11556-119 ad instructions on reverse before completing form 8-9-2002

OMB No. 2070-0060. Approval expires 2-28

SEPA

United States

Environmental Protection Agency

Registration Amendment
Amendment

OPP Identifier Number

Washington, DC 20	0460	v	Other		
Applicati	ion for Pestici	ide - Section			
1. Company/Product Number	I	Product Manager		3. Proposed Classification	
11556-119	PM#	Meredith Laws		None Restricted	
4. Company/Product (Name) Advantage 20 for Dogs	PW#				
5. Name and Address of Applicant (Include ZIP Code)	1 -	6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)			
Bayer Corporation, Animal Health, Agriculture D P.O. Box 390)ivision (b)(i), r				
Shawnee Mission, KS 66201		EPA Reg. No.			
Check if this is a new address	Prod	Product Name			
	Section -	ii			
Amendment - Explain below.	V	Final printed labe	els in repsonse to	NOTIFICA	
Resubmission in response to Agency letter dated		"Me Too" Applic		NOTIFICATION	
Notification - Explain below.		Other - Explain below. AUG - 9 2002			
Explanation: Use additional page(s) if necessary. (For section	on I and Section II.)				
Notification of label changes as per PR Notice 97-6	6 and PR Notice 200	1-6. Please see atta	sched explanation	for details.	
	Section - I				
Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging	Marea Soluble		To To and Con		
Yes Yes	Water Soluble Packaging 2. Ty		2. Type of Cor	Metal	
No No	No No) 	Plastic Glass	
* Certification must	If "Yes"	No. per	P.	aper	
be submitted Unit Packaging wgt. container	Package wgt	container	[0	ther (Specify)	
3. Location of Net Contents Information 4. Size(s) Re	etail Container	5. Lo	ocation of Label C	Directions .	
Label Container			On Label On Label accom	panying product	
6. Manner in Which Lebel is Affixed to Product Litho	ograph or glued ciled	Other			
Sten			.		
	Section - I		,		
1. Contact Point (Complete items directly below for identification)	T	e contacted, it nec			
F. Terry McNamara	Title Director, Preclini			(913) 268-2588	
Certific			*111	6. Dete Application	
I certify that the statements I have made on this form an I acknowledge that any knowlingly false or misleading st both under applicable law.				Received (Stamped)	
2. Signature	3. Title			• • • •	
Gr. Terry Mc Namara	Director, Preclinical Development & EPA Regulatory Affairs			•	
4. Typed Name	5. Date			••••	
F. Terry McNamara	7/3/102				

30

Attachment for Application for Pesticide Registration Advantage[®] 20 for Dogs, EPA Reg. No. 11556-119

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® 20 for Dogs product (EPA Reg. No. 11556-119) 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® 20 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and Puppies 7 Weeks and Older and 11-20 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	90.9%
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

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 1.0 mL Tube

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-119

Manufactured For

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

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

Supersedes: None

(Back Panel)

Advantage® 20

(imidacloprid) Topical Solution Fast Effective

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and 11-20 lbs

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

One 1.0 mL Tube

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

Supersedes: None

(Inside Right Panel)

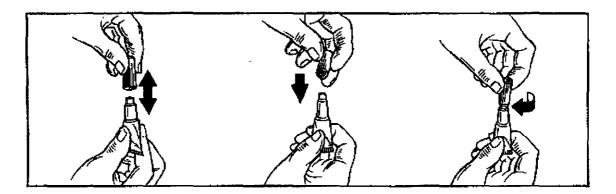
For prevention and treatment of flea infestation on dogs and puppies 7 weeks and 11-20 lbs.

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 one applicator tube from the package.



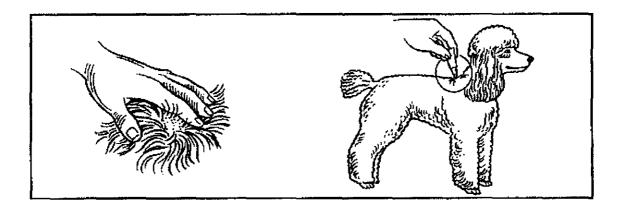
- 3. Hold applicator tube in an upright position. Pull cap off tube.
- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.

