



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

EPA Reg. Number:

72642-11

Date of Issuance:

1/13/21

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 01/13/2023

Name of Pesticide Product:

Advantage XD Small Cat

Name and Address of Registrant (include ZIP Code):

Johnna Bridges
 Elanco Animal Health, 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:

Date:

1/13/21

Michael Walsh, Product Manager 11
 Invertebrate & Vertebrate Branch 2, Registration Division (7505P)

2. This registration is time-limited and expires 01/13/2023.
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. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 72642-11."
7. 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.

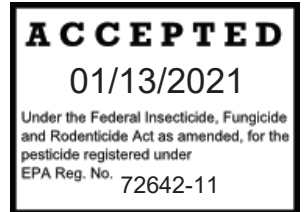
Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/07/2021

If you have any questions, please contact Frank Antwi by phone at (703) 347-0554, or via email at antwi.frank@epa.gov.

Attachment

Note to Reviewer: Text Appearing in [] is optional label language; Text appearing in braces { } will not appear on the final label; When referring to cat weight throughout the label, either “lbs.” or “pounds” will be used in all instances.



CARTON LABEL

FRONT PANEL

Advantage® XD Small Cat

{Alternate brand names: Advantage 2M Small Cat; Advantage XX Small Cat; Cheristin Plus Small Cat}

{Note to Reviewer: Size of the words “Small Cat” will be at least 75% the height of the largest letter in the primary brand name.}

Spinetoram

AN EIGHT WEEK TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER
AND WEIGHING BETWEEN 1.8 AND 9 [LBS.] [POUNDS]

{Marketing claims: see list at end of the label}

Large, Clear Picture of Cat or
Kitten within the Age and
Weight Range for the
Product

ACTIVE INGREDIENT

Spinetoram* 15.0%

OTHER INGREDIENTS 85.0%

TOTAL 100.0%

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY

STATEMENTS READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

[1] [one] [2] [two] [3] [three] [4] [four] [5] [five] [6] [six] [7] [seven] [8] [eight] [9] [nine] [10] [ten] [11] [eleven] [12] [twelve] – 0.0338 fl oz [1 mL] applicator[s]

BACK PANEL

DIRECTIONS FOR USE

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

Do not allow children to apply product. Do not allow children to come in contact with the treated cat until after the application has dried. Do not use on cats or kittens less than 8 weeks of age and weighing less than 1.8 [lbs.] [pounds]. Do not double dose cats larger than 9 [lbs.] [pounds]. Do not allow your cat to ingest this product. Cat must be dry at time of application.

More detailed directions for use, including storage and disposal, are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Application every two months [every other month] is recommended to prevent and treat flea infestations. Advantage® XD Small Cat starts working in 30 minutes – 4 hours and kills fleas for up to [two months] [8 weeks] after application on cats up to 9 [lbs.] [pounds].

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing cats or cats known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

{Note to Reviewer: The "Side Effects" box will be located at the lower right hand corner of the back panel.}

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Manufactured for
Elanco Animal Health
Greenfield, IN 46140

EPA Reg. No. 72642-xx
EPA Est. No.

PACKAGE INSERT LABEL

Advantage® XD
Small Cat

{Note to Reviewer: Size of the words "Small Cat" will be at least 75% the height of the largest letter in the primary brand name.}

Spinetoram

AN EIGHT WEEK TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE AND OLDER AND WEIGHING 1.8 [LBS] [POUNDS] TO [-] 9 LBS [POUNDS]

ACTIVE INGREDIENT

Spinetoram* 15.0%

OTHER INGREDIENTS 85.0%

TOTAL 100.0%

*CAS #s 187166-40-1 and 187166-15-0

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

HAZARDS TO HUMANS

CAUTION. Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. As with any product, consult your veterinarian before using the product on medicated, debilitated, aged, pregnant or nursing cats or cats known to be sensitive to pesticides. In multiple cat households, do not allow the cats to groom each other until the product has dried.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

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.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

DIRECTIONS FOR USE:

