



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

11556-135

Date of Issuance:

3/31/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 03/31/2018

Name of Pesticide Product:

K9 ADVANTIX LARGE DOG

Name and Address of Registrant (include ZIP Code):

J. Todd Frank
 Regulatory Affairs Consultant
 Bayer Health Care LLC
 Animal Health
 P.O. Box 390
 Shawnee Mission, KS 66201-0390

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Jennifer Saunders, Ph.D., Product Manager 04
 Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

3/31/16

2. This registration is time-limited and expires 03/31/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. 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
4. 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 cats and table for dogs 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, as applicable.
- 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, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- 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.

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.

5. You are required to comply with the data requirements described in the DCI and EDSP Orders identified below:
 - a. Permethrin GDCI-109701-1252
 - b. Permethrin GDCI-109701-1281
 - c. Permethrin GDCI-109701-1113
 - d. Permethrin EDSP-109701

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 11556-135.”
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is

subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/11/2016
- Alternate CSF 1 dated 01/12/2016

If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at fertich.elizabeth@epa.gov.

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

[Front Panel]

K9 Advantix[®] Large Dog

Alternate Brand Name: DefenseCare Flea & Tick Protection Large Dog

Note: [The “Large Dog” text size will be 75% of the height of the largest letter in the primary brand name.]

Visual image of a dog within the weight range for product.

Topical prevention and treatment of fleas, ticks, 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 optional claims section]

-
-
-

ACTIVE INGREDIENTS:	% By Weight
Imidacloprid	8.8%
Permethrin*	44.0%
OTHER INGREDIENTS:	<u>47.2%</u>
Total.	100.0%

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

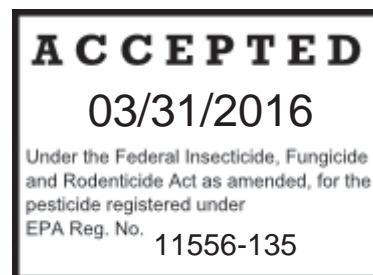
EPA Reg. No. 11556-RGL

EPA Est. 11556-XXX-X

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for Precautionary Statements.



Reason To Issue: Submitted for reregistration.

Date: 01/12/2016
Supersedes 10/31/13
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For Directions for Use, Storage and Disposal, and First Aid see supplemental labeling inside.



DO NOT USE ON CATS

[Icon Size 1.5 cm X 1.5 cm, Background yellow with black text]

[Back Panel]

K9 Advantix[®] Large Dog

Topical prevention and treatment of fleas, ticks, 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

DO NOT USE ON CATS

[Selected optional claims bulleted here from optional claims section]

-
-
-

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 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.

Side Effects: Monitor your dog after application. Side effects 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

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.

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

[Sample – Not for (Re)Sale]

EPA Est. 11556-XXX-X-X

EPA Reg. No. 11556-RGL

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

Made in Germany

[Back Panel and/or Insert]

K9 Advantix[®] Large Dog

Topical prevention and treatment of fleas, ticks, 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

DO NOT USE ON CATS

[Selected optional claims bulleted here from optional claims section]

-
-
-

ACTIVE INGREDIENTS:	% By Weight
Imidacloprid	8.8%
Permethrin*	44.0%
OTHER INGREDIENTS:	<u>47.2%</u>
Total.	100.0%

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

EPA Reg. No. 11556-RGL

EPA Est. 11556-XXX-X

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 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.

Side Effects: Monitor your dog after application. Side effects 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

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

	<p>treatment advice.</p> <ul style="list-style-type: none"> • 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.

[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.
3. Hold applicator tube in an upright position. Pull cap off tube.

[Visuals Depicting How to Open Applicator 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. Do not get this product in your dog's eyes, or allow your dog to ingest this product.

[Visuals Depicting Application To Animal]

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

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.

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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.

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

Reason To Issue: Submitted for reregistration.

Date: 01/12/2016
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[Label on Individual Tube]

K9 Advantix[®] Large Dog

8.8% imidacloprid
44.0% permethrin

0.084 fl. oz. (2.5 mL)

EPA Reg. No. 11556-RGL

Keep out of reach of children

WARNING

DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Submitted for reregistration.

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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[®] 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

See leaflet for complete product information.

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

EPA Reg. No. 11556-RGL

BAYER

Lot No. 0000000



Do Not Use on Cats

[Selected optional claims]

- [For use on only 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 only dogs 7 weeks of age or older]
- [K9 Advantix is indicated for the prevention and treatment of fleas, ticks, biting flies, mosquitoes, and lice only 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]
- [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)]
- [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]]

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- [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]
- [From the makers of ExpertCare]