

11556-133

10-2-2007

1/15



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 2 2007

Mary McKinney Hunt
Pesticide Regulatory Manager
Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201-0390

RE: Proposed Label Revision
EPA Reg. No.: 11556-133
Date of Submission: September 10, 2007

Dear Ms. Hunt:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 10, 2007, for the product K9 Advantix 20. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Joyce Edwards of my staff at 703-308-5479.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

ATTACHMENT FOR OPP
APPLICATION FOR PESTICIDE NOTIFICATION
Page 1 of 1

K9 Advantix 20, EPA Reg. No. 11556-133
September 10, 2007

Enclosed for Agency acceptance is a draft label for K9 Advantix 20,
EPA Reg. No. 11556-133.

The four proposed revisions are as follows:

- 1) Changes to label per Agency letter dated 2/22/2007 (enclosed)
- 2) Include fluid ounces to net weight (in addition to net weight in ml)
- 3) Replace "inert" with "other" in Other Ingredients
- 4) Remove the word, "only,"

from: Available only through licensed practicing veterinarians.
to: **Available through licensed practicing veterinarians.**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46 and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

9/15



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 11556-133	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) K9 Advantix 20	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Enclosed for Agency acceptance is a draft label for K9 Advantix 20, Registration Number 11556-133. Four proposed revisions include: 1) changes to label per Agency letter dated 2/22/2007 (enclosed); 2) include fluid ounce to net weight (in addition to net weight in ml); 3) replace "inert" with "other" in Other Ingredients; and 4) remove the word, "only," in the following statement: Available "only" through licensed practicing veterinarians. The proposed statement is: "Available through licensed practicing veterinarians." Please see attachment for further detail.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Mary McKinney Hunt		Title Pesticides Regulatory Manager		Telephone No. (Include Area Code) (913) 268-2311	
<p align="center">Certification</p> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Mary McKinney Hunt</i>			3. Title Pesticides Regulatory Manager		
4. Typed Name Mary McKinney Hunt		5. Date Sept. 10, 2007			

11556-133

02/22/2007

4/15

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

~~FEB 22 2007~~

Dear Mr. Gagliano:

Subject: Amendment- efficacy to add label claims (MRID 46978901 and MRID 46978902)
K9 Advantix 10
EPA Registration Number 11556-132
K9 Advantix 20
EPA Registration Number 11556-133
K9 Advantix 100
EPA Registration Number 11556-134
K9 Advantix 55
EPA Registration Number 11556-135
Your submissions dated October 6, 2006

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

1. Please delete "Starts working/ repels before biting flies bite." The study counted blood-fed flies, not number of bites.
2. Please delete all "kills flies" claims. The data do not support these claims.

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

A copy of the review is enclosed for your records.

A stamped copy of the labels are enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505P)

Enclosure

5/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

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

(Front Panel of Outer Box)

K9 Advantix™ 20

Topical prevention and treatment of ticks, fleas, biting flies, and mosquitoes for monthly use on dogs and puppies 7 weeks of age and older, weighing 11-20 lbs.

ACCEPTED with COMMENTS in EPA Letter Dated

FEB 22 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, this product is registered under...

1556-133

READ THE ENTIRE LABEL BEFORE EACH USE

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

- Available ~~only~~ through licensed practicing veterinarians
- 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
- Kills 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least four weeks
- Kills and repels fleas before they lay eggs
- Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix™ treated dog
- Repels and kills mosquitoes for up to four weeks
- Remains effective after bathing and swimming
- ~~[(Kills) (and), (repels)]~~ biting flies
- ~~Kills, repels, and inhibits blood-feeding by~~ biting flies
- ~~Kills, repels, and prevents blood-feeding by~~ biting flies
- ~~Kills~~ [(annoying) (bothersome) (nuisance)] biting flies
- Repels [(annoying) (bothersome) (nuisance)] biting flies
- Inhibits [(annoying) (bothersome) (nuisance)] biting flies
- [(Prevents) (inhibits)] blood-feeding by biting flies
- ~~[(Starts working) (Repels)] before [biting] flies bite~~
- [(Prevents blood-feeding by) (~~Kills and repels~~)] biting flies

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

Active Ingredients	%
	By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine ...	8.8%
Permethrin*	44.0%
Inert ^{Other} Ingredients	<u>47.2%</u>
Total	100%
* 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.

For consumer questions call 1-800-255-6826. For medical emergencies call 1-877-258-2280.

7/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

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.

Six (1.0 mL) Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-133

~~0.034~~ A. 02.

Manufactured For
Bayer Corporation
Agriculture Division
Animal Health
Shawnee Mission, Kansas 66201 USA

Made in Germany

f/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

(Back Panel of Outer Box)

K9 Advantix™ 20

Topical prevention and treatment of ticks, fleas, biting flies, and mosquitoes for monthly use on dogs and puppies 7 weeks of age and older, weighing 11-20 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 ~~and kills~~ biting flies

DO NOT USE ON CATS

Six (1.0 mL) Tubes

0.034 fl. oz.

7/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

(Top Panel of Outer Box)

K9 ADVANTIX™ 20

DO NOT USE ON CATS

(Side Panel of Outer Box)

- Available ~~only~~ 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
- Repels and kills mosquitoes
- Repels ~~and kills~~ biting flies

4/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

(Package Insert)

K9 Advantix™ 20

Topical prevention and treatment of ticks, fleas, biting flies, and mosquitoes for monthly use on dogs and puppies 7 weeks of age and older, weighing 11-20 lbs.

