

11556-120

8-9-2002

1/30

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 11556-120	2. EPA Product Manager Meredith Laws	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 55 for Dogs	PM#	
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Animal Health, Agriculture Division P.O. Box 390 Shawnee Mission, KS 66201 <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 checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____	<b>NOTIFICATION</b> <b>AUG - 9 2002</b>
<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.)

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:				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	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> 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 <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
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 F. Terry McNamara	Title Director, Preclinical Dev. & EPA Reg. Affairs	Telephone No. (Include Area Code) (913) 268-2589
<b>Certification</b> 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>F. Terry McNamara</i>	3. Title Director, Preclinical Development & EPA Regulatory Affairs	
4. Typed Name F. Terry McNamara	5. Date 9/31/02	

2/30

Attachment for Application for Pesticide Registration  
Advantage<sup>®</sup> 55 for Dogs, EPA Reg. No. 11556-120

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> 55 for Dogs product (EPA Reg. No. 11556-120) 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 CFR 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.

3/30

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

(Front Panel)

**Advantage® 55**  
(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

**READ THE ENTIRE LABEL BEFORE EACH USE**

**For the Prevention and Treatment of Flea Infestations on Dogs**

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within 12 Hours
- One Treatment Prevents Further Flea Infestation For At Least 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 . . . . .	<u>90.9%</u>
Total . . . . .	100%

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

**NOTIFICATION**

**AUG - 9 2002**

4/30

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 puppies under seven 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 2.5 mL Tube

EPA Est. 11556-DEU-1  
EPA Reg. No. 11556-120

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

5/30

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

---

(Back Panel)

## Advantage® 55

(imidacloprid) Topical Solution  
Fast  
Effective

Once-A-Month Topical Flea Treatment for Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

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

One 2.5 mL Tube

6/30

(Inside Right Panel)

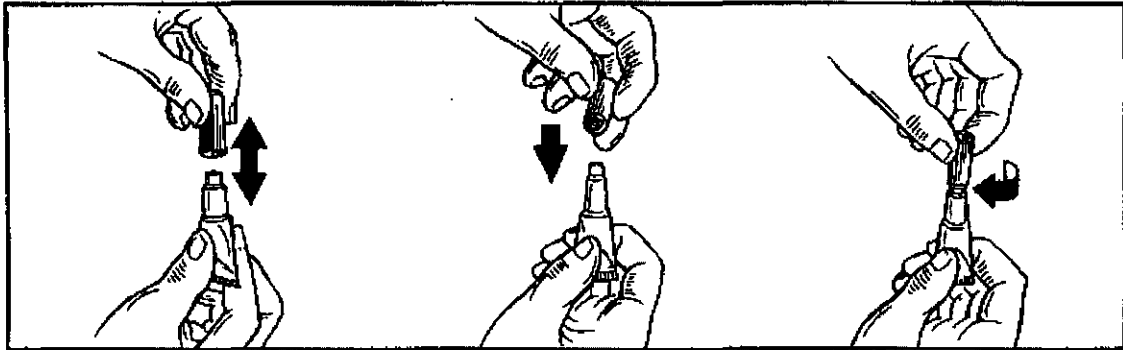
For the prevention and treatment of flea infestation on dogs and puppies 7 weeks and older and 21 – 55 lbs.

