

11556-117

1-26-2001

1/23

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, 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 11556-117	2. EPA Product Manager Dr. Tina Levine	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Advantage 10 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 checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	NOTIFICATION JAN 26 2001
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

First Aid section of the product labels (4-pack and 6-pack) have been revised in accordance with PR Notice 2001-1. 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 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 Manager, Preclinical Development	Telephone No. (Include Area Code) (913) 268-2588
Certification 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 Manager, Preclinical Development	
4. Typed Name F. Terry McNamara	5. Date 01/09/01	

2/23

NOTIFICATION

JAN 26 2001

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 10 for Dogs, EPA Reg. No. 11556-117. 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 10 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.

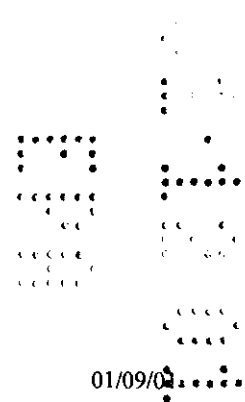
If in eyes: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes. then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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 vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

3/23

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.



4/23

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

Date: 01/08/01

Supersedes: 9/13/99

NOTIFICATION

JAN 26 2001

(Front Panel)

Advantage® 10
(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and Puppies 7 Weeks and Older and 10 lbs and Under

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	<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.

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5/23

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 0.4 mL Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-117

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

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

Date: 01/08/01

Supersedes: 9/13/99

6/23

(Back Panel)

Advantage® 10

(imidacloprid) Topical Solution

Fast
Effective

Once-A-Month Topical Flea Treatment for Dogs and
Puppies 7 Weeks and Older and 10 lbs and Under

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

Four 0.4 mL Tubes

7/23

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

Date: 01/08/01

Supersedes: 9/13/99

(Inside Left Panel)

Advantage® 10

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and 10 lbs and Under

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%
Inert 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.

8/23

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.

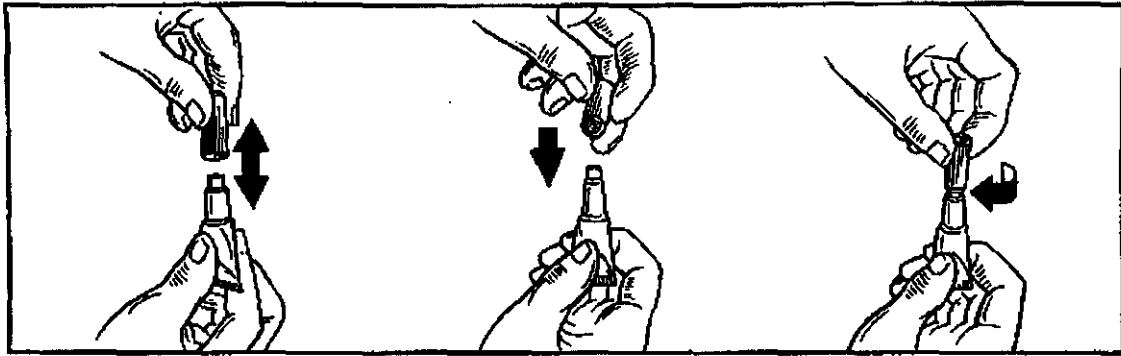
To Physician: Treat the patient symptomatically.

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 one applicator tube from the package.



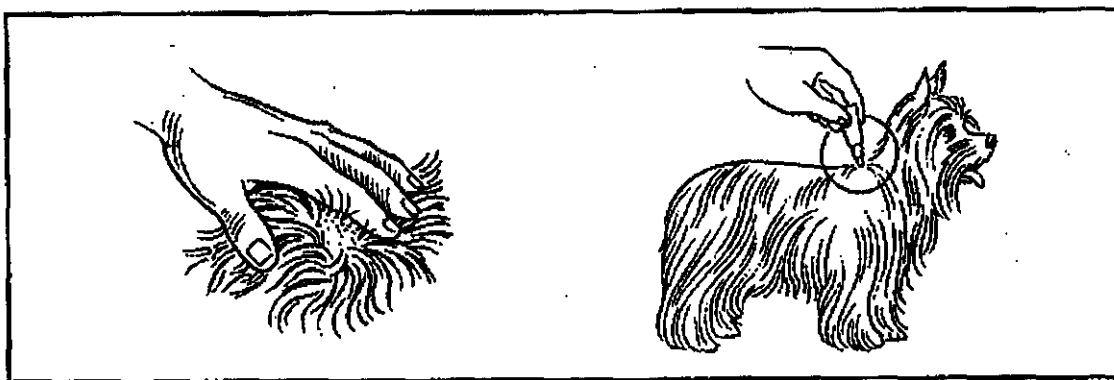
3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.

10/23

(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.

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.

