11556-118

8-9-2002

1/26

Form Approved. OMB No. 2070-0060. Approval expires lesse read instructions on reverse before completing form. **OPP Identifier Number** Registration United States **Environmental Protection Agency Amendment** Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 3. Proposed Classification 2. EPA Product Manager 11556-118 Meredith Laws None Restricted PM# 4. Company/Product (Name) Advantage 18 for Cats 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling Bayer Corporation, Animal Health, Agriculture Division P.O. Box 390 EPA Reg. No. \_ Shawnee Mission, KS 66201 Check if this is a new address **Product Name** Section - II Final printed labels in repsonse to Amendment - Explain below. Agency letter dated "Me Too" Application. Resubmission in response to Agency letter dated \_\_\_ NOTIFICATION Notification - Explain below. Other - Explain below. AUG - 9 2002 Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of label changes as per PR Notice 97-6 and PR Notice 2001-6. Please see attached explanation for details. Section - III 1. Material This Product Will Be Packaged In: Unit Packaging Child-Resistant Packaging Water Soluble Packaging 2. Type of Container Yes Yes Metal Yes Plastic Nο No No Glass Paper If "Yes" If "Yes" No. per No. per \* Certification must Unit Packaging wgt. container Package wgt container Other (Specify) be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions Container On Label accompanying product 6. Manner in Which Label is Affixed to Product Other Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Title Telephone No. (Include Area Code) Director, Preclinical Dev. & EPA Reg. Affairs (913) 268-2588 F. Terry McNamara 6. Deta Application Certification Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or (Stamped) both under applicable law. Director, Preclinical Development & EPA Regulatory Affairs DEN Mc Namara 5. Date F. Terry McNamara

## Attachment for Application for Pesticide Registration Advantage<sup>®</sup> 18 for Cats, EPA Reg. No. 11556-118

Enclosed with this application are five (5) copies of the revised text label (single tube, 4-tube and 6-tube package sizes) for Bayer's Advantage<sup>®</sup> 18 for Cats product (EPA Reg. No. 11556-118) as per PR Notices 97-6 and 2001-6. The changes made are exactly as specified in the PR Notices, specifically:

As per PR Notice 97-6, the word "Inert" has been changed to "Other" in the ingredients statement on the label.

As per PR Notice 2001-6, the Storage and Disposal Statement has been revised to read:

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 1-877-258-2280 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Please note the telephone number is for Bayer's toll free consumer information hotline.

This notification is consistent with the guidance in PR Notice 97-6 and PR Notice 2001-6 and the requirements of EPA's regulations in 40 CFR 156.10 and 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. Bayer understands it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. Bayer further understands that if this notification is not consistent with the guidance of PR Notice 97-6 and PR Notice 2001-6 and the requirements of 40 CFR 156.10 and 40 CRF 152.46, this product may be in violation of FIFRA and Bayer may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02 Supersedes: None

(Front Panel)

# Advantage® 18 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats and Kittens 8 Weeks and Older and Over 9 lbs.

#### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Cats Within 12 Hours
- One Treatment Prevents Further Flea Infestation For Up to Four Weeks
- Kills Fleas Before They Lay Eggs

Active Ingredient	% By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine	9.1%
Other Ingredients	90.9%
Total	100%

#### KEEP OUT OF REACH OF CHILDREN

WARNING
See Below for First Aid and Precautionary Statements

NOTIFICATION AUG - 9 2002

#### 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. Keep out of reach of children. Do not contaminate feed or food.

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

#### HAZARDS TO DOMESTIC ANIMALS

For external use only.

Do not use on kittens under eight weeks of age.

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

#### 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.

One 0.8 mL Tube

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-118

Manufactured For

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

5/Jb

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

(Back Panel)

### Advantage® 18

(imidacloprid) Topical Solution Fast Effective

Once-A-Month Topical Flea Treatment for Cats and Kittens 8 Weeks and Older and Over 9 lbs.

- Available only through licensed practicing veterinarians
- Kills fleas within 12 hours
- Prevents reinfestation for up to 4 weeks
- Convenient, easy to apply

One 0.8 mL Tube

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

#### (Inside Right Panel)

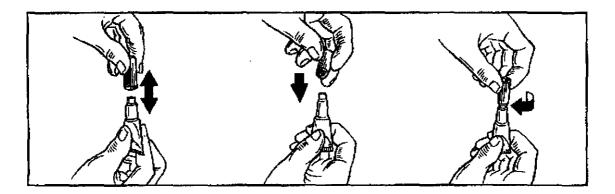
## For the Prevention and Treatment of Flea Infestation on Cats and Kittens 8 Weeks and Older and Over 9 lbs

#### **DIRECTIONS FOR USE**

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

#### **HOW TO APPLY**

- 1. Use only on cats. Do not use on other animals.
- 2. Remove one applicator tube from the package.

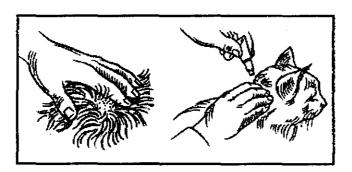


- 3. Hold applicator tube in an upright position. Pull cap off tube.
- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

6. Part the hair in the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to expel the entire contents of the tube directly on the skin. Do not get this product in your pet's eyes or mouth. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product.



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

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

(Inside Left Panel)

#### Advantage® 18

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats

The successive feeding activity of fleas on pets frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage® rapidly kills fleas and reduces the incidence of this condition.

Advantage® kills 98-100% of the fleas on pets within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic condition.

Larval flea stages in the pet's surroundings are killed following contact with an Advantage® treated pet.