### DIRECTIONS FOR USE

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

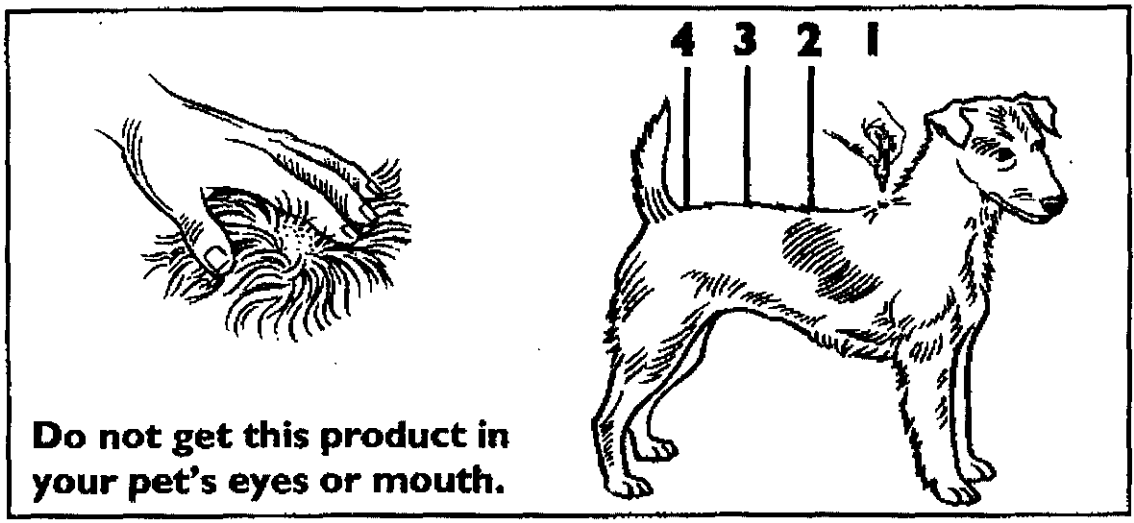
### HOW TO APPLY

1. Use only on dogs. Do not use on other animals.
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. The entire contents of the Advantage® 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 pet's eyes or mouth.

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

8/30

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

---

(Inside Left Panel)

Advantage® 55

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

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 existing fleas on pets 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 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 drain.



9/30

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. 11556-120

10/30

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

2.5 mL

EPA Reg. No. 11556-120

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

11/30

Reason To Issue: Remove flea feeding inhibition claim, revised to comply with PR Notice 2001-6. Date: 07/24/02  
Supersedes: 05/07/01

(Front Panel)

**Advantage® 55**  
(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

**READ THE ENTIRE LABEL BEFORE EACH USE**

**For the Prevention and Treatment of Flea Infestations on Dogs**

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within 12 Hours
- One Treatment Prevents Further Flea Infestation For At Least 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 . . . . .	<u>90.9%</u>
Total . . . . .	100%

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

**NOTIFICATION**

**AUG - 9 2002**

12/30

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

Date: 07/24/02  
Supersedes: 05/07/01

## HAZARDS TO DOMESTIC ANIMALS

### **For external use only.**

Do not use on puppies under seven 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 2.5 mL Tubes

EPA Est. 11556-DEU-1  
EPA Reg. No. 11556-120

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

13/30

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

Date: 07/24/02  
Supersedes: 05/07/01

---

(Back Panel)

## Advantage® 55

(imidacloprid) Topical Solution  
Fast  
Effective

Once-A-Month Topical Flea Treatment for Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

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

Four 2.5 mL Tubes

14/30

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

Date: 07/24/02  
Supersedes: 05/07/01

(Inside Left Panel)

Advantage® 55

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

Read entire label before use.

For the Prevention and Treatment of Flea Infestations on Dogs

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within 12 Hours
- One Treatment Prevents Further Flea Infestation For At Least 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 . . . . .	<u>90.9%</u>
Total . . . . .	100%

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

15/30

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 puppies under seven 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.

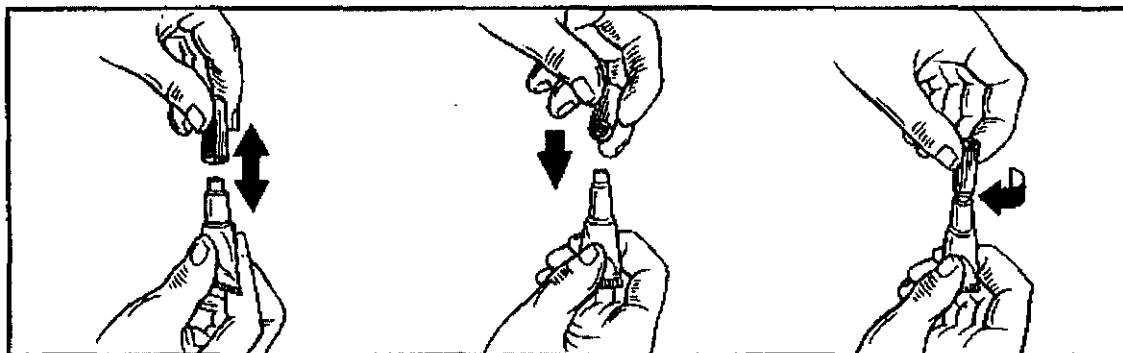
**To Physician:** Treat the patient symptomatically.

