

11556-143

5/20/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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

MAY 20 2013

Subject: K9 Advantix Plus 55
EPA Reg. No. 11556-143
Submission dated 4/5/2012 implementing label changes to pet spot-on products
EPA Decision No. 473237

Dear Dr. Spilker,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the alternate brand name of "K9 Advantix II Large Dog" is accepted as the primary brand name, the previous primary brand name of "K9 Advantix Plus 55" is no longer active, and the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action. This registration is now time-limited and expires two years from the date of this letter.

Per the additional requirements of this letter, you must continue to submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. 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 attention of Kaitlin Keller, Pesticide Reevaluation Division.

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, 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

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.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



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

Enclosure: Label stamped "Accepted"

4/13

Reason To Issue: Revise according to EPA "Implementation of Label Changes to Pet Spot-On Products" document; add optional opening instructions; revise primary brand name

Date: 05/16/13
Supersedes: 03/01/12 (Re-Reg Book), 3/26/12 and 02/07/13
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NOTE TO REVIEWER: [(Brackets and parentheses indicate alternate language)]

K9 Advantix® II Large Dog

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

[Selected optional claims bulleted here from page 9 and/or 10]

-
-
-

| 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

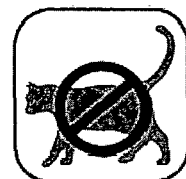
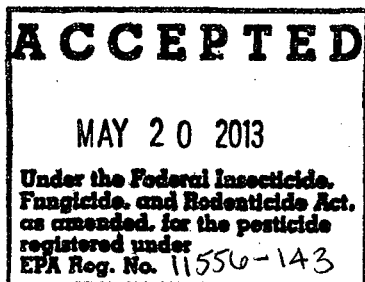
EPA Est. No. 11556-DEU-1

EPA Reg No. 11556-143

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for Precautionary Statements.
For Directions for Use, Storage and Disposal, and First Aid, see package insert inside.



DO NOT USE ON CATS

5/13

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Date: 05/16/13
Supersedes: 03/01/12 (Re-Reg Book), 3/26/12 and 02/07/13
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K9 Advantix® II Large Dog

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

READ THE ENTIRE LABEL BEFORE EACH USE

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

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 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 (7) 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 dogs. 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.

Side Effects:

Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy or agitation) occur, consult your veterinarian or call 1-800-422-9874.

DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately .



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

ENVIRONMENTAL HAZARDS

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This pesticide 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. | |

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 OPEN

[OPTION 1: INSTRUCTIONS FOR BLISTER PACK]

1. Being careful not to cut close to the blister cavities, take scissors and cut off one section of the card containing a single tube.
2. Take the separated section, and cut into the blister cavity across the small side, close to the cap of the tube.
3. Peel off the foil, and take out the tube.
4. Repeat steps 1 to 3 for each tube.

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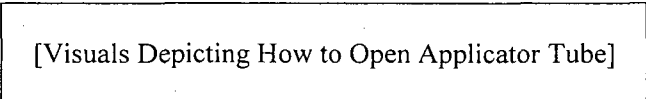
Date: 05/16/13
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[OPTION 2: INSTRUCTIONS FOR POUCH PACK]

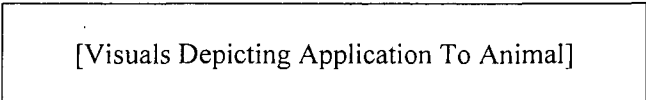
- 1. Be sure tube is at bottom of pouch.
- 2. Using scissors, cut the pouch across the top and remove tube.

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® II 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 dog's eyes, or allow your dog to ingest this product.



- 7. Discard empty tube as described in Storage and Disposal.
- 8. In cases of severe pest infestation, retreatment is allowable earlier than four (4) weeks. Do not retreat more often than once every seven (7) days. After pest control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

8/13

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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® II rapidly kills fleas and may reduce the incidence of this condition.

K9 Advantix® II 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® II treated dog.

K9 Advantix® II 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 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.

For additional information visit www.petparents.com

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Net Contents: 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® II Large Dog

8.8% imidacloprid
44.0% permethrin
0.44% pyriproxyfen

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-143

Keep out of reach of children

WARNING

DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000

11/13

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[OPTION 1: Label on blister card; one card containing 1, 2, 3, 4, 5, or 6 tubes]
[OPTION 2: Label on pouch containing one tube]

[Additional label text for OPTION 2: THIS UNIT NOT FOR RETAIL SALE]

K9 Advantix® II Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing 21 - 55 lbs.

8.8% imidacloprid
44.0% permethrin
0.44% pyriproxyfen

[X] - 0.084 fl. oz. (2.5 mL) Tube(s)

EPA Reg. No. 11556-143

BAYER

Lot No. 0000000



Do Not Use on Cats

| | | |
|------------------|--|--|
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|------------------|--|--|

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® II 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® II 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, fleas and mosquitoes
- 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® II treated dog
- Kills larval stages of fleas in the dog's environment following contact with K9 Advantix® II 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® II 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

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- [(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
- 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