

1007-91

08/22/2013

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

8-22-13

Mr. John B. Baker
Pfizer Inc.
7000 Portage Road, KZO 300-403 SW
Kalamazoo, MI 49001

Subject: Amended Reregistration Label
Product Name: Durasect II
EPA Registration Number: 1007-91
EPA Decision Number(s): D411160

Dear Mr. Baker:

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 Pyrethrins, Piperonyl Butoxide and 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 Any previously dated CSFs are superseded.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 [April 22, 2013]

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 Dani Daniel at (703)305-5409 or via e-mail at daniel.dani@epa.gov

Sincerely,



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

*Enclosures: Label stamped "Accepted," dated 8/22/13
Acute Toxicity Review, dated (November 9, 2011)
Product Chemistry Review, dated (May 16, 2013)*

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. Harmful if inhaled. Avoid breathing vapor.

All handlers must wear:

- long-sleeved shirt and long pants
- socks and shoes
- chemical-resistant gloves (such as those made out of any waterproof material, selection category A).

Wash thoroughly with soap and water after handling.

First Aid

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: 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 eyes. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-888-963-8471 for emergency medical treatment information.

User Safety Requirements

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

User Safety Recommendations

- User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- User should remove clothing/ PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- User 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.

Durasect II

- Ready to use Pour-On for beef cattle, lactating and non-lactating dairy cattle, and calves

- Patented water repellent formulation
- Effective in the control of pyrethroid-resistant horn flies
- Up to 6-week control of horn flies*
- Controls face flies for at least 4 weeks
- Controls biting lice
- No withdrawal time
- Treats 60 500-lb cattle or 30 1000-lb cattle

Active Ingredients:

*Permethrin (3-phenoxyphenyl) methyl + cis,
trans-3-(2,2-dichloroethenyl)-2,2-dimethyl-cyclopropanecarboxylate...5.0%
Pyrethrins.....0.1%
Piperonyl butoxide**.....1.0%
Other Ingredients.....93.90%
TOTAL.....100.00%

*cis/trans ratio: Min 35%(+) dis and max 65% (+-) trans

**[butyl carbonyl(6-propylpiperonyl) ether and related compounds

Keep Out of Reach of Children

CAUTION

See Back Panel for Precautionary Statements

Net Contents: 900 mL (30.43 fl. oz.)

+Duration of activity for horn fly control may vary due to pyrethroid resistance, environmental conditions and management factors (i.e., sanitation, animal husbandry, facilities, etc.)

Distributed by:

Zoetis Inc.

333 Portage Street

Kalamazoo, MI 49007

EPA Est. No. 67517-MO-1

EPA Reg. No. 1007-91

Directions for Use

It is a violation of Federal Law to use this product in a labeling.

- Except when applying to livestock, do not will contact workers or other persons, either protected handlers may be in the area during use. Do not enter treated areas until the spray has dried. Do not contaminate food or feed with treated surfaces.
- When used in dairy barns or facilities: close doors and windows to prevent spray and from dead c milk utensils before application. Wash teat before milking.
- Do not make applications during rain.

READY TO USE-No dilution necessary, see directions below.

Animal Treatments

Lactating and Non-lactating Dairy Cattle, Beef Cattle, and Target Insects: Controls Horn Flies, Face Flies, and Biting Insects. Application: Apply along back and down face. Use 0.1 oz per 100 lbs of animal, up to 1 fl oz for any one animal. For optimum lice control, additional treatments at 14-day intervals are recommended.

Durasect II is to be applied with the squeeze-and-pour method. Remove the cap and inner seal. Estimate the animal's weight and calculate the amount of product to be applied. Apply product to the dosing chamber to the desired level. Apply product as a spray. Repeat treatment as needed, but not more than once per week. For optimum lice control, additional treatments at 14-day intervals are recommended.

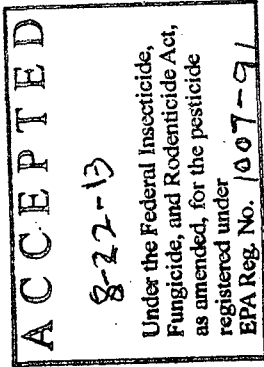
Storage and Pesticide Disposal and Container Handling
Do not contaminate water, food or feed by storage or disposal. Store in original container. Do not store near food or feed.

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of in an approved waste disposal facility. Do not reuse or refill this container. Do not re-enter this container for recycling, if available.

Environmental Hazards

This pesticide is extremely toxic to aquatic organisms. Do not apply to waterways, streams, or drainage ditches, gutters or surface waters. Applying this product to waterways may result in the death of aquatic life. Do not apply to waterways. Do not apply to waterways. Do not apply to waterways. Do not apply to waterways.

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



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and long pants

gloves (such as those made out of any waterproof
category A).

nd water after handling.

ke off contaminated
ly with plenty of water for
ontrol center or doctor for
resh air. If person is not
ice, then give artificial
to-mouth, if possible. Call a
or for further treatment
: rinse slowly and gently
Remove contact lenses, if
tes, then continue rinsing
ter or doctor for further
r label with you when
: or doctor or going for
tact 1-888-963-8471 for
Information.

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Other Ingredients93.90%

TOTAL.....100.00%

*cis/trans ratio: Min. 35%(+/-) cis and max 65% (+/-) trans

**[butyl carbonyl][6-propylpiperonyl] ether and related compounds

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Kalamazoo, MI 49007

EPA Est. No 67517-MO-1
EPA Reg. No. 1007-91

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

- Except when applying to livestock, 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.
- When used in dairy barns or facilities, close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milk utensils before application. Wash teats of animals before milking.
- Do not make applications during rain

READY TO USE-No dilution necessary, see directions below.

Animal Treatments

Lactating and Non-lactating Dairy Cattle, Beef Cattle, and Calves
Target Insects: Control Horn Flies, Face Flies, and biting Lice.

Application: Apply along back and down face. Use 0.1 fl oz (3 mL) per 100 lb (45 kg) of body weight of animal, up to 1 fl oz for any one animal. If face flies are a particular concern, apply 0.1 fl oz (3 mL) down centerline of forehead and rest of dose along back of animal

Durasect II is to be applied with the squeeze-and-pour bottle provided. To use the squeeze-and-pour bottle, remove the cap and inner seal from the calibrated dosing chamber. Estimate the animal's weight and calculate the dose. Squeeze the bottle to fill the dosing chamber to the desired level. Apply product per directions above; do not use product as a spray. Repeat treatment as needed, but no more than once every 2 weeks. For optimum lice control, additional treatments at 14-day intervals may be necessary.

Storage and Pesticide Disposal and Container Handling
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 must be disposed of at an approved waste disposal facility.
Container Disposal: Non-refillable container. Do not reuse or refill. Place in trash or offer for recycling if available.

Environmental Hazards

This pesticide is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather, when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

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.