Read The Entire Label Before Use

DO NOT USE ON CATS

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

- Available ~~only~~ through licensed practicing veterinarians
- 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
- Kills 98-100% of the fleas on dogs within 12 hours and continues to prevent infestations for at least four weeks
- Kills and repels fleas before they lay eggs
- Larval flea stages in the dog's surroundings are killed following contact with a K9 Advantix™ treated dog
- Repels and kills mosquitoes for up to four weeks
- Remains effective after bathing and swimming
- ~~[(Kills) (and) (repels)]~~ biting flies
- ~~Kills,~~ repels, and inhibits blood-feeding by biting flies
- ~~Kills,~~ repels, and prevents blood-feeding by biting flies
- ~~Kills~~ [(annoying) (bothersome)(nuisance)] biting flies
- Repels [(annoying)(bothersome)(nuisance)] biting flies
- Inhibits [(annoying)(bothersome)(nuisance)] biting flies
- [(Prevents)(inhibits)] blood-feeding by biting flies
- ~~[(Starts working)(Repels)]~~ before [biting] flies bite
- [(Prevents blood-feeding by) (Kills and repels)] biting flies

4/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

Active Ingredients	%
	By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine ...	8.8%
Permethrin*	44.0%
Inert ^{Other} Inert Ingredients	<u>47.2%</u>
Total	100%
6. cis/trans ratio: Max 55% (±) cis and min 45% (±) trans	

KEEP CUT 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.

For consumer questions call 1-800-255-6826. For medical emergencies call 1-877-258-2280.

12/15

Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

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.

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

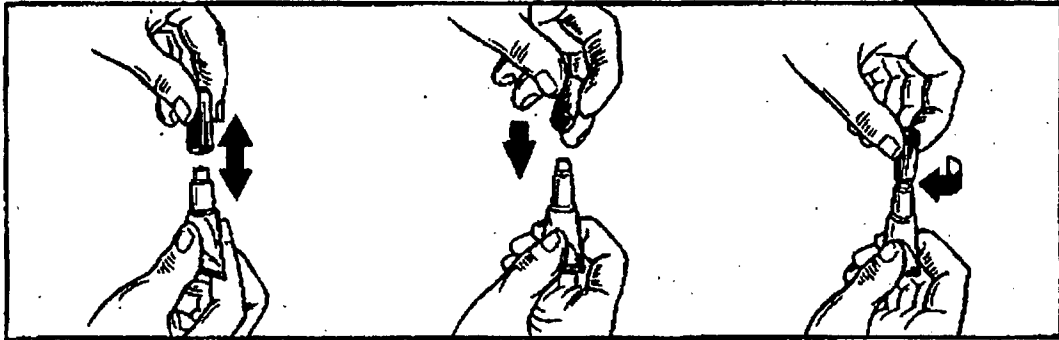
1. Use only on dogs. DO NOT USE ON CATS or on other animals.

Reason To Issue: Add biting flies claim.

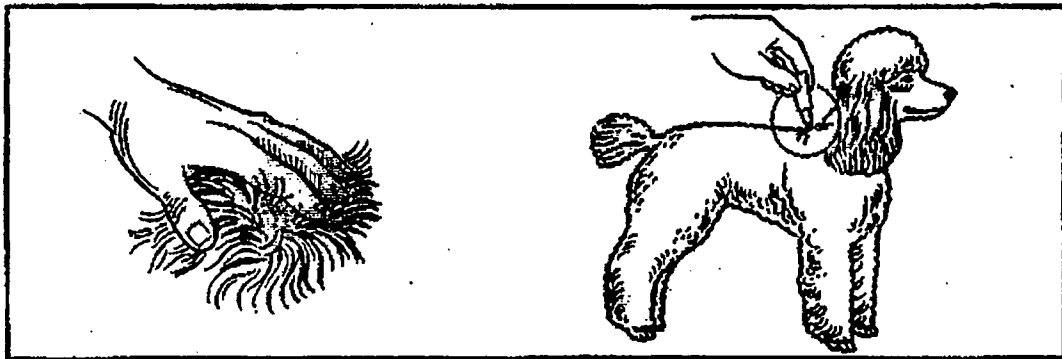
Date: 10/03/06

Supersedes: 10/01/03

2. Remove applicator tube from the package.



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. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to expel the entire contents directly on the skin.



Do not get this product in your dog'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™ rapidly kills fleas and may reduce the incidence of this condition.

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Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

K9 Advantix™ 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™ treated dog.

K9 Advantix™ remains efficacious 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. **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 Corporation, Agriculture Division, Animal Health warrants that this material conforms to the chemical description on the label. BAYER CORPORATION MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer Corporation 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. 11556-133

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Reason To Issue: Add biting flies claim.

Date: 10/03/06

Supersedes: 10/01/03

(Label on Individual Tube)

K9 Advantix™ 20

8.8% imidacloprid
44.0% permethrin

~~0.034 (1.0 oz) (1.0 mL)~~

EPA Reg. No. 11556-133

WARNING

Keep out of reach of children
DO NOT USE ON CATS

Read The Entire Label Before Use

BAYER

Lot No. 0000000