

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



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 14, 2012

Douglas A. Spilker
Bayer Health Care, LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: Amended Reregistration Label
Product Name: K9 Advantix® 55
EPA Registration Number: 11556-135
EPA Decision Number: 413751

Dear Dr. Spilker,

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, 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.

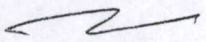
Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated March 8, 2010
- Alternate CSF 1, dated March 8, 2010

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 Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Sincerely,



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

*Enclosures: Label stamped "Accepted," dated February 14, 2012
Acute Toxicity Review, dated August 23, 2011
Product Chemistry Review, dated September 27, 2011*

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Reason To Issue: Revise according to EPA (ReReg) letter of 02/09/12

Date: 02/10/12

Supersedes: 08/27/10 (h)
& 02/18/10 (ha)

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NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

K9 Advantix[®] 55

Topical prevention and treatment of ticks, fleas, mosquitoes, biting flies, and lice for monthly use on dogs and puppies 7 weeks of age and older, weighing 21-55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

DO NOT USE ON CATS

For the Prevention and Treatment of Ticks, Fleas, Mosquitoes, Biting Flies, and Lice on Dogs

- For use on dogs and puppies 7 weeks of age and older
- A single topical application remains effective for [(a month) (four (4) weeks)]
- Convenient, easy to apply topical solution
- Once a month topical flea treatment for dogs 7 weeks of age or older
- K9 Advantix is indicated for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice on dogs 7 weeks of age and older
- Repels and kills ticks including Deer ticks (vector of Lyme disease), American dog ticks (vector of Rocky Mountain spotted fever), Brown dog ticks (vector of ehrlichiosis), and Lone Star ticks (vector of ehrlichiosis) for up to four (4) weeks
- Kills fleas on dogs within 12 hours and continues to prevent infestations for [(a month) (four (4) weeks)]
- Kills and repels fleas before they lay eggs
- Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix[®] treated dog
- For the treatment and prevention of flea infestations
- One treatment prevents further flea infestations for [(a month) (four (4) weeks)]
- Controls existing flea infestations by killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents fleas on treated dogs from infesting (reinfesting) your home.
- Treatment with K9 Advantix kills fleas and may reduce the incidence of Flea Allergy Dermatitis (FAD)

K9Advantix55ia.doc

ACCEPTED

FEB 14 2012

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**

EPA. Reg. No: 11556-135

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- Repels and kills mosquitoes for up to four (4) weeks
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- Remains effective after bathing and swimming [(for a month) (for up to four weeks)]
- Repels biting flies
- Repels and inhibits blood-feeding by biting flies
- Repels and prevents blood-feeding by biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome)(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations
- 5-way protection (against fleas, ticks, biting flies, mosquitoes, and lice)
- Treats, prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice
- Remains effective after exposure to rain or sunlight
- Waterproof
- Fragrance free

| Active Ingredients | % By Weight |
|-----------------------------|--------------|
| Imidacloprid | 8.8% |
| Permethrin* | 44.0% |
| Other Ingredients | <u>47.2%</u> |
| Total | 100% |

* cis/trans ratio: Max 55% (±) cis and min 45% (±) trans

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-135

[For Directions for Use and other labeling; see supplemental labeling inside.]

See [back panel] (or) [below] for first aid and precautionary statements.

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KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

WARNING. Causes substantial but temporary eye injury. Do not get in eyes or on skin or clothing. Harmful if swallowed. Harmful if absorbed through the skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on animals other than dogs. Do not use on puppies under seven weeks of age. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product.

DO NOT USE ON CATS

May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.



For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

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ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

| 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. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything to an unconscious person. |
| If On Skin or Clothing: | <ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice. |
| 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. For consumer questions call 1-800-255-6826. | |
| NOTE TO PHYSICIAN | |
| Treat the patient symptomatically. | |

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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Do not contaminate feed or food.

HOW TO APPLY

1. Use only on dogs. **DO NOT USE ON CATS** or on other animals.
2. Remove applicator tube from the package.

[Visuals Depicting How to Open Applicator Tube]

3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.
6. The dog should be standing for easy application. The entire contents of the K9 Advantix[®] tube should be applied evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

[Visuals Depicting Application To Animal]

Do not get this product in your dog's eyes or mouth.

7. Discard empty tube as described in Storage and Disposal.

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[PRODUCT INFORMATION]

Kills fleas which may cause flea allergy dermatitis (FAD).

K9 Advantix[®] kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix[®] treated dog.

K9 Advantix[®] is waterproof and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight.

Monthly treatments are required for optimal control and prevention of fleas and ticks.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place. Protect from freezing. **Pesticide Disposal and Container Handling:** Nonrefillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency or 1-800-422-9874 for disposal instructions. Never place unused product down any indoor or outdoor drain.

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. To the extent consistent with applicable law 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.

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Net Contents: XX Tubes each 0.084 fl. oz. (2.5 mL)

[Sample – Not for (Re)Sale]

Manufactured For

Bayer HealthCare LLC

Animal Health Division

P.O. Box 390

Shawnee Mission, Kansas 66201 USA

Made in Germany

10/10

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(Label on Individual Tube)

K9 Advantix[®] 55

8.8% imidacloprid
44.0% permethrin

0.084 fl. oz. (2.50 mL)

EPA Reg. No. 11556-135

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000