

11556-120

8/29/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460



AUG 29 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Douglas Spilker Ph D
Bayer HealthCare LLC Animal Health Division
P O Box 390
Shawnee Mission KS 66201 0390

Dear Dr Spilker

Subject Amendment to update labels per spot on mitigation letter sent by the Agency dated September 30 2011
EPA Registration Nos /Product name
11556 116 Advantage 9 Topical Solution (small cats)
11556 117 Advantage 10 Topical Solution (small dogs)
11556 118 Advantage 18 Topical Solution (large cats)
11556 119 Advantage 20 Topical Solution (medium dogs)
→ 11556 120 Advantage 55 Topical Solution (large dogs)
11556 122 Advantage 100 Topical Solution (extra large dogs)

The labeling referred to above submitted in connection with the Federal Insecticide Fungicide and Rodenticide as amended are acceptable

A stamped copy of the labeling is enclosed for your records Please submit one final printed copy of the labeling before releasing the product for shipment If you have any questions regarding this label please contact Autumn Metzger at (703) 305 5314

Sincerely

Venus Eagle
Product Manager 01
Insecticide Rodenticide Branch
Registration Division (7505P)

Reason To Issue Revise according to EPA Implementation Date 08/20/2012
of Label Changes to Pet Spot On Products Supersedes 07/17/2012
document dated 9/30/11 (Rec d 10/11/11) 03/01/2012 & 08/27/2010

[Front panel]

Advantage® 55 Topical Solution

Alternate Brand Name **Advantage for Large Dogs**

Once A Month Topical Flea and Lice Treatment
For Use Only on Dogs and Puppies 7 Weeks and Older and and Weighing 21 to 55 lbs

READ THE ENTIRE LABEL BEFORE EACH USE

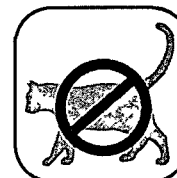
For the Prevention and Treatment of Flea and Lice Infestations on Dogs

- One treatment prevents further flea infestation for at least four (4) weeks
- Kills fleas on dogs within 12 hours
- Kills fleas before they lay eggs
- Convenient easy to apply
- Kills [(biting) (chewing)] lice
- For treatment and prevention of [(biting) (chewing)] lice [infestations]
- Controls existing [(biting) (chewing)] lice infestations
- Dual protection (against fleas and lice)
- Treats prevents and controls [(biting) (chewing)] lice [infestations]
- Provides effective control of [(biting) (chewing)] lice [infestations]
- Kills [(biting) (chewing)] lice and prevents further infestations
- For treatment and prevention of infestations with [(biting) (chewing)] lice
- Waterproof
- Fragrance free

	<u>% By Weight</u>
Active Ingredient	
Imidacloprid	9.1%
Other Ingredients	<u>90.9%</u>
Total	100.0%
EPA Est No 11556 XXX X	EPA Reg No 11556 120

- See Back Panel for First Aid and Precautionary Statements
- For Directions For Use and Storage and Disposal (instructions) see supplemental labeling inside

Icon size 1.5cm x 1.5cm



**KEEP OUT OF REACH OF CHILDREN
WARNING**

ACCEPTED
AUG 29 2012

**Under the Federal Insecticide Fungicide
and Rodenticide Act as amended, for the
pesticide registered under**

EPA Reg No 11556-120

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[Back Panel]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING Causes substantial but temporary eye injury Do not get in eyes or on clothing 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

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Call a 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	<ul style="list-style-type: none"> • 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
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor or going for treatment For medical emergencies call 1 800 422 9874 For customer questions call 1 800 255 6826	
NOTE TO PHYSICIAN	
Treat the patient symptomatically	

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 dogs 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 1 800 422 9874


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Side Effects Monitor your dog after application Side effects although very rare may include signs of skin irritation such as redness scratching or other signs of discomfort Gastrointestinal signs such as vomiting or diarrhea have also been reported If these or other side effects (such as lethargy) occur consult your veterinarian or call 1 800 422 9874

DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours If applied to a cat or ingested by a cat contact your veterinarian

Icon size 1 5cm x 1 5 cm



RESTRICTIONS

- Use only on dogs 7 weeks and older and weighing 21 to 55 lbs Do not use on other animals
- Do not apply more than one (1) tube per treatment
- Do not have contact or allow children to have contact with treated area until completely dry

Net Contents Tube(s) each 0 084 fl oz (2 5 mL)
[Sample – Not for (Re)Sale]

Manufactured For
Bayer HealthCare LLC
Animal Health Division
P O Box 390
Shawnee Mission Kansas 66201 USA

Made in Germany

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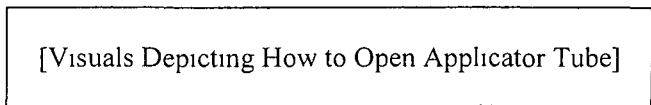
[Back Panel and/or insert]

DIRECTIONS FOR USE

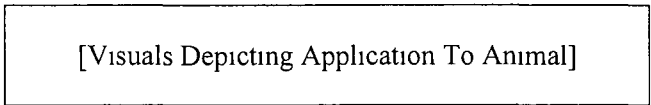
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

HOW TO APPLY

- 1 Remove one applicator tube from the package
- 2 Hold applicator tube in an upright position facing away from you and your pet's face and eyes Pull cap off tube



- 3 Turn the cap around and place other end of cap back on tube
- 4 Twist cap to break seal then remove cap from tube
- 5 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 dog's eyes or allow your dog to ingest this product* Do not allow the product to run off



- 6 Discard empty tube as described in Storage and Disposal
- 7 In case of severe flea infestation retreatment may be necessary earlier than four weeks Do not retreat more often than once every seven days After flea control is attained return to a monthly retreatment schedule

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PRODUCT INFORMATION

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD) Treatment of dogs with Advantage kills fleas and may reduce the incidence of this condition

Advantage kills fleas on dogs within 12 hours Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting for up to four (4) weeks Pre existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions

Larval flea stages in the dog s surroundings are killed following contact with an Advantage treated dog

Advantage is waterproof and remains effective following a shampoo treatment swimming or after exposure to rain or sunlight

Monthly treatments are required for optimal control and prevention of fleas

STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage or disposal

Pesticide Storage Store in a cool dry place inaccessible to children and pets **Pesticide Disposal and Container Handling** Nonrefillable container **If empty** Do not reuse or refill this container Place in trash or offer for recycling if available **If partly filled** Call your local solid waste agency or 1 800 422 9874 for disposal instructions Never place unused product down any indoor or outdoor drain

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC Animal Health Division warrants that this material conforms to the chemical description on the label TO THE EXTENT CONSISTENT WITH APPLICABLE LAW BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY and no agent of Bayer 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

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[Label on Individual Tube]

Advantage® 55

9.1% Imidacloprid

0.084 fl oz (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

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[Label on blister card one card containing 1 2 3 4 5 or 6 tubes]

Advantage® 55
Topical Solution

For external use only on dogs and puppies 7 weeks and older and weighing 21 to 55 lbs

9.1% Imidacloprid

[X] 0.084 fl oz (2.5 mL)

EPA Reg No 11556-120

BAYER

