

9/7/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001



OFFICE CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Bruce Martin
Bayer HealthCare, LLC
Animal Health Division
12707 Shawnee Mission Parkway
Shawnee Mission, KS 66201

SEP 7 2012

Subject: Amended Reregistration Label
Product Name: 1% Permethrin Pour-On Insecticide
EPA Registration Number: 11556-177
EPA Decision Number(s): 413326

Dear Mr. Martin:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Permethrin RED(s), and has concluded that your submission is acceptable.

NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated [February 23, 2011]
- Alternate CSF #A, [February 23, 2011]
- Alternate CSF #B, dated [February 23, 2011]
- Alternate CSF #C, dated February 23, 2011

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Melody Banks at (703)305-5413 or via e-mail at banks.melody@epa.gov

Sincerely,



Richard J. Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7504P)

*Enclosures: Label stamped "Accepted," September 7, 2012
Acute Toxicity Review, dated (August 24, 2010)
Product Chemistry Review, dated (October 26, 2011)*

Reason to Issue:

Update Label with Bayer EPA Reg. No. and
information per EPA Letter 7/31/2012

Date:

08/13/2012

Supersedes:

09/06/2010

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1% PERMECTRIN™ POUR-ON INSECTICIDE

Ready-To-Use Pour-On & Spray Insecticide

Treats up to 25 Cows per Gallon

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

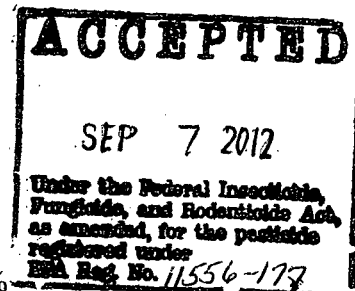
EPA Reg. No. 11556-177

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

Reason to Issue: Update Label with Bayer EPA Reg. No. and information per EPA Letter 7/31/2012

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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	<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>

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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.	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 $\frac{1}{4}$ 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.