plastic Glass	
* Certification must be submitted	If "Yes" No. per Unit Peckaging wgt. container	if "Yes" No. per Package wgt containe	ır	Paper Other (Sp	pecify)
3. Location of Net Contents I	nformation 4. Size(s) Retail ontainer	Container	5. Location of La	bel Direction	ns .
6. Manner in Which Label is	Affixed to Product Lithogre Paper glu Stenciled	ph Othe ued d			
		Section - IV			
1. Contact Point   Complete	items directly below for identification	of individual to be contacted,	if necessary, to p	rocess this e	application.)
Name Mary M. Hunt	1	itle Pesticides Regulatory Mana	ger ·	, ,	No. (Include Area Code) 268-2311
	Certification nents I have made on this form and all how whingly false or misleading states aw.	attachments thereto are true		mpleta.	6. Date Application Received (Stamped)
2. Signatura Mary M., 9	: A	Title resticides Regulatory Manager			
4. Typed Name Mary M. Hunt	5.	7/25/20	80		

# Bayer HealthCare Animal Health

July 25, 2008

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac yard 2777 South Crystal Drive Arlington, VA 22202-4501

ATTN:

Mr. George LaRocca, PM 13

**Registration Division** 

SUBJECT:

Application for Pesticide Notification

Tempo® 1% Dust Insecticide EPA Registration No. 11556-136

Dear Mr. LaRocca:

Please find enclosed, for the Agency's acceptance, an Application for Pesticide Notification and five (5) copies of the draft label for the subject product.

Revisions have been proposed in order to further clarify that no residential or household uses are permitted on this label as well as other minor revisions permitted by PR Notice 98-10 and PR Notice 97-5. The changes are described in detail on the Application attachment.

Bayer HealthCare LLC Animal Health P.O. Box 390 Shawnee Mission, KS 66201

Phone: 913 268-2000

Thank you for your assistance with this notification process, and please contact me at 913-268-2311 or <u>mary hunt.b@bayer.com</u> if you have any questions or need further information.

Respectfully,

BAYER HEALTHCARE LLC ANIMAL HEALTH DIVISION

Mory McKerney Heart

Mary McKinney Hunt

Pesticides Regulatory Manager

Encl: EPA Application for 8570-1

Application Attachment

Proposed draft label (5 copies)

EPA stamped letter/label dated 9/12/2003

4/

# **Non-PRIA 2 Notification Action**

# ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE NOTIFICATION

# Tempo 1% Dust Insecticide, EPA Reg. No. 11556-136

July 25, 2008 Page 1 of 3

Enclosed for Agency acceptance are five (5) copies of the draft label dated 7/08/08 for Tempo 1% Dust Insecticide, EPA Reg. No. 11556-136.

Please note that the draft label is identical to the currently registered label (please see enclosed label stamped accepted with comments dated September 12, 2008 and with the changes highlighted) with only minor changes described below:

# 1) Added product highlights/claims language on page 1 of draft label

This language is copied from and highlighted directly on the enclosed Agency label stamped accepted with comments dated September 12, 2008. Page numbers (in parenthesis) below indicate which page this claim can be found on the currently EPA stamped label.

Controls exposed adults and immature stages of beetles (page 6/7)

Provides effective knockdown and residual control (page 6/7)

Ready to use dust formulation (page 6/7)

For use in and around poultry facilities (page 6/7)

Apply using hand or power dusters or other suitable equipment (page 6/7)

Apply lightly and uniformly (page 6/7)

Controls ants, beetles, fire ants, spiders and other listed pests (page 6/7)

Where to use – floors, walls, cracks, crevices, wall voids, and around window and door frames (page 6/7)

When to use - to control crawling and flying pests (page 3/7)

How much to use -0.5 to 1 pound per 1000 sq ft (page 6/7)

### 2) Delete active ingredient chemical name and add CAS Number

From: Cyfluthrin, cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

To: Cyfluthrin [CAS No. 68359-37-5]

Per PR Notice 97-5 Use of Common Names for Active Ingredients on Pesticide Labeling

# ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE NOTIFICATION

# Tempo 1% Dust Insecticide, EPA Reg. No. 11556-136 July 25, 2008

Page 2 of 3

# 3) Replace EPA Est. No.

From: EPA Est. No. 34704-NB-001 **To:** EPA Est. No. XX-XX-XX

# 4) Replace Contents

From: 10 Pounds (4.50 kg)

