



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

88051-1

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 CATS

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 an 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 1/24/18

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Decision No. 535219, 535492

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 Cats

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

FOR USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE OR OLDER AND 1.5 LBS OR OVER
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[Zeronil Spot-On Solution for Cats provides protection that controls adult fleas, ticks, 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.]

ACTIVE INGREDIENT:

Fipronil.....9.70%

OTHER INGREDIENT: 90.30%

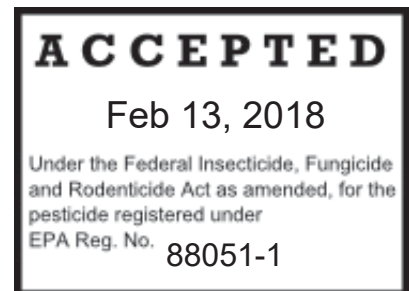
TOTAL **100.00%**

**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: 0.051 fl oz (1.5 mL)
Three 0.017 fl oz (0.50 mL) tubes**

{End - Front Panel of Outer Packaging/Carton}



{Back Panel of Outer Packaging/Carton}

Zeronil Spot-On Solution for Cats

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

[Zeronil Spot-On Solution for Cats provides a once-a-month, easy to use spot treatment for quick-acting, long-lasting control of adult fleas, ticks, 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 cat, 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:

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

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

FREQUENCY OF APPLICATION:

Apply Zeronil Spot-On Solution for Cats 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. 88051-1
EPA Est. No.

[CHANELLE BRAND LOGO]

{A box labeled Side Effects will be in the lower right hand corner of the back panel}

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 vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or 1-800-xxx-xxxx.

{END - Back Panel of Outer Packaging/Carton}

{PACKAGE INSERT}

Zeronil Spot-On Solution for Cats

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

FOR USE ONLY ON CATS AND KITTENS OVER 8 WEEKS OF AGE OR OLDER AND 1.5 LBS OR OVER

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 cats 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 cats.

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 included on the package insert}

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 vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or 1-800-xxx-xxxx.

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 cat, 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:

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

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

RESTRICTIONS

Do not use on kittens under 8 weeks of age or weighing less than 1.5 lbs.

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

Do not allow your cat to ingest this product.

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

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

Do not allow cats to groom one another until product has dried in multi-cat households. Separate treated cats from one another and other pets until product has dried.

Do not re-apply for one month.

FREQUENCY OF APPLICATION:

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

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

Ticks – Zeronil Spot-On Solution for Cats controls ticks for up to one month. A once a month application is recommended where tick control is desired.

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

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 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.]

[BAR CODE AREA]

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[CHANELLE BRAND LOGO]

{END – Package Insert}

{Single treatment CRP pouch with tube}

{START – INDIVIDUAL POUCH }

{Scissor marks}

Zeronil Spot-On Solution for Cats
over 8 weeks old, over 1.5 lbs
9.7% fipronil
Keep Out of Reach of Children
CAUTION
Read Entire Label Before Use
EPA Reg. No. 88051-1

{END – INDIVIDUAL POUCH}

{START – TUBE}

Zeronil CAT
EPA No. 88051-1
0.017 fl oz
Lot#

{ END – TUBE}

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

[To control adult fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), and chewing lice, apply only on cats and kittens 8 weeks of age or older and 1.5 lbs or over.]

[Zeronil Spot-On Solution for Cats provides an easy to use spot treatment for quick-acting, long-lasting control of adult fleas, ticks, and chewing lice.]

[Zeronil Spot-On Solution for Cats provides an easy to use spot treatment for quick-acting, long-lasting protection from adult fleas, ticks, and chewing lice.]

[Zeronil Spot-On Solution for Cats and kittens 8 weeks of age or older and 1.5 lbs or over. Easy to use spot treatment for quick-acting, long lasting control of adult fleas, ticks, and chewing lice.]

[Zeronil Spot-On Solution for Cats and kittens 8 weeks of age or older and 1.5 lbs or over. Easy to use spot treatment for quick-acting, long lasting protection from adult fleas, ticks, and chewing lice.]

[Zeronil Spot-On Solution for Cats provides easy to use and effective flea, tick, and chewing lice control for cats and kittens over 8 weeks of age or older and 1.5 lbs or over.]

[Zeronil Spot-On Solution for Cats provides easy to use and effective protection from flea, tick, chewing lice for cats and kittens over 8 weeks of age or older and 1.5 lbs or over.]

[Adult Fleas]

- [Controls adult fleas for up to six weeks]
- [Cats with a high risk for flea reinfestation apply once monthly]
- [Controls adult 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], [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 brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- [Controls American Dog Ticks for up to 1 month]

- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]

[Multiple Infestations]

- [Controls chewing lice]
- [Quickly halts chewing lice infestations]
- [Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old and older and 1.5 lbs and over]
- [Controls adult fleas, ticks, and chewing lice]
- [Once a month protection from flea, tick, and chewing lice]
- [Three Way [Action][Control] against adult fleas, ticks, and chewing lice]
- [One Month Flea and Tick and Application]
- [One Month Protection from Flea, Tick, and Chewing Lice]
- [Monthly Flea and Tick Treatment]
- [Use Zeronil Spot-On Solution for Cats once a month to protect from ticks and chewing lice]
- [Once a month protection from flea, tick, and chewing lice.]
- [Controls adult Fleas and Ticks for up to 1 month]

[All Others]

- [Fipronil (9.7%)]
- [Use ONLY on cats and kittens over 1.5 lbs, and over 8 weeks of age or older]
- [Use ONLY on cats over 1.5 lbs, and over 8 weeks of age or older]
- [Apply on kittens 8 weeks of age or older and over 1.5 lbs]
- [Easy to Use]
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every month]
- [Protects against reinfestation]