

11556-177

11/30/2012

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

NOV 30 2012

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. J. Todd Frank
Bayer HealthCare LLC, Animal Health Division
P.O. Box 390
Shawnee mission, KS 66201-0390

Subject: Label Notification(s) for Pesticide Registration 98-10 & 2007-4

Dear Mr. Frank:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated for November 8, 2012 for:

Alternate Brand Name

Permethrin™ Pour-On Insecticide

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

EPA Registration Number: 11556-177 1% Permethrin Pour-On Insecticide

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 non-refillable 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 Melody Banks on 703 305-5413 or E-mail at banks.melody@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager
Insecticide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-177	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 1% Permethrin Pour-On Insecticide	PM# Team Number 10	
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. _____ 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.)

Notification of addition of an Alternate Brand Name for subject product and added the Warranty and Limitation of Damages statement as allowed per PR Notice 98-10.

E-mail Contact: todd.frank@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <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 type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input 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 J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (include Area Code) 913-268-2585
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)
2. Signature 	3. Title Regulatory Affairs Consultant	
4. Typed Name J. Todd Frank	5. Date 11/08/2012	

Bayer HealthCare



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

Attention: Richard Gebken, Team 10

November 8, 2012

Subject: **1% Permethrin Pour-On Insecticide (EPA Reg. No. 11556-177)**
Application for Notification

Dear Mr. Gebken,

Please find enclosed, for the Agency's acceptance, an Application for Pesticide Notification, one copy of the highlighted label, and three copies of the unhighlighted labels for the subject product.

As allowed by PR Notice 98-10 Bayer HealthCare LLC Animal Health is adding an Alternate Brand Name and adding the Warranty and Limitation of Damages statement. No other changes have been made to the label.

Thank you for your assistance with this notification process, and please contact me at (913) 268-2585 or todd.frank@bayer.com if you have any questions or need further information.

Regards,

BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION

4. Too Full

J. Todd Frank
Regulatory Affairs Consultant

Bayer HealthCare LLC

Animal Health

P.O. Box 390
Shawnee Mission, KS
66201-0390

Reason to Issue:

Add ABN and Warranty Statement

Date:

11/06/2012

Supersedes:

08/13/2012

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1% PERMECTRIN™ POUR-ON INSECTICIDE

Ready-To-Use Pour-On & Spray Insecticide

Treats up to 25 Cows per Gallon

[Alternate Brand Name: **Permethrin™ Pour-On Insecticide**]

**Kills Flies, Lice and Ticks on Beef and
Lactating Dairy Cattle, and Keds on Sheep**

NOTIFICATION

NOV 30 2012

ACTIVE INGREDIENT

Permethrin (CAS # 52645-53-1)..... 1.0%

OTHER INGREDIENTS*99.0%

Total 100.0%

*Contains petroleum distillate

EPA Reg. No. 11556-177

EPA Est. No. XXXXXX

Keep Out of Reach of Children

CAUTION

See back panel for additional precautionary statements

FIRST AID	
If in eyes	<ul style="list-style-type: none">• 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.
If swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give any liquid to the person.• Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-422-9874 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

Net Contents: XXXXX

Manufactured For:
Bayer HealthCare, LLC
Animal Health Division
PO Box 390
Shawnee Mission, KS 66201 USA

PRECAUTIONARY STATEMENTS**Hazards to Humans and Domestic Animals**

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS: This pesticide is extremely toxic to fish. Use with care when applying to areas adjacent to any body of water. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this product only as specified on this label.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Chemical resistant gloves.

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

USER SAFETY REQUIREMENTS**Follow Manufacturer's Instructions****APPLICATION INSTRUCTIONS**

APPLY TO	TARGET PESTS	APPLICATION INSTRUCTIONS
Beef Cattle, Lactating and Non-Lactating Dairy Cattle and Calves	Horn Flies, Face Flies and Lice. Aids in the insecticidal control of Horse Flies, Stable Flies, Mosquitoes, Black Flies and Ticks	<p>DOSAGE: Apply ½ fl. oz. per 100 lbs. body weight of animal, up to a maximum of 5 fl. oz. for any one animal.</p> <p>POUR-ON: Pour along back line and down face.</p> <p>READY-TO-USE SPRAY: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears.</p> <p>BACK RUBBER USE: Mix one pt. per gal. of #2 diesel or mineral oil. Keep rubbing device charged. For Back Rubber applications, results are improved by daily forced use.</p>
Sheep	Sheep Keds, Lice, Horn Flies and Face Flies. Aids in the insecticidal control of Horse Flies, Stable Flies, Mosquitoes, Black Flies and Ticks	<p>DOSAGE: Apply ¼ fl. oz. per 50 lbs. body weight of animal, up to a maximum of 3 fl. oz. for any one animal.</p> <p>POUR-ON: For Keds, pour along back line over neck, shoulders and rump. Pour along back line and down face for lice, flies and ticks.</p> <p>READY-TO-USE SPRAY: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears.</p> <p>BACK RUBBER USE: Mix one pt. per gal. of #2 diesel or mineral oil. Keep rubbing device charged. For Back Rubber applications, results are improved by daily forced use.</p>

TARGET PESTS APPLICATION INSTRUCTIONS continued

APPLY TO	TARGET PESTS	APPLICATION INSTRUCTIONS
Premises – In and around Horse, Beef, Dairy, Swine, Sheep and Poultry premises, Animal Hospital Pens and Kennels and “outside” Meat Processing Premises	House Flies, Stable Flies, Face Flies, Gnats, Mosquitoes, Black Flies, Fleas, and Little House Flies. Aids in the control of cockroaches, ants, spiders and crickets.	READY-TO-USE SPOT SPRAY OR PREMISE SPRAY: Use undiluted in a mist sprayer. Apply directly to surface to leave a residual insecticidal coating, paying particular attention to areas where insects crawl or alight. One gallon will treat approximately 7,300 square feet.

NOTE: For Pour-On and Ready-To-Use Spray applications, repeat treatment as needed, but do not exceed 5 fl. oz. during any 14 day interval. For optimum insecticidal effectiveness against lice, a second treatment at 14 day intervals is recommended.

USE RESTRICTIONS:

Do not breathe vapors, or spray mist

When used in dairy barns or facilities:

Close milk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking utensils before application. Wash teats of animal before milking.

When applying to premises:

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

All outdoor applications must be limited to spot or crack-and-crevice treatments only.

Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain or after application.