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

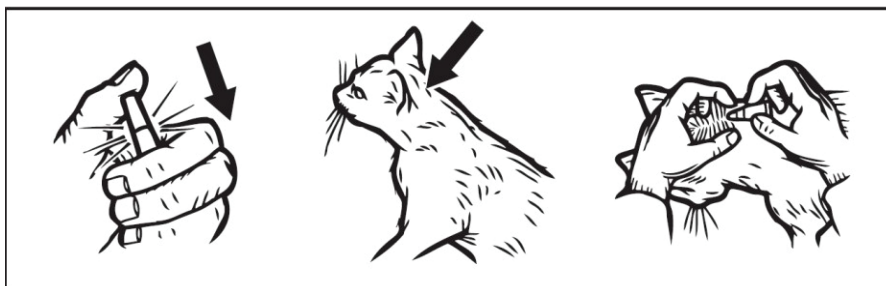
Read the entire label, directions for use and frequency of application each time before using the product. Do not allow children to apply product. Do not allow children to come in contact with the treated cat until after the application has dried. Do not use on cats or kittens less than 8 weeks of age and weighing less than 1.8 [lbs.] [pounds]. Do not double dose cats larger than 9 [lbs.] [pounds]. Do not allow your cat to ingest this product. Cat must be dry at time of application.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply one applicator tube, every two months [every other month], only to cats and kittens 8 weeks of age and older and weighing between 1.8 [lbs.] [pounds] and 9 [lbs.] [pounds].

HOW TO APPLY

1. Remove one applicator tube from the blister package.
2. Hold applicator tube in an upright position.
3. Press cap down until it clicks [indicating the tube has been punctured]. Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
4. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your cat's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. [There may be a small residual remaining in the tube after a full dose is expelled.]
5. Discard empty applicator tube in the trash.



Application every two months [every other month] is recommended to prevent and treat flea infestations. Advantage® XD Small Cat starts working in 30 minutes – 4 hours and continues killing fleas for [two full months] [eight full weeks] after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place inaccessible to children and animals.

Pesticide Disposal:

Call your local solid waste agency or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy

of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
Greenfield, IN 46140

EPA Reg. No. 72642-xx
EPA Est. No.

Applicator Labeling

Advantage® XD Small Cat

Spinetoram 15%

Only for cats & kittens 8 weeks & older between
1.8 - 9 lbs.

0.0338 fl oz [1 mL]

EPA Reg 72642-xx

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Advantage® XD Small Cat

Spinetoram 15%

Only for cats & kittens 8 weeks & older between
1.8 - 9 lbs.

0.0338 fl oz [1 mL]

EPA Reg. No 72642-xx

CAUTION

Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Optional Marketing Claims

1. Every two months
2. Every 8 weeks
3. Every other month
4. Topical
5. Topical Solution
6. Single topical [spot-on] application
7. For the prevention and treatment of flea infestations [*Ctenocephalides felis*] and only for use on cats [and kittens] 8 weeks of age or older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds]
8. Kills fleas for up to [8 weeks] [2 months]
9. Prevents [fleas][re]infestations
10. [Fast Acting] kills fleas on cats within 8 hours
11. [Fast Acting] starts killing fleas [in] [within] 30 minutes – 4 hours
12. [Fast Acting] starts working [in] [within] 30 minutes – 4 hours
13. Kills fleas which may cause flea allergy dermatitis [FAD]
14. [Long Lasting] one treatment prevents further flea infestations for 8 weeks [2 months]
15. [Long Lasting] one treatment remains effective for 8 weeks [2 months]
16. [Long Lasting] remains effective for 8 weeks [2 months]
17. Fragrance-free
18. Formulated only for cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to [-] 9 [lbs.] [pounds]
19. Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
20. Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
21. For indoor and outdoor cats and kittens

22. Long-lasting flea control [through] [for] [8 weeks] [2 months]
23. The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors [nAChRs].
24. Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
25. Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
26. Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
27. Topical application
28. One dose (1 mL) size for cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds].
29. One [applicator tube] [1 mL] [size] [package] [dose] [treatment] [application] treats cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds].
30. [1] [one] [2] [two] [3] [three] [4] [four] [5] [five] [6] [six] [7] [seven] [8] [eight] [9] [nine] [10] [ten] [11] [eleven] [12] [twelve] [applications] [applicator tubes] [individual doses] [topical applicators]
31. Single Pack [Single dose] [individual dose]
32. Topical flea treatment
33. Topical flea infestation prevention
34. Convenient
35. Easy to apply [Easy to use]
36. Spinetoram, the active ingredient in Advantage® XD Small Cat, is a member of the spinosyn class of pesticides.
37. Protects cats and kittens 8 weeks of age and older and weighing between 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds] from fleas for [8 weeks] [two months].
38. One [size] application is effective for cats and kittens 8 weeks of age and older and weighing 1.8 [lbs.] [pounds] to 9 [lbs.] [pounds].
39. [Flea infestations may vary] [treatment][application][administration] every two months [every other month] [every 8 weeks] [year-round] is recommended for optimal control and prevention of flea infestations.