Advantage® 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.

If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

#### STORAGE AND DISPOSAL

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

**Storage**: Store in a cool, dry place. **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 1-877-258-2280 for disposal instructions. Never place unused product down any indoor or outdoor chain.

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

#### 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. 11556-118

Reason To Issue: Revised to comply with PR Notice 2001-6. Date: 07/24/02

Supersedes: None

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

 $0.8 \ mL$ 

EPA Reg. No. 11556-118

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

**BAYER** 

Lot No. 0000000

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Front Panel)

# Advantage® 18 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats and Kittens 8 Weeks and Older and Over 9 lbs.

#### READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Cats Within 12 Hours
- One Treatment Prevents Further Flea Infestation For Up to Four Weeks
- Kills Fleas Before They Lay Eggs

Active Ingredient	% By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine	9.1%
Other Ingredients	90.9%
Total	100%

#### KEEP OUT OF REACH OF CHILDREN

WARNING
See Below for First Aid and Precautionary Statements

NOTIFICATION

AUG - 9 2002

## 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. Keen out of reach of children. Do not contaminate feed or food.

Ppb

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

#### HAZARDS TO DOMESTIC ANIMALS

For external use only.

Do not use on kittens under eight weeks of age.

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

#### 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 0.8 mL Tubes

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-118

Manufactured For

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

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Back Panel)

### Advantage® 18

(imidacloprid) Topical Solution Fast Effective

Once-A-Month Topical Flea Treatment for Cats and Kittens 8 Weeks and Older and Over 9 lbs.

- Available only through licensed practicing veterinarians
- Kills fleas within 12 hours
- Prevents reinfestation for up to 4 weeks
- Convenient, easy to apply

Four 0.8 mL Tubes

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Inside Left Panel)

#### Advantage® 18

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats

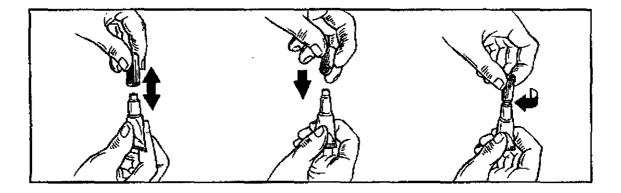
For the Prevention and Treatment of Flea Infestation on Cats and Kittens 8 Weeks and Older and Over 9 lbs

#### **DIRECTIONS FOR USE**

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

#### **HOW TO APPLY**

- 1. Use only on cats. Do not use on other animals.
- 2. Remove one 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.

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

6. Part the hair in the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube twice to expel the entire contents of the tube directly on the skin. Do not get this product in your pet's eyes or mouth. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product.



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

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

#### (Inside Right Panel)

The successive feeding activity of fleas on pets frequently elicits a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with Advantage® rapidly kills fleas and reduces the incidence of this condition.

Advantage® kills 98-100% of the fleas on pets within 12 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four (4) weeks. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic condition.

Larval flea stages in the pet's surroundings are killed following contact with an Advantage® treated pet.

Advantage® 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.

If re-treatment becomes necessary earlier than four weeks, do not re-treat more than once weekly.

#### STORAGE AND DISPOSAL

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

**Storage**: Store in a cool, dry place. **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 1-877-258-2280 for disposal instructions. Never place unused product down any indoor or outdoor chain.

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EPA Est. 11556-DEU-1 EPA Reg. No. 11556-118

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

0.8 mL

EPA Reg. No. 11556-118

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

**BAYER** 

Lot No. 0000000

Date: 07/24/02 Reason To Issue:

Remove flea feeding inhibition claim, revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Back of Blister Package)

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Front Panel)

# Advantage® 18 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats and Kittens 8 Weeks and Older and Over 9 lbs.

#### READ THE ENTIRE LABEL BEFORE EACH USE

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Active Ingredient	% By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine	9.1%
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Total	100%

#### KEEP OUT OF REACH OF CHILDREN

WARNING
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**NOTIFICATION** 

AUG - 9 2002

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Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

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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 0.8 mL Tubes

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-118

Manufactured For

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

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Back Panel)

### Advantage® 18

(imidacloprid) Topical Solution
Fast
Effective

Once-A-Month Topical Flea Treatment for Cats and Kittens 8 Weeks and Older and Over 9 lbs.

- Available only through licensed practicing veterinarians
- Kills fleas within 12 hours
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- Convenient, easy to apply

Six 0.8 mL Tubes

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

(Inside Left Panel)

#### Advantage® 18

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Cats

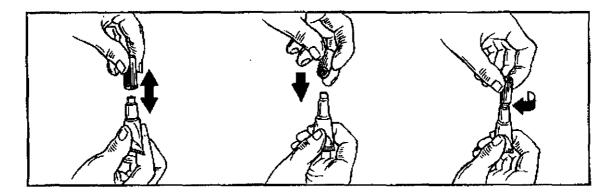
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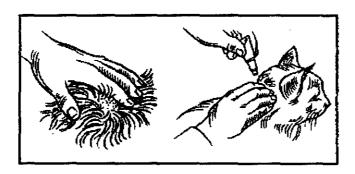


- 3. Hold applicator tube in an upright position. Pull cap off tube.
- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

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

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

#### (Inside Right Panel)

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EPA Est. 11556-DEU-1 EPA Reg. No. 11556-118

Reason To Issue:

Remove flea feeding inhibition claim, revised to comply with PR Notice 2001-6.

Date: 07/24/02

Supersedes: 05/07/01

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

0.8 mL

EPA Reg. No. 11556-118

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

**BAYER** 

Lot No. 0000000

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

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(Back of Blister Package)