To: XX (contents)

# 5) Add PO Box 390 to address

From: Bayer HealthCare LLC, Animal Health Division

Shawnee Mission, Kansas 66201, USA

To: Bayer HealthCare LLC, Animal Health Division

PO Box 390, Shawnee Mission, Kansas 66201, USA

# 6) Update emergency medical treatment telephone number

From: 1-877-258-2280 **To:** 1-800-422-9874

8) Remove "residential" from under GENERAL INFORMATION 2<sup>nd</sup> paragraph to more clearly emphasize product for use in poultry and livestock facilities.

From: Tempo 1% Dust Insecticide is for *residential* pest control in and around livestock and poultry housing facilities.

To: Tempo 1% Dust Insecticide is for pest control in and around livestock and poultry housing facilities.

9) Remove "commercially" from under GENERAL INFORMATION 3<sup>rd</sup> paragraph to more clearly emphasize product for use in poultry and livestock facilities.

From: Do not use in food/feed handling establishments, restaurants or other areas where food/feed is *commercially* prepared or processed.

To: Do not use in food/feed handling establishments, restaurants or other areas where food/feed is prepared or processed.

# ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE NOTIFICATION

# Tempo 1% Dust Insecticide, EPA Reg. No. 11556-136

July 25, 2008 Page 3 of 3

# 10) Update Conditions of Sale

From: The directions on this label were determined through research to be appropriate for the correct use of this product. This product has been tested under different environmental conditions both indoors and outdoors similar to those that are ordinary and customary where the product is to be used. Insufficient control of pests or plant injury may result from the occurrence of extraordinary of unusual conditions, or from failure to follow label directions. In addition, failure to follow label directions may cause injury to animals, man, and damage to the environment. Bayer offers, and the buyer accepts and uses, this product subject to the conditions that extraordinary or unusual environmental conditions or failure to follow label directions are beyond the control of Bayer and are therefore the responsibility of the buyer.

To: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

# 11) Add Limited Warranty and Limitation of Damages as follows:

Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of Bayer is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use of handling of this product.

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 of 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.

# TEMPO® 1% Dust Insecticide

For control of crawling and flying insect pests in poultry and livestock facilities.

- Controls exposed adults and immature stages of beetle
- Provides effective knockdown and residual control
- Ready-to-use dust formulation
- For use in and around poultry houses
- Apply using hand or power dusters or other suitable equipment
- Apply lightly and uniformly

Controls: Ants, beetles, fire ants, spiders, and other listed pests

Where to use: Floors, walls, cracks, crevices, wall voids, and around window and door frames

When to use: To control crawling and flying pests How much to use: 0.5 to 1 pound per 1,000 sq. ft.

	Percent By Weight
ACTIVE INGREDIENT: Cyfluthrin (CAS No. 68359-37-5)	1%
OTHER INGREDIENTS	99%
	100%

EPA Reg. No. 11556-136

EPA Est. No. XX-XX-XX

STOP - Read The Label Before Use

Keep Out Of The Reach Of Children

### **CAUTION**

XX (CONTENTS)

Bayer HealthCare LLC, Animal Health Division PO Box 390, Shawnee Mission, Kansas 66201, USA

Reason To Issue:

Make minor revisions as permitted by PR

Notice 98-10

Date: 07/08/08 Supersedes: 07/21/03 Page 2 of 5

PRECAUCION AL USUARIO: Si usted no puede leer o entender inglés, no use este producto hasta que la etiquetea le haya sido explicada ampliamente.

(TO THE USER: If you cannot read or understand English, do not use this product until the label has been fully explained to you.)

### PRECAUTIONARY STATEMENTS

# HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CAUTION:** Causes moderate eye irritation. Harmful if swallowed, inhaled or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Avoid breathing dust. If clothing becomes contaminated, remove and wash before reuse. Wash hands thoroughly with soap and warm water after handling. Keep out of reach of children. Do not contaminate feed or food.

**SYMPTOMS OF POISONING:** In case of poisoning, call physician or poison Control Center immediately. Have the patient lie down and keep quiet.

