

11556-107

9/11/2009

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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

SEP 11 2009

Subject: Notification(s) for Label Revisions under PRN 97-4, 97-5, 98-10  
and 2007-4

Dear Dr. Spilker:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices (PRN) 98-10, 97-4, 97-5 and 2007-4 dated, July 29, 2009 for:

**EPA Registration 11556-107**

**CyLence Pour-On Insecticide**

The Registration Division (RD) has conducted a review of the request(s) for applicability under PRN 97-4, 97-5, 98-10 and 2007-4, and finds that the label changes requested fall within the scope of PRN-98-10, 97-4, 97-5 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,

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

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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

<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 11556-107	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CyLence Pour-On 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: 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 _____	<b>NOTIFICATION</b> <b>SEP 11 2009</b>
<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 type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 pint / 6 pints		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other <u>Self adhesive</u>		

### 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
<b>Certification</b> 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 <b>(Stamped)</b>  rec'd 8-19-09
Signature 	3. Title Manager, EPA Regulatory Affairs	
4. Typed Name Douglas A. Spilker, Ph.D.	5. Date 29 July 2009	

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

CyLence® Pour-On Insecticide (EPA Reg. No. 11556-107)

Enclosed with this Application for Pesticide Notification is a draft label (5 copies) for CyLence Pour-On Insecticide, dated June 29, 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 97-5, PRN 98-10, PRN 2007-4 or may be accomplished as Non-notifications, and include:

1. Deletion of the long chemical name in the ingredient statement to only list common chemical name (Cyfluthrin). This is allowed pursuant to PRN 97-5. See page 1.
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.
4. Revision of the CONDITIONS OF SALE and WARRANTY sections. See page 5.

*This notification is consistent with the provisions of PR Notices 97-4, 97-5, 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*

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*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.*

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

Date: 07/28/09  
Supersedes: 05/01/03  
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**NOTIFICATION**

**SEP 11 2009**

**CyLence® Pour-On Insecticide**

For Control of Horn Flies, Face Flies, Biting Lice and Sucking Lice  
on Beef and Dairy Cattle (Including Lactating)

	<u>Percent By Weight</u>
Active Ingredient	
Cyfluthrin .....	1%
Other Ingredients .....	<u>99%</u>
Total .....	100%

EPA Reg. No. 11556-107

EPA Est. No. 67517-MO-1

**Keep Out of Reach of Children**

**WARNING**

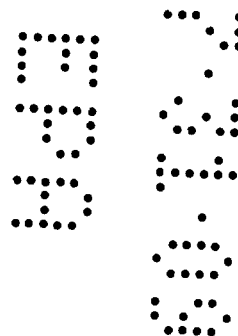
**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Causes substantial but temporary eye injury. Harmful if swallowed, or absorbed through the skin. Avoid contact with skin, eyes or clothing. Wear goggles, face shield or safety glasses. Wash hands thoroughly with soap and warm water after handling. Do not contaminate feed or food.

See Rear [and Side] Panels for First Aid and Other Precautionary Statements

NET CONTENTS: 6 Pints (2.839 L)  
1 Pint (473 mL)

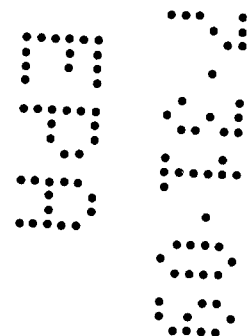
Bayer HealthCare LLC  
Animal Health Division  
P.O. Box 390  
Shawnee Mission, Kansas 66201, USA



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<b>FIRST AID</b>	
If in Eyes:	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, and then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If Swallowed:	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have a person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything to an unconscious person.</li> </ul>
If on skin or clothing:	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
If Inhaled:	<ul style="list-style-type: none"> <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 treatment advice.</li> </ul>
<p><b>HOTLINE NUMBER:</b> 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.</p>	

**Environmental Hazards:** This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters. Apply this product only as specified on the label.



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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 labeling must be in the possession of the user at the time of pesticide application.

For Control of Horn Flies, Face Flies, Biting Lice and Sucking Lice on Beef and Dairy Cattle (Including Lactating).

**How to Apply:** Apply **CyLence Pour-On Insecticide** is a **ready-to-use** solution. [To use the package dispenser, hold the container upright, remove the cap from the dosage chamber and gently squeeze the sides of the bottle to fill the chamber to the desired dosage.\*] Apply the required amount of solution directly along the top of the back and top of the head of the animal.

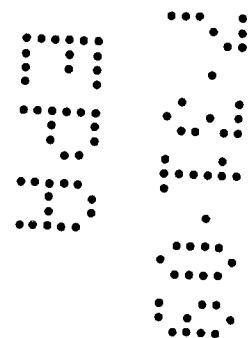
**Amount to Use:** Apply **CyLence Pour-On Insecticide** at the dosages shown on the following table. Due to the small amount of material required, care must be taken to apply the correct dosage.

Animal Weight	Horn and Face Flies		Biting and Sucking Lice	
	Dosage (mL)	Number of Animals This Container Will Treat	Dosage (mL)	Number of Animals This Container Will Treat
Less than 400 lbs	4	709 [118*]	8	354 [59*]
400 - 800 lbs	8	354 [59*]	16	177 [29*]
Over 800 lbs	12	236 [39*]	24	118 [19*]

**CyLence Pour-On Insecticide** can be used on beef and dairy cattle (including lactating) of all ages and sizes. Treatment for flies can be repeated as needed but not more often than once every 3 weeks. For optimal lice control, an initial application followed by a second treatment 3 weeks later is recommended.

**CyLence Pour-On Insecticide** does not control cattle grubs.

\*Substitutions for the 1 pint size.



## NOTICE TO VETERINARIANS

As with all synthetic pyrethroids, a small percentage of animals may experience a temporary skin sensation known as paresthesia within 24 hours after application. Paresthesia is characterized by one or more of the following signs: head tossing, tail twitching, restlessness, and irritability. Generally, affected animals return to normal within 48 hours without treatment.

## STORAGE AND DISPOSAL

### Not for Use or Storage In or Around the Home

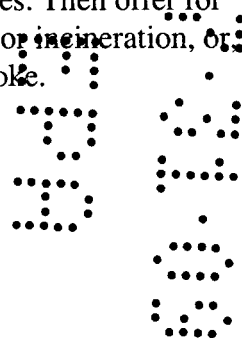
Do not contaminate water, food or feed by storage or disposal.

#### Pesticide Disposal:

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

#### Container Disposal:

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Offer for reconditioning, if appropriate. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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 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.





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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 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, invert to prevent leakage. If the container is leaking or material spilled for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose as directed for pesticides above.

**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.