### 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 dogs. Do not use on other animals.
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.

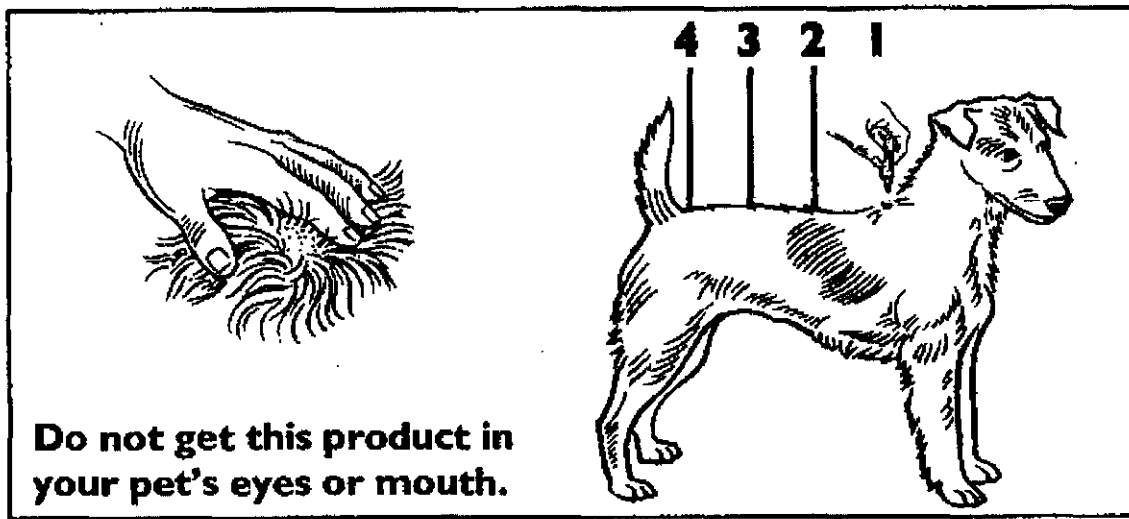


Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6.

Date: 07/24/02  
Supersedes: 05/07/01

(Inside Right Panel)

- 6. The dog should be standing for easy application. The entire contents of the Advantage® 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 pet's eyes or mouth.

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

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 existing fleas on pets 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 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.

18/30

Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02  
revised to comply with PR Notice 2001-6. Supersedes: 05/07/01

---

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.

#### 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. 11556-120

19/30

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

2.5 mL

EPA Reg. No. 11556-120

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

20/30

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

Date: 07/24/02  
Supersedes: 05/07/01

---

(Back of Blister Package)

21/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

(Front Panel)

**Advantage® 55**  
(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

**READ THE ENTIRE LABEL BEFORE EACH USE**

**For the Prevention and Treatment of Flea Infestations on Dogs**

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within 12 Hours
- One Treatment Prevents Further Flea Infestation For At Least 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 . . . . .	<u>90.9%</u>
Total . . . . .	100%

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

**NOTIFICATION**

**AUG - 9 2002**

22/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

HAZARDS TO DOMESTIC ANIMALS

**For external use only.**

Do not use on puppies under seven 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.

Six 2.5 mL Tubes

EPA Est. 11556-DEU-1  
EPA Reg. No. 11556-120

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

23/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

---

(Back Panel)

## Advantage® 55

(imidacloprid) Topical Solution  
Fast  
Effective

Once-A-Month Topical Flea Treatment for Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

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

Six 2.5 mL Tubes

24/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

(Inside Left Panel)

Advantage® 55

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and  
Puppies 7 Weeks and Older and 21-55 lbs

Read entire label before use.

For the Prevention and Treatment of Flea Infestations on Dogs

- Available Only Through Licensed Practicing Veterinarians
- Kills 98-100% of the Fleas on Dogs Within 12 Hours
- One Treatment Prevents Further Flea Infestation For At Least 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 . . . . .	<u>90.9%</u>
Total . . . . .	100%

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



25/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

## HAZARDS TO DOMESTIC ANIMALS

### **For external use only.**

Do not use on puppies under seven 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.

