

11556-168

2/6/2014

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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. Todd Frank  
Bayer Healthcare LLC  
Animal Health Division  
P.O. Box 390  
Shawnee Mission, KS 66201

FEB - 6 2014

Dear Mr. Frank:

Subject: Application for Pesticide Notification (PRN 98-10)  
Add alternate package size and additional optional language,  
Update EPA Reg. No. and warranty text to reflect changed ownership  
Permethrin Fly & Louse Dust  
EPA Reg. No. 11556-168  
Your submission dated December 18, 2013

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated December 18, 2013 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested falls within the scope of PRN 98-10. The label submitted with the application has been 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 regarding this letter, please contact Dana Pilitt, Ph.D. at (703) 305-7071 or via e-mail at [pilitt.dana@epa.gov](mailto:pilitt.dana@epa.gov).

Sincerely,

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

Richard Gebken  
Product Manager 10  
Insecticide Branch  
Registration Division (7505P)

11556-168 D 486926



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

|  |  |  |
|--|--|--|
| 1. Company/Product Number<br>11556-168   | 2. EPA Product Manager<br>Richard Gebken   | 3. Proposed Classification<br><input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Permethrin Fly & Louse Dust   | PM#<br>Team Number 10  |  |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Bayer HealthCare LLC, Animal Health Division<br>P.O. Box 390<br>Shawnee Mission, KS 66201-0390<br><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:<br><b>NOTIFICATION</b><br>EPA Reg. No. <u>FEB - 6 2014</u><br>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.)

Minor label changes as allowed by per PR Notice 98-10. See Cover Letter for explanation.

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

## Section - III

|   |   |  |  |   |                   |
|---|---|--|--|---|-------------------|
| 1. Material This Product Will Be Packaged In:   |   |  |  | 2. Type of Container  |                   |
| Child-Resistant Packaging<br><input type="checkbox"/> Yes*<br><input type="checkbox"/> No   | Unit Packaging<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No | <input type="checkbox"/> Metal<br><input type="checkbox"/> Plastic<br><input type="checkbox"/> Glass<br><input type="checkbox"/> Paper<br><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<br><input type="checkbox"/> Label <input type="checkbox"/> Container  |   | 4. Size(s) Retail Container  |  | 5. Location of Label Directions<br><input type="checkbox"/> On Label<br><input type="checkbox"/> On Labeling accompanying product |                   |
| 6. Manner in Which Label is Affixed to Product<br><input type="checkbox"/> Lithograph<br><input type="checkbox"/> Paper glued<br><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<br>J. Todd Frank | Title<br>Reg. Affairs Consultant | Telephone No. (Include Area Code)<br>913-268-2185 |
|-----------------------|----------------------------------|---|

## Certification

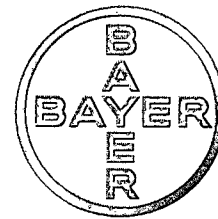
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received  
(Stamped)

|                                |   |
|--------------------------------|---|
| 2. Signature<br>               | 3. Title<br>Regulatory Affairs Consultant |
| 4. Typed Name<br>J. Todd Frank | 5. Date<br>12/18/2013                     |

# Bayer HealthCare

## Animal Health



December 18, 2013

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

Subject: **Permethrin Fly & Louse Dust, EPA Reg. No. 11556-168**  
**Application for Notification**

Dear Mr. Gebken,

Please find the enclosed Pesticide Notification application for subject product which includes one highlighted label copy and three un-highlighted label copies.

As allowed by PR Notice 98-10, Bayer HealthCare LLC Animal Health Division is adding an alternate package size and additional optional labeling. The alternate package size will include two fully labeled 12.5 pound containers of bulk dust as well as an application bag. Full labeling will be on the new outer package identical to the individual packages with the optional text stating that an application bag is included. We have also updated the EPA Registration number and revised the condition of sale and warranty statement as the label has not been converted into the Bayer format after the product was acquired from KMG-Bernuth in March of 2012.

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

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.

Regards,

BAYER HEALTHCARE LLC  
ANIMAL HEALTH DIVISION

J. Todd Frank

Regulatory Affairs Consultant

Bayer HealthCare LLC  
Animal Health  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

Reason to Issue:

Update Label with Bayer EPA Reg. No. and  
optional text.

