



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

EPA Reg. Number:
11556-122

Date of Issuance:
9/16/24

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:
Conditional

Name of Pesticide Product:
Advantage Extra Large Dog

Name and Address of Registrant (include ZIP Code):

J. Todd Frank
Senior Regulatory Affairs Consultant
Elanco US Inc.
2500 Innovation Way
Greenfield, IN 46140

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:

Venus Eagle, Product Manager 01
Invertebrate and Vertebrate Branch 3, Registration Division

Date:

9/16/24

2. Consistent with the guidance on [Pet Spot-On Enhanced Reporting Implementation \(updated Aug. 2019\)](#), the Agency has reviewed your request to remove the two-year registration expiration date and has found your company to be in compliance with the terms and conditions for the subject product. The accepted label dated 03/24/2016 contains appropriate mitigation measures. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 3. hereafter, and concluded that the use of the standardized templates for enhanced reporting for this product will considerably improve pharmacovigilance and thus the continued safety of this product. Therefore, the Agency is removing the two-year registration expiration date for this product. The product remains subject to all other previously required conditions of registration, including the submission of enhanced incident reports and sales information as stated in the amendment letter dated 03/24/2016 and amended below to require continued use of the standardized templates.
3. The Agency has reviewed your request to change the terms of your registration from quarterly to annual submission of enhanced incident and sales reports using EPA's standardized templates. Based on an initial screening of sample enhanced reports, the sample submission was determined to be adequate and the templates were successfully used. Therefore, the condition of quarterly submission of enhanced incident and sales reports is hereby amended to annual submission with continued use of these standardized templates. You must submit enhanced incident and sales reports for this product to the Agency every 12 months from the date the product is first released for shipment, or from the end date in the last quarterly enhanced reporting submission. The initial released-for-shipment date must be provided to the Product Manager, once known. The enhanced reporting submission should be addressed to the Product Manager's attention and must use the standardized, electronic templates available on the EPA website through the following links: [Enhanced Incident Reporting Template](#), [Sales Reporting Template](#). Submissions must be received by the Agency no later than 60 days following the completion of the 12-month period. If the product is not marketed or sold, you must submit to the Product Manager a letter to this effect every 12 months in lieu of the enhanced incident and sales reports. Please follow appropriate procedures and flag any Confidential Business Information as such.
4. 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 terms and conditions, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). A stamped copy of the label is enclosed for your records.

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

Page 3 of 3
EPA Reg. No. 11556-122
Case No. 481335

- Basic CSF dated 4/9/2021

Any CSFs other than those listed above are superseded/no longer valid.

If you have any questions, please contact Marianne Lewis via email at lewis.marianne@epa.gov.

Enclosure

NOTE TO REVIEWER: Braces “{ }” indicate notes to reviewer. Brackets “[]” indicate optional language.

{Front Panel}

For Use only on Dogs and Puppies
7 weeks and older and weighing Over 55 lbs.

{A large, clear picture of a dog in the appropriate weight range for product will appear on the front panel. See page 8.}

Advantage™ Extra Large Dog

{Alternate Brand Names are listed at the end of this document.}

{The “Extra Large Dog” text size will be 40% to 75% of the height of the largest letter in the primary brand name.}

{Selected optional marketing claims bulleted and pictograms from page 8}

Once-A-Month Topical Flea and Lice Treatment for Dogs and Puppies
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing Over 55 lbs.

ACTIVE INGREDIENT:	<u>% by Weight</u>
Imidacloprid	9.1%
OTHER INGREDIENTS:	<u>90.9%</u>
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

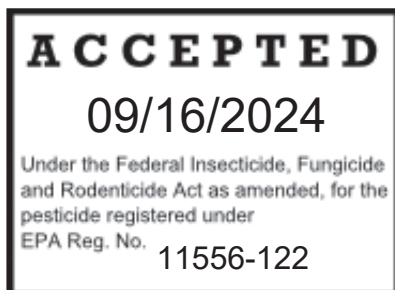
See back panel [inside booklet] [insert] [leaflet] for First Aid and Precautionary Statements.
For Directions for Use and Storage and Disposal [instructions], see insert [leaflet] [back panel].