11/23

Reason To Issue: 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. 11556-117

12/23

(Label on Individual Tube)

Advantage®

9.1% Imidacloprid

0.4 mL

EPA Reg. No. 11556-117

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

13/23

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

Date: 01/08/01

Supersedes: 9/13/99

(Back of Blister Package)

14/23

(Front Panel)

NOTIFICATION

JAN 26 2001

Advantage® 10
(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment For Dogs and Puppies 7 Weeks and Older and 10 lbs and Under

READ THE ENTIRE LABEL BEFORE EACH USE

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- 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	<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.

15/23

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 0.4 mL Tubes

EPA Est. 11556-DEU-1
EPA Reg. No. 11556-117

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

16/23

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

Date: 01/08/01

Supersedes: 9/13/99

(Back Panel)

Advantage® 10

(imidacloprid) Topical Solution

Fast
Effective

Once-A-Month Topical Flea Treatment for Dogs and
Puppies 7 Weeks and Older and 10 lbs and Under

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

Six 0.4 mL Tubes

17/23

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

Date: 01/08/01

Supersedes: 9/13/99

(Inside Left Panel)

Advantage® 10

(imidacloprid) Topical Solution

Once-A-Month Topical Flea Treatment for Dogs and Puppies 7 Weeks and Older and 10 lbs and Under

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Inert Ingredients	90.9%
Total	<u>100%</u>

KEEP OUT OF REACH OF CHILDREN

WARNING

See Below for First Aid and Precautionary Statements

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

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18/23

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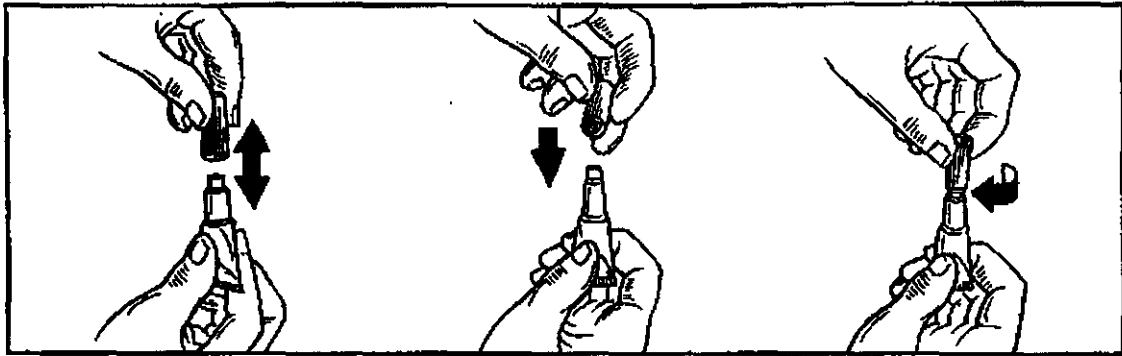
DIRECTIONS FOR USE

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HOW TO APPLY

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

19/23



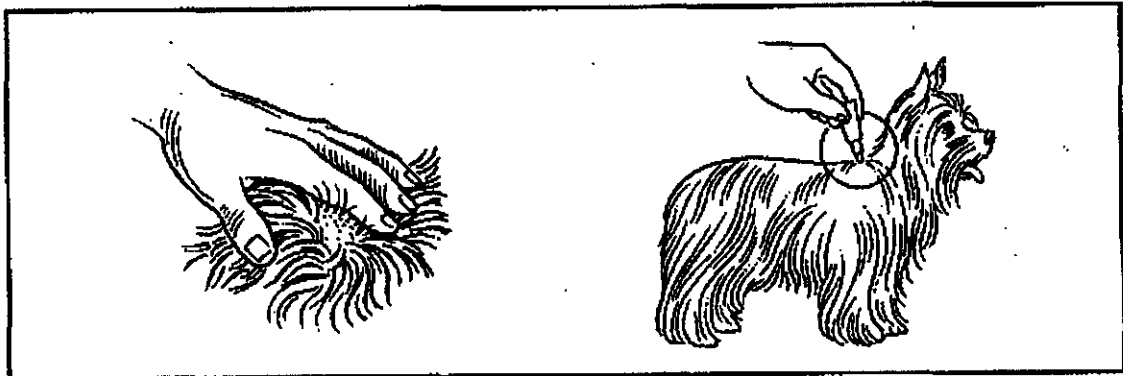
3. Hold applicator tube in an upright position. Pull cap off tube.
4. Turn the cap around and place other end of cap back on tube.
5. Twist cap to break seal, then remove cap from tube.

20/23

(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.

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LIMITED WARRANTY AND LIMITATION OF DAMAGES

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EPA Est. 11556-DEU-1

EPA Reg. No. 11556-117

22/23

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

0.4 mL

EPA Reg. No. 11556-117

Warning

Keep Out of Reach of Children

Read The Entire Label Before Use

BAYER

Lot No. 0000000

23/23

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

Date: 01/08/01

Supersedes: 9/13/99

(Back of Blister Package)