

11556-136

8/27/2009

1049



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Douglas A. Spilker, Ph.D.
Manager, EPA Regulatory Affairs
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

AUG 27 2009

Subject: Notification(s) for Label Revisions under PRN 98-10 and PRN 2007-4

Dear Dr. Spilker:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices (PRN) 98-10 and 2007-4 dated, July 29, 2009 for:

EPA Registration 11556-136

Tempo 1% Dust Insecticide

The Registration Division (RD) has conducted a review of the request(s) for applicability under PRN 98-10 and PRN 2007-4 and finds that the label changes requested fall within the scope of PRN-98-10 and PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

2049

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-136	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tempo 1% Dust Insecticide	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <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: NOTIFICATION EPA Reg. No. _____ AUG 27 2009 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.)

See attachment, dated 7/29/2009.
email: doug.spilker.b@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <i>Pail</i> <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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 x 10 lb. sleeves		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input checked="" 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 Douglas A. Spilker, Ph.D.		Title Manager, EPA Regulatory Affairs	
		Telephone No. (Include Area Code) (913) 268-2751	
Certification I certify that the statements 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)
Signature <i>Douglas A. Spilker</i>		3. Title Manager, EPA Regulatory Affairs	
4. Typed Name Douglas A. Spilker, Ph.D.		5. Date 29 July 2009	

3089

ATTACHMENT FOR
APPLICATION FOR PESTICIDE REGISTRATION - Notification
July 29, 2009

Tempo 1% Dust Insecticide (EPA Reg. No. 11556-136)

Enclosed with this Application for Pesticide Notification is a draft label (5 copies) for Tempo 1% Dust Insecticide, dated July 28, 2009, which has been modified only to change those items (see highlighted copy) that fall under the scope of Pesticide Registration Notice (PRN) 97-4, PRN 98-10, and PRN 2007-4 or may be accomplished as Non-notifications, and include:

1. Add a "Total" line to the ingredient statement.
2. Revision of the emergency telephone numbers; we are transitioning to another medical service, but the previous telephone numbers will remain in effect for some time. The customer service statement was also revised. This is allowed pursuant to PRN 97-4. See page 2.
3. Revision of the storage and disposal statements pursuant to PR Notice 2007-4. See page 4.

This notification is consistent with the provisions of PR Notice 97-4, 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been proposed for the labeling or the confidential statement of formula of this product. Bayer understands that it is a violation of 18 U.S. C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands 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 Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA'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. Bayer understands that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. Bayer further understands that if the amended label is not consistent with the requirements of 40

CFR §156.10, 156.140, 156.144, 156.146 and 156.156, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

50 of 9

Reason To Issue: Revise according to PRN 2007-4 and make other minor revisions.

Date: 07/28/09
Supersedes: 07/08/08
Page 1 of 5

TEMPO® 1% Dust Insecticide

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

- Controls exposed adults and immature stages of beetles
- 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%
Total	100%

EPA Reg. No. 11556-136

EPA Est. No. XX-XX-XX

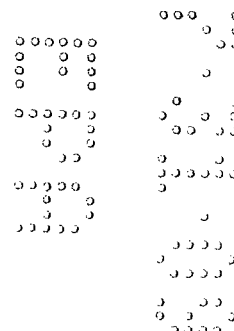
STOP - Read The Label Before Use

Keep Out of Reach of Children

CAUTION

Net Contents:

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



609

PRECAUCION AL USUARIO: Si usted no puede leer o entender inglés, no use este producto hasta que la etiqueta 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.

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• 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 rinsing eye.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• 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 on skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 to 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.
Note to Physician: No specific antidote is available. Treat the patient symptomatically.	
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency medical treatment, call 1-800-422-9874. For customer service or to obtain product information, including the MSDS, call 1-800-633-3796.	

7 of 9

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.

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.

8049

Reason To Issue: Revise according to PRN 2007-4 and make other minor revisions.

Date: 07/28/09
Supersedes: 07/08/08
Page 4 of 5

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

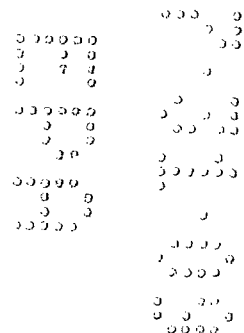
Do not contaminate water, food or feed by storage or disposal.

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: ~~Nonrefillable container. Do not reuse or refill this container.~~ Do not use container in connection with food, feed, or drinking water. Completely empty container into application equipment. Offer for recycling or reconditioning, if available, 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: Revise according to PRN 2007-4 and make other minor revisions.

Date: 07/28/09
Supersedes: 07/08/08
Page 5 of 5

909

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.

