



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

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

JAN 19 2011

Bayer HealthCare LLC, Animal Health
c/o Ms. Mary McKinney Hunt
P.O. Box 390
Shawnee Mission, KS 66201-0390

Subject: [Label Amendment] Notification PR Notice 98-10 Label Revision to K9 Advantix
Plus 55, EPA Reg. No. 11556-143
Submission Dated September 15, 2010
Decision: D441273

Dear Ms. McKinney Hunt:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the conditions of registration and comments below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. Per the March 17, 2010 meeting with registrants of spot-on pet products, this registration is now time-limited and expires two years from the date this product is released for shipment bearing the revised language. You must provide the Agency with a projected release for shipment date within 30 days of the date of this letter. The Agency will calculate the expiration date based on the projected release date until an actual release date is provided in writing.
2. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on January 1, 2011. The quarterly reports are due two months after the quarter ends.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Ms. Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #

Where purchased: internet, store, or veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

3. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).

- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
4. Please note that registrants of all spot-on pet products are asked to consider limiting the formulations of each product to one basic confidential statement of formula, if applicable. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
5. Revise the following statement on page 5 of the label, because this is contradictory to the reapplication instructions of a monthly treatment:

Delete:

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

Replace with:

"Under normal conditions this product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than 4 weeks. Do not retreat more often than once every 7 days. After flea control is attained, return to a monthly retreatment schedule."

If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform registrants, and if needed, EPA may take regulatory action. If you have any questions, please call me directly at 703-305-6701 or Rosanna Louie-Juzwiak of my staff at 703-308-0037.

Sincerely,



Richard Gebken, Product Manager 10
Insecticide Branch, Registration Division
Office of Pesticide Programs (7504P)

Enclosure: K9 Advantix Plus 55 Label Stamped *Accepted with Comments*

Reason To Issue: Add ABN and optional text [Sample-not for (re)sale] to all SKUs; delete CVBD claims and remove "Nylar." Reformatted. Date: 09/15/2010 Supersedes: 02/26/10

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

K9 Advantix® Plus 55
Alternate Brand Name: K9 Advantix II Large Dog

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

[Selected optional claims bulleted here from page 8 and/or 9]

-
-
-

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

JAN 19 2011

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.**

11556-143
%

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

EPA Reg No. 11556-143

EPA Est. No. 11556-DEU-1

KEEP OUT OF REACH OF CHILDREN

WARNING

[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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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.

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



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.

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	
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. For consumer questions call 1-800-255-6826. For medical emergencies call 1-800-422-9874.	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

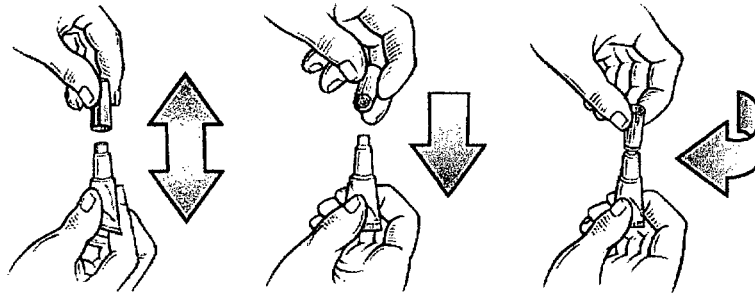
DIRECTIONS FOR USE

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

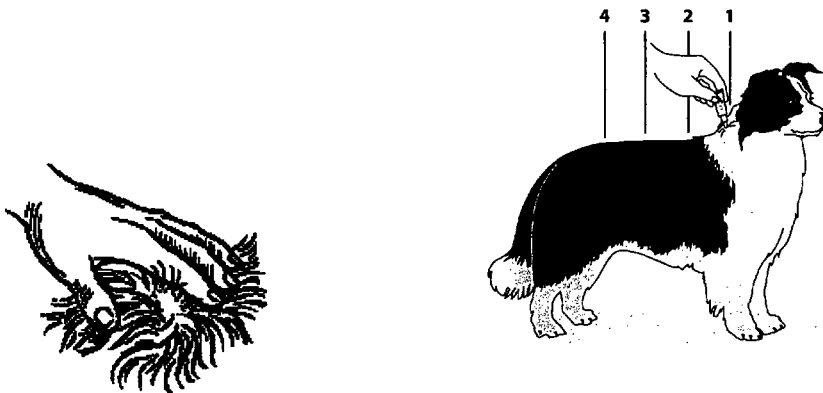


HOW TO APPLY

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.



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.

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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.

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: XX Tube(s) – each 0.084 fl. oz. (2.5 mL)

[Sample – Not for (Re)Sale]

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

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

OPTIONAL MARKETING CLAIMS

- 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]
- 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
- Effectively breaks the flea life cycle
- Flea adulticide, larvicide and ovicide.
- 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]
- 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 weeks
- 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

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- 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
- 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