EPA Reg. No. 11556-122 EPA Est. No. XXX
{EPA Reg. No. and EPA Est. No. to appear on front or back panel}

Lot No.
{Lot No. to appear on any panel (front, side, top, or bottom) of outer container}



DO NOT USE ON CATS
{Icon Size 1.5 cm X 1.5 cm, Background yellow with black text. Positioned in the lower right hand of package.}



{Back Panel}

Advantage™ Extra Large Dog

{The “Extra Large Dog” text size will be 40% to 75% of the height of the largest letter in the primary brand name.}

READ THE ENTIRE LABEL BEFORE EACH USE.

[USE ONLY ON DOGS.]

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

{Selected optional marketing claims bulleted from page 8}

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, doctor, veterinarian, or going for treatment. [For medical emergencies or consumer questions call 888-545-5973.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 888-545-5973.] {choice of either or both phone number statements will be used}	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies or dogs under seven [7] weeks of age or weighing less than 55 lbs. DO NOT use on any other animals. As with any product, consult a veterinarian before using this product on a medicated, debilitated, aged, pregnant or nursing dog. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately.

Side Effects: Monitor your dog after application. Side effects 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 888-545-5973.

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}



{Do Not Use on Cats box will be located immediately below Side Effects box on back panel.}

RESTRICTIONS:

- FOR EXTERNAL USE ONLY.
- DO NOT use on puppies or dogs under seven [7] weeks of age or weighing less than 55 lbs.
- DO NOT use on animals other than dogs.
- Weigh your dog before applying to ensure you are applying the correct dose for the weight of your dog.
- 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.
- DO NOT allow your dog to ingest this product.
- In multi-dog households DO NOT allow dogs to have contact with each other until the product has dried.
- DO NOT allow children to apply the product.
- Dog is to be dry prior to application and remain dry for 24 hours after application.

Net Contents: 1[2][3][4][5][6][8][9][10][12][15][18][24] Tube[s] each 0.135 fl. oz. (4.0 mL)
{one of the above Net Content quantities will be used based on the number of tubes in the carton}

[Sample – NOT for Sale]

{Cartons containing 1 or 2, individually pouched, tubes are completely labeled (all components) as the 3, 4, 5, 6, 8, 9, 10, 12, 15, 18, and 24 tubes. The “Sample – NOT for Sale” is used as text for the 1 or 2 carton only.}

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140

Product of Germany

{Insert/Leaflet}

Advantage™ Extra Large Dog

{The “Extra Large Dog” text size will be 40% to 75% of the height of the largest letter in the primary brand name.}

READ THE ENTIRE LABEL BEFORE EACH USE

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

Once-A-Month Topical Flea and Lice Treatment for Dogs and Puppies
For Use Only on Dogs and Puppies 7 Weeks and Older and Weighing Over 55 lbs.

{Selected optional marketing claims bulleted from page 8}

ACTIVE INGREDIENT:	<u>% by Weight</u>
Imidacloprid	9.1%
OTHER INGREDIENTS:	90.9%
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN
WARNING**

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, doctor, veterinarian, or going for treatment. [For medical emergencies or consumer questions call 888-545-5973.] [For product questions, to report adverse reactions, or for a copy of the Safety Data Sheet (SDS), call Elanco Product & Veterinary Support at 888-545-5973.] {choice of either or both phone number statements will be used}	
NOTE TO PHYSICIAN	
Treat the patient symptomatically.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies or dogs under seven [7] weeks of age or weighing less than 55 lbs. DO NOT use on any other animals. As with any product, consult a veterinarian before using this product on a medicated, debilitated, aged, pregnant or nursing dog. Individual sensitivities may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a veterinarian immediately.

Side Effects: Monitor your dog after application. Side effects 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 888-545-5973.

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:

- FOR EXTERNAL USE ONLY.
- DO NOT use on puppies or dogs under seven [7] weeks of age or weighing less than 55 lbs.
- DO NOT use on animals other than dogs.
- Weigh your dog before applying to ensure you are applying the correct dose for the weight of your dog.
- 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.
- DO NOT allow your dog to ingest this product.
- In multi-dog households DO NOT allow dogs to have contact with each other until the product has dried.
- DO NOT allow children to apply the product.
- Dog is to be dry prior to application and remain dry for 24 hours after application.

DIRECTIONS FOR USE

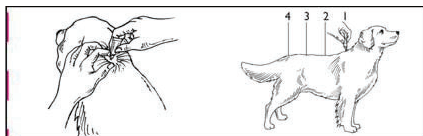
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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 the tube to expel a portion of the contents directly 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.

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.

