

11556-130

3/28/2013

1/12



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

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Douglas Spilker
Bayer HealthCare LLC, Animal Health Division
PO Box 390
Shawnee Mission, KS 66201

MAR 28 2013

Dear Mr. Spilker:

Subject: Amendments to add new child resistant packaging
Advantage II Extra Large Dog
EPA Registration No. 11556-130
Decision Numbers: 473309
Submission Dates: December 14, 2012, and February 19, 2013

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records. Please submit two copies of your final printed labeling before you release the product for shipment. If you have any questions regarding these labels, please contact Dr. Jennifer Urbanski at 703-347-0156 or urbanski.jennifer@epa.gov.

Sincerely yours,

A handwritten signature in black ink, which appears to read "Venus Eagle", is written over the typed name.

Venus Eagle
Product Manager (01)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure- Stamped Label and Science Reviews (DP408185 and 409881)

Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13
Supersedes: 12/12/12,
11/28/12 and 09/25/12

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

[Front Panel]

Advantage® II Extra Large Dog

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing Over 55 lbs.

[Selected optional claims bulleted here from page 10 and/or 11]

-
-
-
-

| <u>Active Ingredients</u> | <u>% By Weight</u> |
|---------------------------|------------------------|
| Imidacloprid | 9.10% |
| Pyriproxyfen | 0.46% |
| Other Ingredients | 90.44% |
| Total | 100.00% |

EPA Est. 11556-XXX-X

EPA Reg. No. 11556-130

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for Precautionary Statements.

For Directions for Use, Storage and Disposal, and First Aid see package insert inside.

ACCEPTED

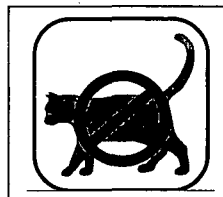
MAR 28 2013

**Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:**

Advantage II Extra Large Dog ka.Doc

DO NOT USE ON CATS

Icon size 1.5cm x 1.5cm



Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13

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11/28/12 and 09/25/12

[Back Panel]

Advantage® II Extra Large Dog

Once-A-Month Topical Treatment for Fleas and Lice
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing Over 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than 55 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. 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 dog 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) occur, consult your veterinarian or call 1-800-422-9874.

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

Icon size 1.5cm x 1.5 cm



For consumer questions call 1-800-255-6826.

For medical emergencies call 1-800-422-9874.

RESTRICTIONS:

- Use only on dogs 7 weeks and older. Do not apply to dogs or puppies weighing less than 55 lbs. Do not use on other animals.

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Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13

Supersedes: 12/12/12,
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- Do not apply more than one (1) tube per treatment, even for larger dogs.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: [X] Tube(s) each 0.135 fl. oz. (4.0 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

5/12

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[Back Panel and/or Insert]

Advantage® II Extra Large Dog

Once-A-Month Topical Treatment for Fleas and Lice

For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing Over 55 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea and Lice Infestations [on Dogs]

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.



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. Remove one applicator tube from the package. See "HOW TO OPEN" section.
2. Hold applicator tube in an upright position facing away from you and your pet's face and eyes. Pull cap off tube.

[Visuals Depicting How to Open Applicator Tube]

3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.

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5. The dog should be standing for easy application. Apply the entire contents of the tube 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]

6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not retreat more often than once every seven (7) days. After flea control is attained, return to a monthly retreatment schedule.

PRODUCT INFORMATION

The successive feeding activity of fleas on dogs frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) or flea bite hypersensitivity. Treatment of dogs with Advantage® II Extra Large Dog rapidly kills fleas within 12 hours which may reduce the incidence of this condition.

Advantage® II Extra Large Dog kills existing fleas on dogs within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Fleas, flea eggs, and flea larvae in the dog's environment are killed following contact with an Advantage® II Extra Large Dog treated dog. Advantage® II Extra Large Dog provides multi-stage flea control effectively breaking all flea life-cycle stages for quick and lasting control of flea populations.

Advantage® II Extra Large Dog kills adult fleas quickly, within 12 hours, inhibits the development of immature flea life stages and prevents them from reaching the biting adult stage.

Advantage® II Extra Large Dog kills [(biting) (chewing)] lice that infest dogs and puppies, and prevents further infestations.

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Reason To Issue: New child-resistant packaging proposal.

