11556-122 1-26-2001

Please read instructions on reverse before completing form.		om Approved.	OMR No. 207	O-OOBO, Approve expires 2-28-95
United States Environmental Protection Washington, DC 20-		V	Registration Amendme Other	
Application	on for Pesticide	- Section		
1. Company/Product Number 11556-122	i	luct Manager Dr. Tina Levi	ne	3. Proposed Classification V None Restricted
4. Company/Product (Name) Advantage 100 for Dogs	PM#			
5. Name and Address of Applicant (Include ZIP Code) Bayer Corporation, Animal Health, Agriculture Di P.O. Box 390 Shawnee Mission, KS 66201	vision (b)(i), my r to:	product is simi	lar or identica	e with FIFRA Section 3(c)(3) all in composition and labeling
Check if this is a new address	Product	Name		
	Section - II			
Amendment - Explain below.	Fir	nal printed label	s in repsonse to	
Resubmission in response to Agency letter dated		le Too" Applica her - Explain be	tion.	JAN 2 6 2001
Notification - Explain below.		nei - Expiain de		
Explanation: Use additional page(s) if necessary. (For section	on I and Section II.)			
First Aid section of the product labels (4-pack and 6-pack) have	been revised in accordan	ce with PR Notice	ce 2001-1. See	attached explanation for details.
	Section - III			
1. Material This Product Will Be Packaged In:				
Child-Resistant Packaging Unit Packaging	Water Soluble Pack	aging	2. Type of Co	entainer
Yes	Yes			Metal Plastic
No No	No No		,	Glass
* Certification must be submitted If "Yes" No. per conteiner	If "Yes" Package wgt	No. per container		Paper Other (Specify)
3. Location of Net Contents Information 4. Size(s) Re	etail Container	5. Lo	cation of Label	Directions
Label Container			On Label On Label accor	mpanying product
6. Manner in Which Label is Affixed to Product Litho Papel Stend	graph r glued ciled	Other		
	Section - IV			
1. Contact Point (Complete items directly below for identificati	on of individual to be co	ontacted, if nec	essary, to proc	ess this application.)
Name F. Terry McNamara	Title Manager Prec	linical Develop		elephone No. (Include Area Code) 913) 268-2578
Certific 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.	d all attachments theret	to are true, acci able by fine or	urate and comp imprisonment o	6. Date Application Received (Stamped)
2. Signature / / / / / / / for	3. Titte Manager, Preclini	cal Developmen	t (6,	• •
4. Typet Name F. Terry McNamara	5. Date 0//0	9/01		• • •

ATTACHMENT FOR OPP APPLICATION FOR PESTICIDE AMENDMENT

Enclosed for Agency acceptance are five (5) copies each of two draft labels (4-pack and 6-pack sizes), dated January 8, 2001, for Advantage 100 for Dogs, EPA Reg. No. 11556-122. Please note that the 4-pack and 6-pack labels are identical except for the net contents statement. The enclosed draft labeling is based on the label which the Agency accepted on June 25, 1998 as well as minor changes made by Notification on September 13, 1999.

The proposed changes to the Advantage 100 for Dogs label are based on PR Notice 2001-1 which requests voluntary changes to the First Aid statement. The only label changes needed for compliance are list below. Please note, all other existing label text is already in compliance with the PR Notice.

Specifically, the following are the changes made to the existing EPA-accepted labeling:

Previous labeling contained the First Aid statement:

FIRST AID

If in eyes: Hold eyelids open and flush with plenty of water. Get medical attention if irritation persists.

If swallowed: Call a physician or Poison Control Center.

If on skin: Wash with plenty of soap and water.

With the enclosed draft labeling, Bayer proposes to change the First Aid statement to the exact wording used in PR Notice 2001-1:

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 vemicing 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.

As the proposed modifications in the enclosed labeling were Agency requested, and as none of the proposed changes require data review, we anticipate ready Agency acceptance of the proposed labeling.



Reason To Issue: Revised according to PR Notice 2001-1. Date: 01/08/01

Supersedes: 9/13/99

(Front Panel)

NOTIFICATION

JAN 26 2001

Advantage® 100 (imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and Puppies 7 Weeks and Older and Over 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%
Inert 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.

Page 1 of 10

Revised according to PR Notice 2001-1.

Date: 01/08/01

Supersedes: 9/13/99

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 4.0 mL Tubes

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-122

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

Revised according to PR Notice 2001-1.

Date: 01/08/01

Supersedes: 9/13/99

(Back Panel)

Advantage® 100

(imidacloprid) Topical Solution Fast Effective

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and Over 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 4.0 mL Tubes

Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

(Inside Left Panel)

Advantage® 100

(imidacloprid) Topical Solution

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

Read entire label before use.

For the Prevention and Treatment of Flea Infestations on Dogs

- Available Only Through Licensed Practicing Veterinarians
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Active Ingredient	% By Weight
Imidacloprid; 1-[(6-Chloro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine	. 9.1%
Inert Ingredients	90.9%
Total	100%

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Reason To Issue: Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

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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.

