



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

88051-2

Date of Issuance:

2/13/18

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 02/13/2020

Name of Pesticide Product:

ZERONIL SPOT-ON SOLUTION
FOR DOGS

Name and Address of Registrant (include ZIP Code):

Cait Brennan
Chanelle Pharmaceuticals Manufacturing Ltd.
c/o Mary Hunt
Exponent, Inc.
1150 Connecticut Avenue NW, Suite 1100
Washington, DC 20036

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:

for
Kable Bo Davis, Product Manager 03
Invertebrate Vertebrate Branch 1, Registration Division (7505P)

Date:

2/13/18

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited and expires 02/13/2020.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated 8/30/12 and the amendment letter dated 6/25/13.
4. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

5. 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 01/24/18
- Alternate CSF 1 dated 01/24/18

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Decision No. 535221, 535491

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

{Text in brackets [] denotes optional statements/images; Text in braces { } are notes to reviewer;
Text in parentheses is meant to be included on the label}

{Front Panel of Outer Packaging /Carton}

Zeronil Spot-On Solution for Dogs

{The word "Dogs" in the brand name will be at least 75% the height of the largest letter in the name.} {A large, clear picture of a dog in the weight range for the product as packaged will be on the front panel.}

FOR USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE OR OLDER AND [7-22][23-44][45-88][89-132] LBS

[Zeronil Spot-On Solution for Dogs provides protection that controls fleas, ticks, sarcoptic mange mites, and chewing lice. Controls deer ticks that may transmit Lyme disease. Controls brown dog ticks, American dog ticks, and lone star ticks. Prevents flea reinfestation.]

**[For use ONLY on Dogs & Puppies 7-22lbs. and 8 weeks of age or older]
[For use ONLY on Dogs [23-44][45-88][89-132] lbs. and 8 weeks of age or older]**

ACTIVE INGREDIENT:

Fipronil.....9.70%

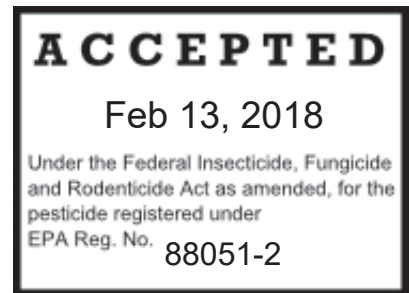
OTHER INGREDIENT:..... 90.30%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Insert for First Aid and Other Precautionary Statements, and Complete Directions for Use including Storage and Disposal

**NET CONTENTS: 0.069 fl. oz. (2.01 mL)
Three 0.023 fl. oz. (0.67 mL) tubes;
0.135 fl. oz. (4.02 mL)
Three 0.045 fl. oz. (1.34 mL) tubes;
0.273 fl. oz. (8.04 mL)
Three 0.091 fl. oz. (2.68 mL) tubes;
0.408 fl. oz. (12.06 mL)
Three 0.136 fl. oz. (4.02 mL) tubes**



{A 1.5cm x 1.5 cm cat prohibition icon in a box will be placed in the lower right hand corner of the front panel in yellow with black images.}

{End - Front Panel of Outer Packaging/Carton}

{Back Panel of Outer Packaging/Carton}

Zeronil Spot-On Solution for Dogs

{The word "Dogs" in the brand name will be at least 75% the height of the largest letter in the name.}

[Zeronil Spot-On Solution for Dogs provides a once-a-month, easy to use spot treatment for quick-acting, long-lasting control of fleas, ticks, sarcoptic mites, and chewing lice.]

DIRECTIONS FOR USE

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

To prevent harm to you and your dog, read entire label and enclosed directions before each use. Follow all directions and precautionary statements carefully. For external use on dogs only.

{CRP package consists of a single sealed foil pouch (CR component) with a tube inside. The CRP text and format will not change from that used in SAUE testing.}

DIRECTIONS FOR HOW TO OPEN:

Use scissors to open the sealed pouch. Cut along the scissors marks near the upper portion of the pouch. Be careful not to damage the tube.

DIRECTIONS FOR APPLICATION OF PRODUCT:

Dog must be dry at time of application and remain dry for 24 hours after application.

1. Place tube tip through the dog's hair to the skin level between the shoulder blades.
2. Squeeze the tube, applying entire contents in a single spot to the dog's skin. Avoid applying product superficially to the dog's hair.

FREQUENCY OF APPLICATION:

Apply Zeronil Spot-On Solution for Dogs once a month to control flea, tick, and chewing lice infestations.

[BAR CODE AREA]

Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea, Co., Galway
Ireland

EPA Reg. No. 88051-2
EPA Est. No.