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11/28/12 and 09/25/12.

Advantage® II Extra Large Dog 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.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling.

| FIRST AID | |
|---|---|
| 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 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 On Skin | <ul style="list-style-type: none"> • Wash with plenty of soap and water. |
| HOT LINE NUMBER | |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies call 1-800-422-9874. For consumer questions call 1-800-255-6826. | |
| NOTE TO PHYSICIAN | |
| Treat the patient symptomatically. | |

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than 55 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. 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 dog is on medication, consult your veterinarian before using this or any other product.

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Reason To Issue: New child-resistant packaging proposal.

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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) occur, consult your veterinarian or call 1-800-422-9874.

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

Icon size 1.5cm x 1.5 cm



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

RESTRICTIONS:

- Use only on dogs 7 weeks and older. Do not apply to dogs or puppies weighing less than 55 lbs. Do not use on other animals.
- Do not apply more than one (1) tube per treatment, even for larger dogs.
- Do not have contact or allow children to have contact with treated area until completely dry.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry place inaccessible to children and pets. **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.

For more information visit www.petparents.com

9/12

Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13
Supersedes: 12/12/12,
11/28/12 and 09/25/12

[Label on Individual Tube]

Advantage® II Extra Large Dog

9.10% Imidacloprid

0.46% Pyriproxyfen

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-130

Keep Out of Reach of Children

CAUTION

Read The Entire Label Before Use

BAYER

Lot No. 0000000

10/12

Reason To Issue: New child-resistant packaging proposal.

Date: 02/14/13

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11/28/12 and 09/25/12

[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]

Advantage® II Extra Large Dog

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

9.10% Imidacloprid

0.46% Pyriproxyfen

[X] - 0.135 fl. oz. (4.0 mL) Tube(s)

EPA Reg. No. 11556-130

BAYER



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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
- Advantage II contains [imidacloprid], and [an/the] [insect growth regulator] [IGR] [pyriproxyfen]
- A single topical application remains effective for [4 weeks] [a month]
- Convenient, easy-to-apply topical solution
- Convenient, easy-to-apply and fragrance free [monthly] [topical solution]
- Once a month topical flea treatment for dogs 7 weeks of age or older
- Advantage II is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older
- For the treatment and prevention of flea [and lice] infestations
- One treatment prevents further flea infestations for [4 weeks] [a month]
- Kills fleas on dogs within [12] hours and continues to prevent infestations for [four weeks] [a month]
- Kills fleas before they lay eggs
- Larval flea stages in the dog's environment are killed following contact with an Advantage II treated dog
- Kills larval stages of fleas in the dog's environment
- Kills fleas within [12] hours of application
- Stops existing flea infestations by killing adult fleas
- Prevents [Stops] reinfestations by killing adult fleas before they lay eggs
- [Prevents] [Stops] flea eggs from hatching [into biting adults]
- Effectively breaks the flea life cycle
- Effectively targets all [life] stages of [fleas]
- [Kills] [Controls] all flea life stages
- 3-way flea protection ([kills] [controls] adults, larvae, and eggs)
- [Prevents] [Stops] flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with Advantage II rapidly kills fleas which may cause flea allergic dermatitis [FAD] or flea bite hypersensitivity
- Flea adulticide, larvicide, and oocide
- Kills flea eggs
- Controls highly [irritating] [annoying] [flea] [insect] bites
- Controls flea problems
- Provides flea protection
- Controls existing fleas and flea eggs [(plus) (and)] [prevents] future flea infestations in the home

12/12

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11/28/12 and 09/25/12

- Starts working through contact
- Use flea [prevention][protection] year-round
- Contains an insect growth regulator (IGR) to kill flea eggs and prevent re-infestation
- Monthly use of Advantage II kills fleas which may cause ([flea allergy dermatitis][flea bite hypersensitivity])
- Multi-stage flea control
- Prevents fleas on treated dogs from infesting (reinfesting) your home
- Kills fleas which may serve as intermediate hosts for tapeworms
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Stops existing [(biting) (chewing)] lice infestations
- Dual protection against fleas 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
- Remains effective after bathing and/or swimming
- Remains effective following swimming and/or shampooing
- Waterproof
- Remains effective after exposure to rain or sunlight
- Fragrance-free
- [In child-resistant packaging]