

11556-143

03/15/2010

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Douglas A. Spiker, Ph. D.
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

MAR 15 2010

Dear Dr. Spiker:

Subject: Amendment-minor revisions
K9 Advantix Plus 55
EPA Registration Number 11556-143
Your submission dated February 26, 2010

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

A stamped label is enclosed for your records.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely yours,

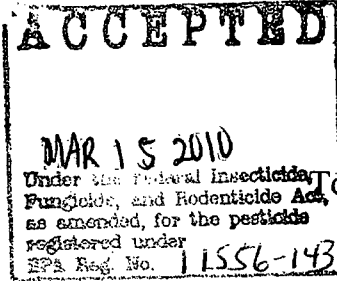
Richard Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure

Reason To Issue: Update Marketing Claims; Minor Revisions; EPA letter of 10/10/07

Date: 02/26/10
Supersedes: 02/29/08
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NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]



K9 Advantix® Plus 55

Topical prevention and treatment of fleas, ticks, 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 Fleas, Ticks, Biting Flies, Mosquitoes, and Lice on Dogs

- For use on dogs and puppies 7 weeks of age and older
- K9 Advantix Plus contains [imidacloprid], [permethrin] and [an/the] [insect growth regulator] [IGR] [pyriproxyfen] [Nylar®]*
- 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 Plus is indicated for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice on dogs 7 weeks of age and older
- For the treatment and prevention of flea infestations
- One treatment prevents further flea infestations for [(a month)(four (4) weeks)]
- Kills fleas on dogs within 12 hours and continues to prevent infestations for [(a month)(four (4) weeks)]
- Repels and kills fleas before they lay eggs
- Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix Plus treated dog
- Kills larval stages of fleas in the pet's environment following contact with K9 Advantix Plus treated dog
- Kills fleas within 12 hours of application
- Controls existing flea infestations by rapidly killing adult fleas
- Prevents reinfestations by killing adult fleas before they lay eggs
- Prevents flea eggs from hatching

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- Effectively breaks the flea life cycle
- Flea adulticide, larvicide and ovcide.
- Prevents fleas on treated dogs from infesting (reinfesting) your home.
- Effectively targets all [life] stages of [fleas] and [ticks]
- 3-way flea protection ([kills] [controls] adults, larvae, and eggs)
- Prevents development of fleas, flea eggs, pupae and larvae [for (a month)(four (4) weeks)]
- Prevents development of all flea stages [for (a month)(four (4) weeks)]
- Repels and kills all [life] stages of fleas
- Prevents flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with K9 Advantix Plus rapidly kills fleas and may reduce the incidence of Flea Allergic Dermatitis [FAD]
- Because K9 Advantix Plus repels and kills fleas, year-around use of K9 Advantix Plus may reduce the risk of Canine Vector Borne Diseases (CVBD)
- 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 ehlichiosis) for up to four weeks
- Because K9 Advantix Plus repels ticks, year-round use of K9 Advantix Plus may reduce the risk of Canine Vector Borne Diseases (CVBD)
- Repels and kills fleas often before they bite and may reduce the risk of Canine Vector Borne Diseases (CVBD)
- Repels and kills mosquitoes that may transmit Canine Vector Borne Diseases (heartworm disease)
- Because K9 Advantix Plus repels and kills mosquitoes, year-around use of K9 Advantix Plus may reduce the risk of Canine Vector Borne Disease (heartworm disease)
- Repels and kills mosquitoes for up to four weeks
- Repels and kills mosquitoes often before they have a chance to take a blood meal
- [(Prevents blood-feeding by) (Kills and repels)] mosquitoes
- 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
- Remains effective after bathing and/or swimming
- Remains effective following swimming and/or shampooing
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations

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- 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
- Waterproof
- Remains effective after exposure to rain or sunlight
- Fragrance free

*NYLAR® - Registered trademark of McLaughlin Gormley King Co.

Active Ingredients	%
	By Weight
Imidacloprid.	8.80%
Permethrin*	44.00%
Pyriproxyfen.	0.44%
Other Ingredients	<u>46.76%</u>
Total	100.00%

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

KEEP OUT OF REACH OF CHILDREN

WARNING

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

See below for first aid and precautionary statements.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS


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

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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.

<p>DO NOT USE ON CATS</p> <p>Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat which actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately.</p>	
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For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

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FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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 eye. Call a poison control center or doctor for treatment advice.

If swallowed: Call 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 by mouth to an unconscious person.

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 treatment advice.

To Physician: Treat the patient symptomatically.

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.

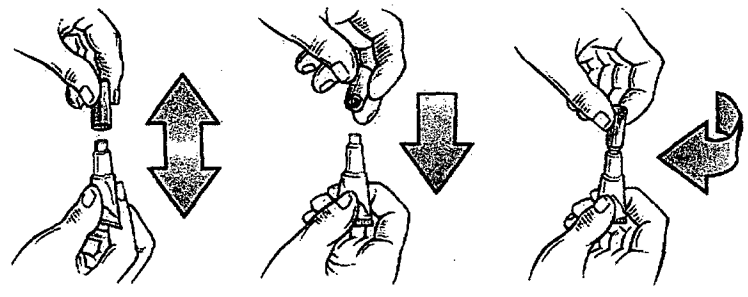


HOW TO APPLY

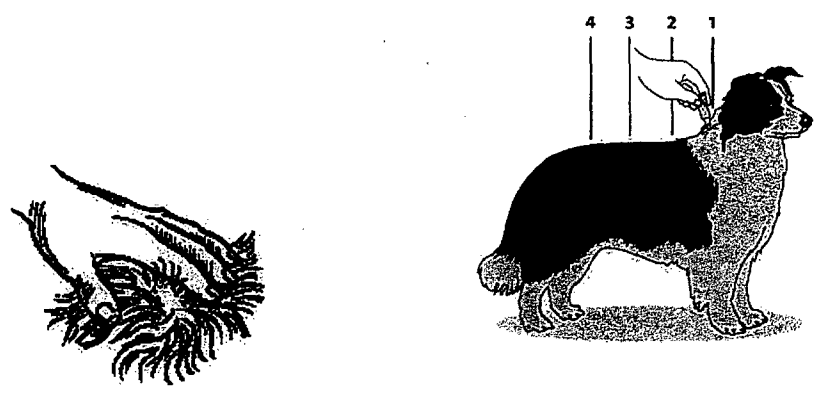
1. Use only on dogs. DO NOT USE ON CATS or on other animals.
2. Remove applicator tube from the package. Use scissors and peel down foil.

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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® Plus tube should be applied evenly to four to six 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.



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

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

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with K9 Advantix® Plus 55 rapidly kills fleas and may reduce the incidence of this condition.

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K9 Advantix® Plus 55 kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting at least 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® Plus 55 treated dog.

K9 Advantix® Plus 55 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.

If re-treatment becomes necessary, do not re-treat more than once every week.

STORAGE AND DISPOSAL

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

Storage: Store in a cool, dry place. Protect from freezing. **Disposal:** Nonrefillable container. **If empty:** Do not reuse 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: [(One)(Two)(Four)(Six)] Tube(s) - 0.084 fl. oz. (2.5 mL) each

OPTIONAL CLAIM FOR THE ONE TUBE PACKAGE: [Sample – Not for (Re)Sale]

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-143

Manufactured For
Bayer HealthCare LLC
P.O. BOX 390
Animal Health Division
Shawnee Mission, Kansas 66201 USA

Made in Germany

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(Label on Individual Tube)

K9 Advantix[®] Plus 55

8.8% imidacloprid
44.0% permethrin
0.44% pyriproxyfen

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-143

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000