If in eyes:	Hold eye open and rinse slowly and gently with water for 15 to 20 minutes.  Remove contact lenses, if present, after the first 5 minutes, then continue
	<ul><li>rinsing eye.</li><li>Call a poison control center or doctor for treatment advice.</li></ul>
If swallowed:	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> </ul>
	<ul> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If on skin	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15 to 20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
control center o call 1-800-422-	MBER: Have the product container or label with you when calling a poison or doctor or going for treatment. For emergency medical treatment information 9874. For product information call 1-800-633-3796.  ian: No specific antidote is available. Treat the patient symptomatically.

Make minor revisions as permitted by PR

Notice 98-10

Date: 07/08/08 Supersedes: 07/21/03

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### **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Cover or remove any fish or aquatic organism tank within structures being treated. Disconnect any air supply sources to such tanks before applications are made and reconnect after any possibility of contamination has passed. Apply this product only as specified on this label.

#### **DIRECTIONS FOR USE**

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

**IMPORTANT:** Read these entire **Directions for Use** and **Conditions of Sale** before using TEMPO 1% Dust Insecticide.

Do not formulate this product into other end use products.

### **GENERAL INFORMATION**

TEMPO 1% Dust Insecticide is a ready-to-use insecticide dust which provides effective knockdown and residual control of the pests listed on this label.

TEMPO 1% Dust Insecticide is for pest control in and around livestock and poultry housing facilities. Permitted areas of use include, **but are not limited to**, livestock housing structures, poultry houses, swine houses, cattle barns, horse stables and pet kennels.

Do not use in food/feed handling establishments, restaurants or other areas where food/feed is prepared or processed.

#### **INDOOR PESTS**

Apply dust using hand or power dusters or other suitable equipment. Apply lightly and uniformly to infested areas. Pay particular attention to floors, walls and bedding, as well as cracks and crevices; wall voids and around window and door frames. Apply 0.5 to 1 pound of TEMPO 1% Dust Insecticide per thousand square feet. Do not make applications of TEMPO 1% Dust when animals are present in area of facility to be treated. Do not apply directly to animal feedstuffs or watering equipment. Repeat treatments as necessary to maintain adequate control.

Reason To Issue:

Make minor revisions as permitted by PR

Notice 98-10

Date: 07/08/08 Supersedes: 07/21/03 Page 4 of 5

Tempo 1% Dust Insecticide controls the following indoor pests: ants (except pharaoh), bedbugs, beetles (exposed adults & immature stages), fire ants, moths, spiders, wasps and yellow-jackets.

#### OUTDOOR PESTS

Wasps and Bees: It is advisable to treat wasp and bee nests in the evening when insects are less active and have returned to the nest. Wear protective clothing if deemed necessary to avoid stings. Using hand-held or power duster or other suitable means, with extension tubes if necessary, thoroughly dust nest and entrance and surrounding areas where insects alight. To treat nests in wall voids, drill a hole in the area, dust entrance and surrounding areas. For best results check nests carefully one or two days after treatment to ensure a complete kill, then remove and destroy nest to prevent emergence of newly-hatched insects. If removal is not feasible, retreat the nest, if necessary.

#### STORAGE AND DISPOSAL

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

**Pesticide Disposal:** Pesticide wastes are hazardous. Improper disposal of excess pesticide 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 EPA Regional Office for guidance.

Container Disposal: Do not use container in connection with food, feed, or drinking water. Completely empty container into application equipment. Offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**Pesticide Storage:** Store in cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food and feed. Store in original containers 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 is 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 above. In spill or leak incidents, keep unauthorized people away.

Reason To Issue:

Make minor revisions as permitted by PR

Notice 98-10

Date: 07/08/08 Supersedes: 07/21/03

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Conditions of Sale: The directions on this label are believed to be adequate and must be followed carefully. This product has been tested under different environmental conditions similar to those that are ordinary and customary for use of the product. However, it is impossible to eliminate all risks associated with the use of this product. Failure to follow label directions may cause injury to animals, humans and damage to the environment. Insufficient control of pests, injury or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer HealthCare LLC. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

Limited Warranty and Limitation of Damages: Bayer HealthCare LLC, Animal Health Division warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL, and no agent of Bayer is authorized to make or modify any warranties beyond those contained herein. Any damages arising from breach of this warranty shall be limited to direct damages and shall not include special, incidental or consequential damages resulting from the use of handling of this product.