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

Supersedes: None

6. 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 pet's eyes or mouth.



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

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

Supersedes: None

(Inside Left Panel)

Advantage® 20

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and 11-20 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 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. 11556-119

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

1.0 mL

EPA Reg. No. 11556-119

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® 20 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and Puppies 7 Weeks and Older and 11-20 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	. 90.9%
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

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.

Four 1.0 mL Tubes

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-119

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® 20

(imidacloprid) Topical Solution
Fast
Effective

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and 11-20 lbs

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

Four 1.0 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® 20

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and 11-20 lbs

Read entire label before use.

For the Prevention and Treatment of Flea Infestation 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	90.9%_
Total	. 100%

KEEP OUT OF REACH OF CHILDREN

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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.

DIRECTIONS FOR USE

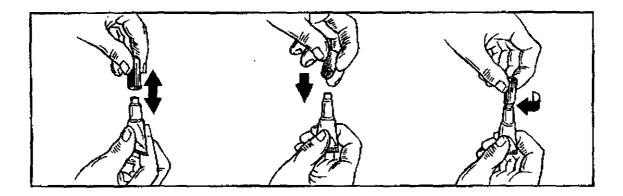
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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

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

HOW TO APPLY

- 1. Use only on dogs. 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.

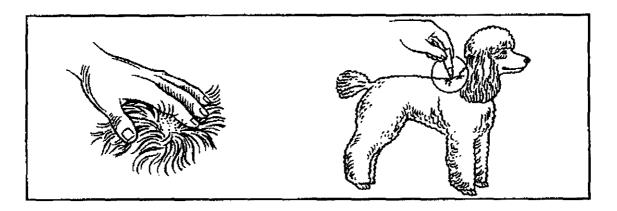
Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

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

(Inside Right Panel)

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 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.

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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.

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

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

STORAGE AND DISPOSAL

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EPA Est. 11556-DEU-1

EPA Reg. No. 11556-119

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

1.0 mL

EPA Reg. No. 11556-119

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

(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® 20 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and Puppies 7 Weeks and Older and 11-20 lbs

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Other Ingredients	. 90.9%
Total	. 100%

KEEP OUT OF REACH OF CHILDREN

WARNING

See Below for First Aid and Precautionary Statements

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NOTIFICATION

AUG - 9 2002

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

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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 1.0 mL Tubes

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-119

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

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(Back Panel)

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- Kills fleas within 12 hours
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- Convenient, easy to apply

Six 1.0 mL Tubes

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

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(Inside Left Panel)

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To Physician: Treat the patient symptomatically.

DIRECTIONS FOR USE

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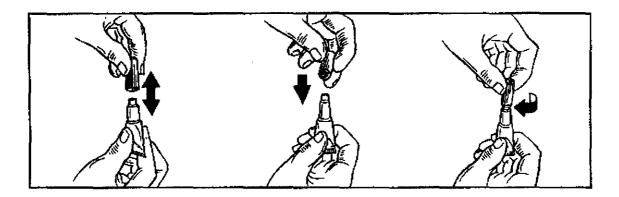
Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

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

HOW TO APPLY

1. Use only on dogs. 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.

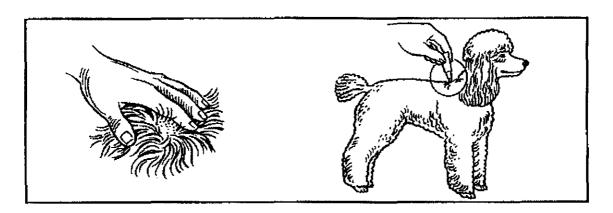
Reason To Issue: Remove flea feeding inhibition claim, Date: 07/24/02

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(Inside Right Panel)

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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.

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

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

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

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. 11556-119

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

1.0 mL

EPA Reg. No. 11556-119

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

(Back of Blister Package)