## DIRECTIONS FOR USE

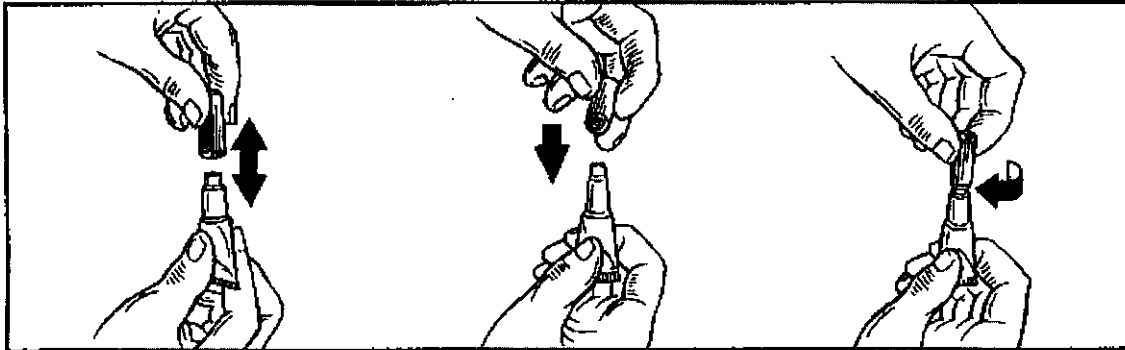
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

HOW TO APPLY

1. Use only on dogs. Do not use on other animals.
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.

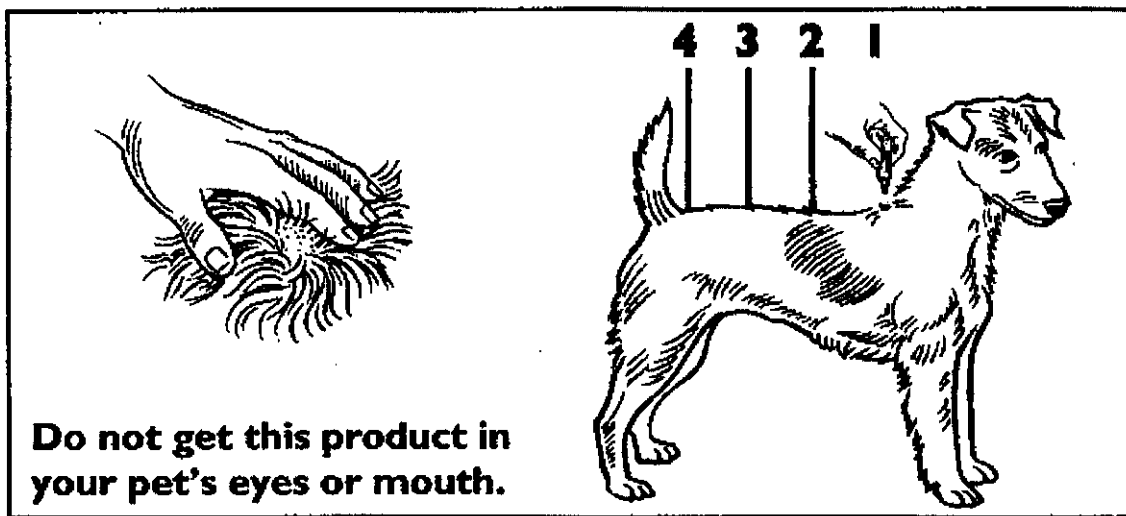
27/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

(Inside Right Panel)

- The dog should be standing for easy application. The entire contents of the Advantage® 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 pet's eyes or mouth.

- Discard empty tube as described in Storage and Disposal.

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 existing fleas on pets 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 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.

28/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

---

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.

#### 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. 11556-120

29/30

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

2.5 mL

EPA Reg. No. 11556-120

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

30/30

Reason To Issue: Remove flea feeding inhibition claim,  
revised to comply with PR Notice 2001-6

Date: 07/24/02  
Supersedes: 05/07/01

---

(Back of Blister Package)