



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

11556-118

Date of Issuance:

3/24/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 01/17/17

Name of Pesticide Product:

Advantage 18 Topical Solution

Name and Address of Registrant (include ZIP Code):

Doug Spilker
 Bayer HealthCare LLC
 Animal Health Division
 P.O. Box 390
 Shawnee Mission, KS 66201

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Sincerely,

Venus Eagle, Product Manager 01
 Invertebrate & Vertebrate Branch 3
 Registration Division (7505P)

Date:

3/24/16

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EPA Form 8570-6

2. This registration is time-limited and expires 01/17/17. This date was agreed upon in your letter to the Agency dated 01/07/16 for the purpose of aligning the expiration of these registrations with your other registrations.

3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred. (mm/dd/yyyy)
 - State in which the incident occurred. (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.

- Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the GDCI and EDSP Order identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid EDSP-129099

You must comply with all of the data requirements within the established deadlines. If you have questions about the GDCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

6. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 11/06/08

If you have any questions, please contact Gene Benbow by phone at 703-347-0235, or via email at Benbow.Gene@epa.gov.

Enclosure

Reason To Issue: Update Label.

Date: 02/22/2016
Supersedes: 02/20/2014

[Front Panel]

Advantage® 18 Topical Solution
Alternate Brand Names: **Advantage® for Large Cats;**
DefenseCare Flea Protection Large Cat

Note: [The “Large Cat” text size will be 75% of the height of the largest letter in the primary brand name.]

Visual image of a cat within the weight range for product.

Once-A-Month Topical Flea Treatment for Cats and Kittens
For Use Only on Cats 8 Weeks and Older and Weighing Over 9 lbs.

READ THE ENTIRE LABEL BEFORE EACH USE

For the Prevention and Treatment of Flea Infestations on Cats

[Selected option claims]

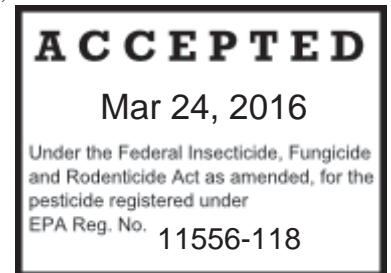
- [One treatment prevents further flea infestation for up to four (4) weeks]
- [Kills fleas on cats within 12 hours]
- [Kills fleas before they lay eggs]
- [Convenient, easy to apply]
- [Waterproof]
- [Fragrance free]
- [From the makers of ExpertCare]

	<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. 11556-118

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



**KEEP OUT OF REACH OF CHILDREN
WARNING**

[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. 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 kittens under eight weeks of age. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. 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.

Reason To Issue: Update Label.

Date: 02/22/2016

Supersedes: 02/20/2014

Side Effects: Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as hypersalivation, 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.

RESTRICTIONS:

- Use only on cats 8 weeks and older. Do not use on other animals. Do not apply to kittens or cats weighing less than 9 lbs.
- Do not apply more than one (1) tube per treatment, even for larger cats.
- Do not have contact or allow children to have contact with treated area until completely dry.

Net Contents: Tubes(s) each 0.027 fl. oz. (0.8 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

[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.

[Visuals Depicting How to Open Applicator 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. Part the hair in the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to *expel the entire contents of the tube directly on the skin. Do not get this product in your cat's eyes or allow your cat to ingest this product.* The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the opportunity for the cat to lick the product. Do not allow the product to run off.

[Visuals Depicting Application To Animal]

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.

Reason To Issue: Update Label.

Date: 02/22/2016

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PRODUCT INFORMATION

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

Advantage kills fleas on cats 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.

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.

Reason To Issue: Update Label.

Date: 02/22/2016
Supersedes: 02/20/2014

[Label on Individual Tube]

Advantage® 18

9.1% Imidacloprid

0.027 fl. oz. (0.8 mL)

EPA Reg. No. 11556-118

Keep Out of Reach of Children

WARNING

Read The Entire Label Before Use

BAYER

Lot No. 0000000

Reason To Issue: Update Label.

Date: 02/22/2016
Supersedes: 02/20/2014

[Label on pouch or blister card; (one card containing 1, 2, 3, 4, 5, or 6 tubes)]

Advantage® 18
Topical Solution

For external use only on cats and kittens 8 weeks and older and weighing over 9 lbs.

9.1% Imidacloprid

See leaflet for complete product information.

[X] - 0.027 fl. oz. (0.8 mL)

[THIS UNIT NOT FOR RETAIL SALE]

EPA Reg. No. 11556-118

BAYER