

11556-177

3/19/2013

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

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

MAR 19 2013

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Mr. Frank:

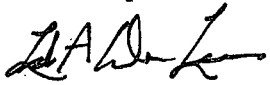
The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated March 11, 2013 for the following product(s):

1% Permethrin Pour-On Insecticide EPA Reg. No. 11556-177

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

If you have any questions, please contact Linda A. DeLuise at 703-305-5428.

Sincerely,


Richard J. 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 to NOTIFICATION in composition and labeling to: EPA Reg. No. <u>MAR 19 2013</u> Product Name _____	

Section - II

Amendment - Explain below. Final printed labels 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 page(s) if necessary. (For section I and Section II.)
 Notification to add California restriction to pests (see page 3 of 4) as allowed per PR Notice 98-10.
 E-mail Contact: todd.frank@bayer.com

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <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
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled 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
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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 03/11/2013

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1% PERMECTRIN™ POUR-ON INSECTICIDE

Ready-To-Use Pour-On & Spray Insecticide

NOTIFICATION

Treats up to 25 Cows per Gallon

MAR 19 2013

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

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

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

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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	DOSAGE: Apply ½ fl. oz. per 100 lbs. body weight of animal, up to a maximum of 5 fl. oz. for any one animal. POUR-ON: Pour along back line and down face. READY-TO-USE SPRAY: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears. 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.
Sheep	Sheep Keds, Lice, Horn Flies and Face Flies. Aids in the insecticidal control of Horse Flies, Stable Flies, Mosquitoes, Black Flies and Ticks	DOSAGE: Apply ¼ fl. oz. per 50 lbs. body weight of animal, up to a maximum of 3 fl. oz. for any one animal. 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. READY-TO-USE SPRAY: Use undiluted in a mist sprayer to apply correct dose. Apply directly to neck, face, back, legs and ears. 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.

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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. *Not Registered for use on this pest in California	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 of 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.

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STORAGE AND DISPOSAL

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

Pesticide Storage: Keep container sealed when not in use. Do not store near food or feed

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. 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. Offer for recycling, if available.

CONDITIONS OF SALE:

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 or 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. To the extent permitted by applicable law, 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.

WARRANTY AND LIMITATION OF DAMAGES:

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