[CHANELLE BRAND LOGO]

{A box labeled Side Effects will be placed above the cat warning box}

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 occur, consult your veterinarian or 1-800-xxx-xxxx.

{A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be in the lower right hand corner of the back panel in yellow with black images and text}

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.

{END - Back Panel of Outer Packaging/Carton}

{PACKAGE INSERT}

Zeronil Spot-On Solution for Dogs

{The word "Dogs" in the brand name will be at least 75% the height of the largest letter in the name.}

FOR USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE OR OLDER AND [7-22][23-44][45-88][89-132] LBS

ACTIVE INGREDIENT:

Fipronil.....9.70%

OTHER INGREDIENT: 90.30%

TOTAL **100.00%**

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Harmful if swallowed. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash hands 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 on dogs only. Individual sensitivities, while rare, may occur after using ANY pesticide product. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs.

FIRST AID	
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or a 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 a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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 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.
HOTLINE NUMBER	

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call 1-800-XXX-XXXX.

{A box labeled Side Effects will be placed above the cat warning box}

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 occur, consult your veterinarian or 1-800-xxx-xxxx.

{A 1.5cm x 1.5cm cat prohibition icon and warning text in a box will be in the lower right hand corner of the back panel in yellow with black images and text}

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.

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 contact treatment area until dry.

To prevent harm to you and your dog, read entire label and enclosed directions before each use. Follow all directions and precautionary statements carefully.

{CRP package consists of a single sealed foil pouch (CR component) with a tube inside. The CRP text and format will not change from that used in SAUE testing.}

DIRECTIONS FOR HOW TO OPEN:

Use scissors to open the sealed pouch. Cut along the scissors marks near the upper portion of the pouch. Be careful not to damage the tube.

DIRECTIONS FOR APPLICATION OF PRODUCT:

Dog must be dry at time of application and remain dry for 24 hours after application.

1. Place tube tip through the dog's hair to the skin level between the shoulder blades.
2. Squeeze the tube, applying entire contents in a single spot to the dog's skin. Avoid applying product superficially to the dog's hair.

RESTRICTIONS

Do not use on puppies under 8 weeks of age or weighing less than [7][23][45][89] lbs.

Do not use on rabbits. Do not use on other animals.

Do not allow your dog to ingest this product.

Do not apply more than one tube per treatment for one dog regardless of the dog's weight.

Do not bathe or allow water immersion for 24 hours after application.

Do not re-apply for one month.

FREQUENCY OF APPLICATION:

Apply Zeronil Spot-On Solution for Dogs once a month for control of flea, tick,-and chewing lice infestations.

Fleas – Studies show that Zeronil Spot-On Solution for Dogs controls adult fleas for up to three months. Although Zeronil Spot-On Solution for Dogs can protect against adult fleas for up to three months, if there is a high risk of reinfestation or if the dog has fleas which can cause flea allergy dermatitis, a once a month application may be necessary.

Ticks – Zeronil Spot-On Solution for Dogs controls ticks for up to one month. Apply once a month to control ticks. Zeronil Spot-On Solution for Dogs can control all three life stages of ticks (larva, nymph, and adult).

Mites - Zeronil Spot-On Solution for Dogs helps control mites that cause sarcoptic mange. Continual treatments over several months are recommended for the complete elimination of mites.

Zeronil Spot-On Solution for Dogs continues to work even after bathing, water immersion, or exposure to sunlight.

{A box labeled Side Effects will be placed above the cat warning box}

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 occur, consult your veterinarian or 1-800-XXX-XXXX.

{A 1.5cm x 1.5cm cat prohibition icon and warning text in a box in yellow with black images and text}

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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°F/[/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. Do not reuse or refill this container. **If empty:** Place in 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.

[WARRANTY AND DISCLAIMER

Read the entire Label, including the Precautionary Statements, First Aid, Use Directions and Warranty Disclaimer before using this Product. Use of this product constitutes acceptance of this warranty by the user or buyer. The directions for use on this product label are believed to

be sufficient and must be followed carefully with every use. Elimination of all risks associated with the use of this product is impossible. Because of factors unforeseen, unintended consequences may result when using this product. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer. Chanelle Pharmaceuticals Manufacturing Ltd. makes a commitment to providing high quality products to consumers. To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. makes no other express or implied warranty of merchantability or fitness for a particular purpose or any other express or implied warranty. To the extent consistent with applicable law, the exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Chanelle Pharmaceuticals Manufacturing Ltd.'s election, one of the following:

- (1) Refund of purchase price paid by buyer or user for product bought, or
- (2) Replacement of amount of product used.

To the extent consistent with applicable law, Chanelle Pharmaceuticals Manufacturing Ltd. shall not be liable for losses or damages resulting from handling or use of this product unless Chanelle Pharmaceuticals Manufacturing Ltd. is promptly notified of such losses or damages in writing. In no case shall Chanelle Pharmaceuticals Manufacturing Ltd. be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Chanelle Pharmaceuticals Manufacturing Ltd. or the seller is authorized to vary or exceed the terms of this Warranty Disclaimer in any manner.]

Distributed by:
Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road
Loughrea, Co., Galway
Ireland

[BAR CODE AREA]

EPA Reg. No. 88051-2
EPA Est. No.

[CHANELLE BRAND LOGO]

{END – Package Insert}

{Single treatment CRP pouch with tube }

{START – INDIVIDUAL POUCH}

{Scissor mark}

Zeronil Spot-On Solution for Dogs
8 weeks & older [7-22][23-44][45-88][89-132] lbs
9.7% fipronil
Keep Out of Reach of Children
CAUTION
Read Entire Label Before Use
EPA Reg. No. 88051-2



{END – INDIVIDUAL POUCH}

{START - TUBE}

Zeronil DOG
EPA No. 88051-2
[0.023] [0.045] [0.091] [0.136] fl oz
Lot#

{END – TUBE INFORMATION}

{Optional claims that may or may not appear anywhere on the final printed labeling as follows:}

[Zeronil Spot-On Solution for Dogs is also used for the treatment and protection from fleas, ticks, sarcoptic mites, and chewing lice infestations on puppies 8 weeks old and weighing 7 to 22 lbs.]

[Easy to use spot treatment for quick-acting, long lasting control of fleas, ticks, sarcoptic mites, and chewing lice.]

[Zeronil Spot-On Solution for Dogs provides easy to use and effective flea, tick, sarcoptic mites, and chewing lice control for dogs.]

[Zeronil Spot-On Solution for Dogs continues to work even after bathing, water immersion, or exposure to sunlight.]

[Zeronil Spot-On Solution for Dogs provides an easy to use and effective monthly protection for dogs from flea, tick, sarcoptic mite, and chewing lice]

[use ONLY on dogs]

[use ONLY on dogs [23-44][45-88][89-132] lbs and 8 weeks of age or older]

[use ONLY on puppies 8 weeks of age or older and weighing 7 to 22 lbs]

[Adult Fleas]

- [Controls adult fleas for up to 3 months]
- [Dogs with a high risk for flea reinfestation should be treated once monthly]
- [Controls adult fleas which may cause flea bite anemia.]
- [Controls fleas which may cause flea allergy dermatitis]
- [Controls newly emerged adult fleas before they lay eggs]

[Ticks]

- [Controls ticks including those that may transmit Lyme disease]
- [Controls Ticks for up to 1 month]
- [Controls Deer Ticks (that may carry Lyme disease) for up to 1 month]
- [Controls Ticks (Including Deer Ticks) for up to 1 month]
- [Controls [brown dog ticks][,] [(*Rhipicephalus sanguineus*)][,] [American dog ticks][,] [and] [lone star ticks][.] [for up to 1 month]
- [Controls [Brown][,] [American][,] [and] [Lone Star] Dog Ticks[for up to 1 month]
- [Controls all stages (larva, nymph and adult) of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Controls American Dog Ticks [(*Dermacentor variabilis*)] for up to 1 month]

[Multiple Infestations]

- [Eliminates chewing lice [and aids in the control of sarcoptic mange mites]]
- [Quickly halts chewing lice infestations]
- [Aids in the control of sarcoptic mange mite infestations that may cause sarcoptic mange.]
- [Controls sarcoptic mange mites that may cause sarcoptic mange]
- [Flea [&] [and] Tick Control for Dogs]
- [Controls fleas, ticks, [&] [and] chewing lice]
- [Controls fleas, ticks, and chewing lice]
- [Once a month protection from flea, tick, and chewing lice]
- [Three Way [Action][Control] against fleas, ticks, and chewing lice]
- [Four Way [Action][Control] against fleas, ticks, sarcoptic mange mites and chewing lice]
- [Flea and Tick Application]
- [1 month protection [from]] [Flea, Tick, and Chewing Lice]
- [Monthly Flea and Tick Treatment]
- [Use Zeronil Spot-On Solution for Dogs once a month to protect from ticks, sarcoptic mange mites, and chewing lice]
- [Once a month protection from flea, tick, and chewing lice]
- [Controls Fleas and Ticks for up to 1 month]

[All Others]

- [Easy to Use]
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every 1 month]
- [Protects against reinfestation]
- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Can be used on puppies 8 weeks of age or older and weighing [7-22lbs.] [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]]
- [Contains Fipronil (9.7%)]