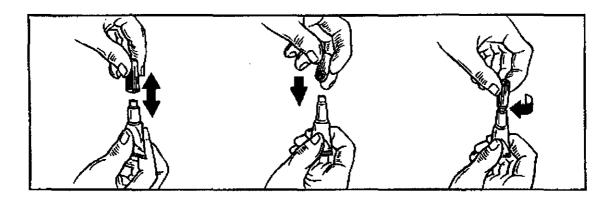
To Physician: Treat the patient symptomatically.

DIRECTIONS FOR USE

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

	HOW TO APPLY	·	-
1.	Use only on dogs. Do not use on other animals.		
2.	Remove applicator tube from the package.		: ··

Reason To Issue: Revised according to PR Notice 2001-1. Date: 01/08/01 Supersedes: 9/13/99



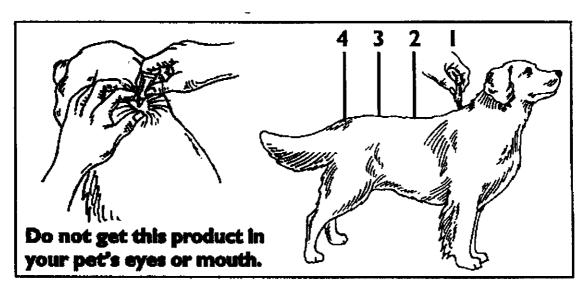
- 3. Hold applicator tube in an upright position. Pull cap off tube.
- 4. Turn the cap around and place other end of cap back on tube.
- 5. Twist cap to break seal, then remove cap from tube.

Reason To Issue: Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

(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

Reason To Issue: Revised according

Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

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. **Pesticide Disposal**: Securely wrap original container in several layers of newspaper and discard in trash. **Container Disposal**: Do not reuse empty container. Wrap container and put in trash.

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. 11556-122

Reason To Issue: Revised according to PR Notice 2001-1.

Date: 01/08/01

Supersedes: 9/13/99

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

4.0 mL

EPA Reg. No. 11556-122

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Revised according to PR Notice 2001-1. Date: 01/08/01

Supersedes: 9/13/99

(Back of Blister Package)

Revised according to PR Notice 2001-1.

Date: 01/08/01

Supersedes: 9/13/99

(Front Panel)

NOTIFICATION

JAN 26 2001

Advantage® 100 (imidacloprid) Topical Solution

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Active Ingredient		% By Weight
Imidacloprid; 1-[(6-Chlo	oro-3-pyridinyl) methyl]-N-nitro-2-imidazolidinimine	. 9.1%
Inert Ingredients	·	90.9%
Total		100%

KEEP OUT OF REACH OF CHILDREN

WARNING
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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 according to PR Notice 2001-1. Date

Date: 01/08/01 Supersedes: 9/13/99

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.

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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 4.0 mL Tubes

EPA Est. 11556-DEU-1 EPA Reg. No. 11556-122

Manufactured For

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

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2 6 10				

Reason To Issue: Revised according to PR Notice 2001-1.

Date: 01/08/01

Supersedes: 9/13/99

(Back Panel)

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Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

(Inside Left Panel)

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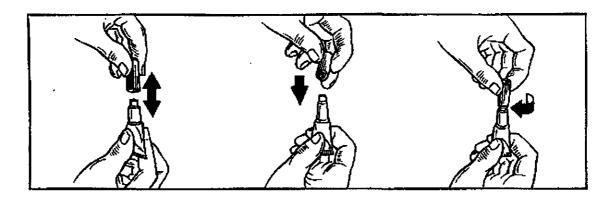
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1.	Use only on dogs. Do not use on other animals.	
2.	Remove applicator tube from the package.	 · · · · · · · · · · · · · · · · · · ·

Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99



- 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.
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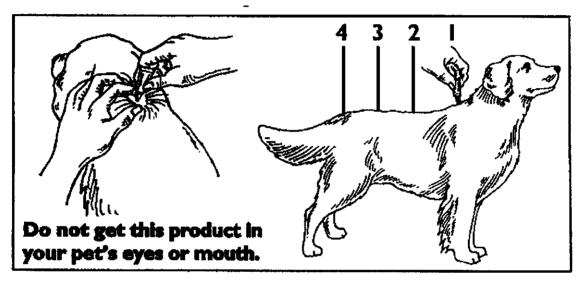


Reason To Issue: Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

(Inside Right Panel)

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Reason To Issue:

Revised according to PR Notice 2001-1.

Date: 01/08/01 Supersedes: 9/13/99

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EPA Est. 11556-DEU-1

EPA Reg. No. 11556-122

Reason To Issue: Revised according to PR Notice 2001-1. Date: 01/08/01

Supersedes: 9/13/99

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

 $4.0 \ mL$

EPA Reg. No. 11556-122

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Revised according to PR Notice 2001-1.

Date: 01/08/01

Supersedes: 9/13/99

(Back of Blister Package)