Date:

12/17/2013

Supersedes:

09/15/2011

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## PERMECTRIN™ FLY & LOUSE DUST

Ready-To-Use Dust Insecticide

**For Control of Horn Flies and Lice on Beef & Dairy Cattle, As an aid in reducing Face Fly  
populations on Beef & Dairy Cattle**

**Control of Lice on Swine**

**For control of Northern Fowl Mites on Poultry**

Optional text in brackets [Contains:]  
[Contains refillable dispenser bag]  
[Two 12.5 lbs. bags of dust]

### **ACTIVE INGREDIENT**

Permethrin (CAS # 52645-53-1)..... 0.25%

**OTHER INGREDIENTS\*** .....99.75%

Total 100.00%

EPA Reg. No. 11556-168

EPA Est. No. XXXXXX

Net Contents: [12.5 pounds], [2 pounds], [Two 12.5 pounds]

Manufactured For:

Bayer HealthCare, LLC

Animal Health Division

PO Box 390

Shawnee Mission, KS 66201 USA

**NOTIFICATION**

**FEB - 6 2014**

**Keep Out of Reach of Children**

### **CAUTION**

[See back panel for additional precautionary statements]

| FIRST AID   |   |
|---|---|
| <b>If on skin or Clothing</b>   | <ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>   |
| <b>If in eyes</b>   | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul> |
| 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. |   |

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

**PERSONAL PROTECTIVE EQUIPMENT (PPE):** Some materials that are chemical-resistant to this product are butyl rubber, neoprene and polyvinyl chloride (PVC). If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves, and
- A NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or any N, R, P, or HE filter.

Application with aerial or motorized ground equipment is prohibited.

#### USER SAFETY REQUIREMENTS

Follow manufacturer's instructions for cleaning/maintain PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched (except as required by directions for use) or heavily contaminated with this product's concentrate. Do not reuse them.

#### USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

**ENVIRONMENTAL HAZARDS:** This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to water, or to area where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment wash waters.

Under some conditions, it may also have a potential for transport into surface water in runoff (primarily absorbed to suspended soil particles), for several months or more after application. These include poorly draining or wet soils with readily visible slopes toward adjacent surface waters, frequently flooded areas, and areas overlying extremely shallow groundwater, areas with in-field canals or ditches that drain to surface water, areas not separated from adjacent surface waters with vegetated filter strips, and areas overlying tile drainage systems that drain to surface waters.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

**DIRECTIONS FOR USE -- Read the entire label prior to use.**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Avoid contamination of feed and foodstuffs.

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

When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination of the product. Remove or cover milking utensils before application.

Wash teats of animals before milking.

Use of handheld power duster equipment is prohibited.

**BEEF & DAIRY CATTLE**

Horn Flies, Lice, Face Flies: Place contents of this package in any commercially available dust bag, suspend bags in areas frequently by cattle or in gateways or lanes through which the animals pass daily for water, feed or minerals. Bags may also be suspended in loafing sheds or in front of protected mineral feeders.

For lactating dairy cows, bags may be suspended in the exit through which cows leave the milking barn. In all cases, the bags should be adjusted so that the bottom of the bag will hang four to six inches below the topline of the cattle. For reduction of face flies, the bags must be located so the animals will be forced to use them daily and hung at the height to insure that the faces of the cattle will be dusted.

Horn Flies, Lice: Direct Application: Apply 2.0 ounces of dust per animal by shaker can over the head, neck shoulders, back and tailhead. Repeat as necessary.

**POULTRY**

Northern Fowl Mites: Direct Application: Apply not more than 1lb/100 birds, directing dust to thoroughly cover vent area.

**SWINE**

Lice on Swine: Direct Application: Apply not more than 1 ounce\* (3 level tablespoons) per head as a uniform coat to the head, shoulders and back by use of a shaker can. Repeat as necessary, but not more often than once every ten days.

Reason to Issue: Update Label with Bayer EPA Reg. No. and optional text.

Date: 12/17/2013  
Supersedes: 09/15/2011  
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In Severe infestations, both individual animals and the bedding may be treated as directed above.

Do not ship animals for slaughter within 5 days of last treatment.

\*Note 1 ounce of this material equals approximately three level tablespoonfuls.

### STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Open as needed. Keep container sealed when not in use.

**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. Completely empty bag into application equipment. Then dispose of empty bag in a landfill or by incineration. Do not burn unless allowed by state and local ordinances.

### 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.

### 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 EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. Any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc.