

11556-144

10/10/2007

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U.S. ENVIRONMENTAL PROTECTION
AGENCYOffice of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460EPA Reg.
Number:
11556-144Date of
Issuance:
OCT 10 2007Term of Issuance:
ConditionalName of Pesticide Product:
K9 Advantix Plus 100

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Bayer HealthCare LLC, Animal Health Division

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/reregistered 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 sec. 3(c)(7)(A), provided that you:

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. You will make the following label changes before you release the product for shipment:

a. Revise the EPA Registration Number to read "EPA Registration Number 11556-144."

Signature of Approving Official:

Date:

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Page 2.

EPA Reg. No. 11556-144

b. Replace the Hazards to Humans and domestic Animal section with "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.

c. Remove the claim "Kills [(biting)(chewing)] lice, which may serve as intermediate hosts for tapeworms (*Dipylidium caninum*). Fleas, not lice, are the intermediate host of *D. caninum*.

d. Add "following contact with K9 Advantix Plus treated dog" to the bullet beginning "Kills larval stages of fleas in the pets environment".

e. Replace "Stops" with "Controls" throughout the labeling.

f. Change "Waterproof" to "Water Resistant" throughout the label.

g. Delete "odor" from the bullet "Fragrance (odor) free".

h. Add "To the extent consistent with applicable law" to the beginning of the sentence "Bayer makes no other express or implied warranty... etc" and "Any damages arising from a breach of this warranty shall be limited ... etc." in the Limited Warranty statement.

ACUTE TOXICITY REVIEW

STUDY	MRID	CATEGORY	CLASSIFICATION
Acute Oral	47014308	III	Acceptable
Acute Dermal	47014306	IV	Acceptable
Acute Inhalation	47014305	IV	Acceptable
Eye Irritation	47014307	II	Acceptable
Dermal Irritation	47014304	III	Acceptable
Dermal Sensitization	47014303	Negative	Acceptable

A copy of the reviews are enclosed for your records.

3. You must generate studies corresponding to guidelines 830.6317 (one year storage stability) and 830.6320 (corrosion characteristics). The results must be submitted to the Agency along with an electronic format also.

4. Please note that a notice of availability of EPA's registration eligibility document (RED) for product containing Permethrin was published in the FR on June 28, 2006 (Vol 71 No. 124 page 36788). Additional data and/or labeling changes may be required for products containing Permethrin.

5. Please submit two (2) copies of your final printed labeling before releasing the product for shipment. If these conditions are not

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complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the 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.

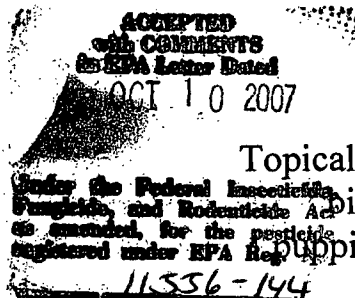
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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

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

(Front Panel of Outer Box)



K9 Advantix® Plus 100

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 over 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

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

- Available through licensed practicing veterinarians
- 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 at least 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 at least 4 weeks
- Kills 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least four 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
- Kills 98-100% of fleas within 12 hours of application
- Stops 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.

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

- 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 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 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)
- 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
- Kills [(biting) (chewing)] lice, which may serve as intermediate hosts for tapeworms (*Dipylidium caninum*)
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Stops 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 (odor) free

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

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

Active Ingredients	% By Weight
Imidacloprid; [CAS 138261-41-3]	8.80%
Permethrin;* [CAS 52645-53-1]	44.00%
Pyriproxyfen; [CAS 95737-68-1]	0.44%
Other Ingredients	46.76%
Total	100.00%
* cis/trans ratio: Max 55% (±) cis and min 45% (±) trans	

KEEP OUT OF REACH OF CHILDREN

WARNING

See below for first aid and precautionary statements.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

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.

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.

Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

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.

[(Four) (Six)] 0.135 fl. oz. (4.0 mL) Tubes

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

Manufactured For
Bayer HealthCare LLC
Animal Health Division
Shawnee Mission, Kansas 66201 USA

Made in Germany

9/18

Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

(Back Panel of Outer Box)

K9 Advantix[®] Plus 100

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 over 55 lbs.

- Repels and kills ticks including those that may transmit Lyme disease
- Kills 98-100% of fleas within 12 hours
- Repels and kills mosquitoes
- Repels biting flies
- Kills chewing lice
- Waterproof

DO NOT USE ON CATS

[(Four) (Six)] 0.135 fl. oz. (4.0 mL) Tubes

10/18

Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

(Top Panel of Outer Box)

K9 Advantix[®] Plus 100

DO NOT USE ON CATS

(Side Panel of Outer Box)

- Available through licensed practicing veterinarians
- Convenient, easy to apply

(Side Panel of Outer Box)

SEE PACKAGE INSERT FOR COMPLETE
PRODUCT INFORMATION

- Repels and kills ticks
- Kills 98-100% of fleas within 12 hours
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- Repels biting flies
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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

(Package Insert)

K9 Advantix® Plus 100

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biting flies, and lice for monthly use on dogs and
puppies 7 weeks of age and older, weighing over 55 lbs.

Read The Entire Label Before Use

DO NOT USE ON CATS

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

- Available through licensed practicing veterinarians
- 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 at least 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
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- Prevents flea eggs from hatching
- Effectively breaks the flea life cycle
- Flea adulticide, larvicide and ovicide.

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

- Prevents fleas on treated dogs from infesting (reinfesting) your home.
- Effectively targets all [life] stages of [fleas] and [ticks]
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- Repels [(annoying)(bothersome)(nuisance)] biting flies
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- Kills [(biting) (chewing)] lice
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- 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 (odor) free

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

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

Active Ingredients	% By Weight
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Permethrin;* [CAS 52645-53-1]	44.00%
Pyriproxyfen; [CAS 95737-68-1]	0.44%
Other Ingredients	46.76%
Total	100.00%
* cis/trans ratio: Max 55% (±) cis and min 45% (±) trans	

KEEP OUT OF REACH OF CHILDREN

WARNING

See below for first aid and precautionary statements.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS**

Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash hands thoroughly with soap and warm water after handling.

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.

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Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

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.

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.

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

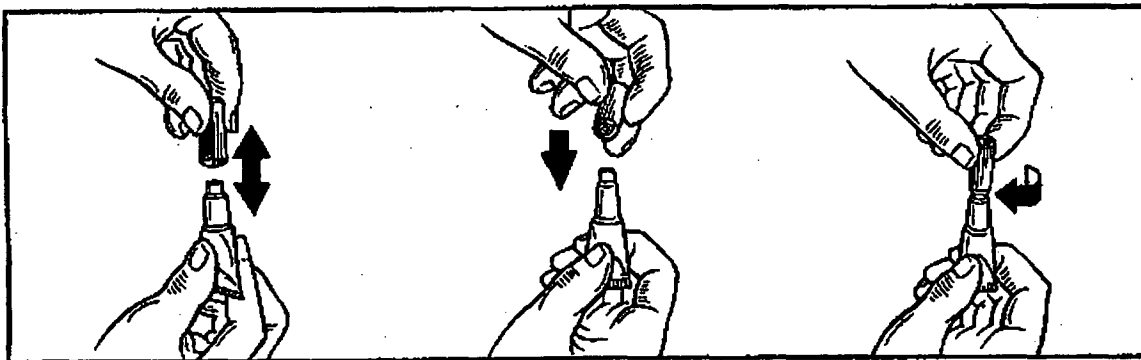
DIRECTIONS FOR USE

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.



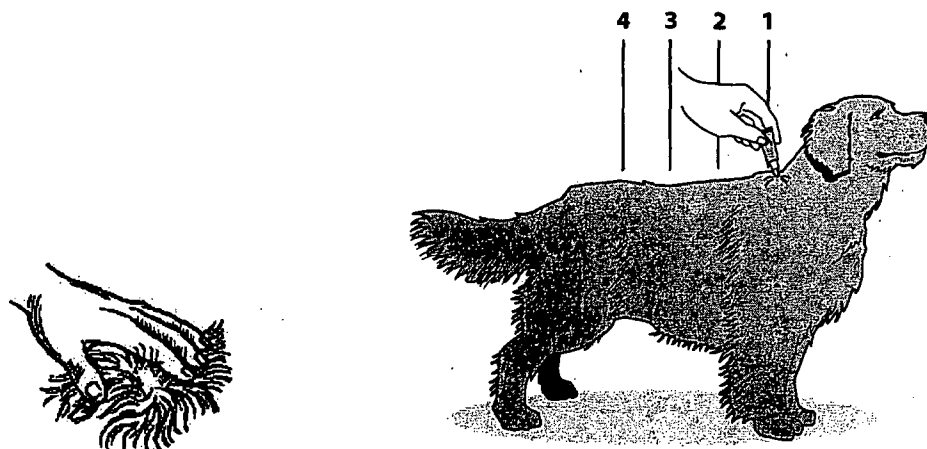
3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.

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

K9 Advantix® Plus 100 kills 98-100% of the 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 100 treated dog.

K9 Advantix® Plus 100 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.

Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

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Date: 09/25/07
Supersedes: 07/10/07

STORAGE AND DISPOSAL

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

Storage: Store in a cool, dry place. Protect from freezing. **Pesticide Disposal: 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 1-800-255-6826 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. 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. 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.

EPA Est. 11556-DEU-1

EPA Reg. No. 11556-RUU

Manufactured For

Bayer HealthCare LLC
Animal Health Division
Shawnee Mission, Kansas 66201 USA

Made in Germany

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Reason To Issue: Propose Registration; Update Marketing
Claims; Minor Revisions

Date: 09/25/07
Supersedes: 07/10/07

(Label on Individual Tube)

K9 Advantix[®] Plus 100

8.8% imidacloprid
44.0% permethrin
0.44% pyriproxyfen

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-RUU

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000