Advantage is waterproof 24 hours after application 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 888-545-5973 for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY, DISCLAIMER, AND LIMITATION OF DAMAGES

By using, buying or handling this product, user and/or buyer accepts the following terms. Subject to the inherent risks referred to above, and to the extent consistent with applicable law, Elanco US Inc.'s ("Elanco") sole and exclusive limited warranty is that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label, when used in accordance with the label under normal use conditions. To the extent consistent with applicable law, the above exclusive express limited warranty is void if the product is used contrary to the label. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, ELANCO DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, AND DISCLAIMS ANY OTHER EXPRESS WARRANTY.** No agent of Elanco is authorized to make any other warranty, except in writing with a specific reference to this warranty. *To the extent consistent with applicable law, Elanco shall not be liable whatsoever for special, incidental or consequential damages resulting from the use or handling of this product. To the extent consistent with applicable law, the sole and exclusive remedy of the user and/or buyer for any and all losses, injuries, or damages, regardless of the legal theory, shall not exceed the purchase price paid for the product, or the replacement of product.* To the extent the above disclaimer of warranties disclaims implied warranties, it may be limited or ineffective if you are a "consumer" and this product is a "consumer product," as those terms are defined by the Magnuson Moss Act, 15 U.S.C. § 2301, in which case the duration of any implied warranties is limited to the earlier of either the applicable statute of limitation or repose, and in no case will any implied warranty extend beyond the term of the Exclusive Express Limited Warranty for the product. To the extent consistent with applicable law, some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Manufactured For:
Elanco US Inc
2500 Innovation Way
Greenfield, IN 46140
[Product of Germany]

EPA Reg. No. 11556-122

[EPA Est. No. XXX]

{Label on Individual Tube}

Advantage™ Extra Large Dog

9.1% Imidacloprid

0.135 fl. oz. (4.0 mL)

EPA Reg. No. 11556-122

KEEP OUT OF REACH OF CHILDREN

WARNING

Read The Entire Label Before Use

ELANCO

Lot No.

{Label on blister card}

{Label on pouch}

{Additional label text for one tube sample package: THIS UNIT NOT FOR SALE}

Advantage™ Extra Large Dog

For external use only on dogs and puppies 7 weeks and older and weighing over 55 lbs.

9.1% Imidacloprid

See insert [leaflet] for complete product information.

1[2][3][4][5][6][8][9][10][12][15][18][24] Tube[s] - 0.135 fl. oz. (4.0 mL)

{one of the above Net Content quantities will be used based on the number of tubes in carton}

[THIS UNIT NOT FOR SALE]

{Additional label text for one tube sample package: THIS UNIT NOT FOR SALE}

EPA Reg. No. 11556-122

ELANCO

[Lot No.]



{Optional marketing claims appearing on any location:}

1. For the Prevention and Treatment of Flea and Lice Infestations on Dogs
2. One treatment prevents further flea infestation for at least four [4] weeks
3. Kills fleas on dogs within 12 hours
4. Prevents reinfestations by killing adult fleas, so they don't lay eggs
5. Convenient, easy to apply
6. Kills [[biting] [chewing]] lice
7. For treatment and prevention of [[biting] [chewing]] lice [infestations]
8. Controls existing [[biting] [chewing]] lice infestations
9. Dual protection against fleas and lice
10. Treats, prevents and controls [[biting] [chewing]] lice [infestations]
11. Provides effective control of [[biting] [chewing]] lice [infestations]
12. Kills [[biting] [chewing]] lice and prevents further infestations
13. For treatment and prevention of infestations of [[biting] [chewing]] lice
14. Waterproof 24 hours after application
15. Fragrance free
16. 1[2][3][4][5][6][8][9][10][12][15][18][24] monthly dose[s]

{Optional pictograms which may appear on the label}



{Alternate Brand Names}

1. Advantage for Extra Large Dogs
2. Advantage Basic for Extra Large Dogs
3. Advantage Classic for Extra Large Dogs
4. Advantage Essential for Extra Large Dogs
5. Advantage Original for Extra Large Dogs
6. Advantage Basic Extra Large Dog
7. Advantage Classic Extra Large Dog
8. Advantage Essential Extra Large Dog
9. Advantage Original Extra Large Dog

{Representative dog; each outer carton will have a representative picture of a dog in the appropriate age and weight range for the product.}

{Representative dog picture optional on insert/leaflet, blister pack, pouch, tube}

