



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

EPA Reg. Number:

88051-6

Date of Issuance:

11/20/18

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited  
 Expires: 11/20/2020

Name of Pesticide Product:

ZERONIL PLUS SPOT-ON  
 SOLUTION FOR DOGS

Name and Address of Registrant (include ZIP Code):

Mary Hunt, Agent  
 Chanelle Pharmaceuticals Manufacturing Ltd.  
 c/o Exponent, Inc.  
 1150 Connecticut Ave., NW, Suite 1100  
 Washington, D.C. 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 (FIFRA).

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.

*Continued on page 2*

Signature of Approving Official:

Mindy Ondish, Acting Product Manager 3  
 Invertebrate & Vertebrate Branch 1  
 Registration Division (7505P)

Date:

11/20/18

2. This registration is time-limited and expires 11/20/2020.
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 dogs 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 cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs 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 dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs 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 Generic Data Call-In Orders (GDCIs) 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>

6. 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.
7. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 88051-6.”
8. 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 FIFRA 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 09/17/2018
- Alternate CSF #1 dated 09/17/2018

If you have any questions, you may contact Dr. Breeden-Alemi at 703-347-0511 or via email at [Breedden-Alemi.Julie@epa.gov](mailto:Breedden-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 Carton}**

### Zeronil Plus 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 8 WEEKS AND OLDER AND [5-22][23-44][45-88][89-132] LBS**

{Note to reviewer: the description below or another listed under Optional Claims will appear on the front panel of carton as product description}

[Zeronil Plus Spot-On Solution for Dogs for dogs and puppies 8 weeks of age or older and [5-22][23-44][45-88][89-132] lbs. Easy to use, spot treatment for quick-acting, long lasting control of fleas, flea eggs, flea larvae, ticks, and chewing lice]

**ACTIVE INGREDIENTS:**

Fipronil.....9.8%  
S-Methoprene.....8.8%

**OTHER INGREDIENTS:.....81.4%**

**TOTAL 100.0%**

**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**

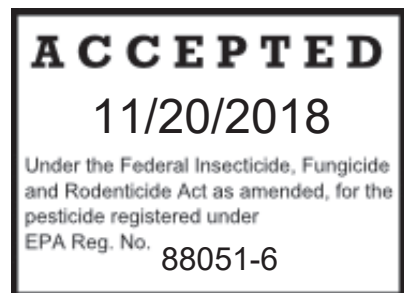
**NET CONTENTS: {total} fl oz {Y – X fl oz tubes}**

- 0.023 fl. oz. (0.67 mL) {or}**
- 0.045 fl. oz. (1.34 mL) {or}**
- 0.091 fl. oz. (2.68 mL) {or}**
- 0.136 fl. oz. (4.02 mL)**

{Note to reviewer: Y indicates number of applicators; i.e. 1, 2, 3, 4, 6}

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

**{End - Front Panel of Carton}**



{**Back Panel of Carton**}

## **Zeronil Plus 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.}

### **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 sachet=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 Plus 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-A  
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 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 8 WEEKS AND OLDER AND [5-22][23-44][45-88][89-132] LBS**

**ACTIVE INGREDIENTS:**

Fipronil.....	9.8%
S-Methoprene.....	8.8%
<b>OTHER INGREDIENTS:.....</b>	<b>81.4%</b>
<b>TOTAL</b>	<b>100.0%</b>

### 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 only. Do not use on puppies under 8 weeks of age. Do not use on dogs or puppies less than [5][23][45][89] lbs. Individual sensitivities, while rare, may occur after using ANY pesticide product. Some dogs may experience some temporary irritation at the site of product application. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs.

<b>FIRST AID</b>	
If swallowed:	<ul style="list-style-type: none"> <li>Call a poison control center or a doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If in eyes:	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
If on skin or clothing:	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>HOTLINE NUMBER</b>	



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.

**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 included 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 sachet=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.  
Do not use on dogs or puppies less than [5][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 Plus Spot-On Solution for Dogs once a month for control of flea, tick, and chewing lice infestations.

**[Fleas –**Zeronil Plus Spot-On Solution for Dogs kills adult fleas, flea eggs, and flea larvae for one month, and breaks the flea life cycle. Controls fleas which may cause flea allergy dermatitis.

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

**[Chewing Lice –** Zeronil Plus Spot-On Solution for Dogs controls chewing lice, applied once a month.]

**[Mites -** Zeronil Plus Spot-On Solution for Dogs aids in control of sarcoptes mites that may cause sarcoptic mange. Continual treatments over multiple months are recommended in conjunction with veterinary guidance for successful treatment of sarcoptes mites.]

Zeronil Plus Spot-On Solution for Dogs 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 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.]

[BAR CODE AREA]

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

EPA Reg. No. 88051-A  
EPA Est. No.

[CHANELLE BRAND LOGO]

**{END – Package Insert}**

**{Single treatment CRP sachet= single sealed foil pouch with tube}**

**{START – INDIVIDUAL POUCH}**

*{Scissor marks}*

Zeronil Plus Spot-On Solution for Dogs  
8 weeks & older, [5-22][23-44][45-88][89-132] lbs  
9.8% fipronil, 8.8% S-methoprene  
Keep Out of Reach of Children  
CAUTION  
Read Entire Label Before Use  
EPA Reg. No. 88051-A



**{END – INDIVIDUAL POUCH}**

**{START - TUBE}**

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

**{END – TUBE INFORMATION}**

**{Optional claims }**

[Zeronil Plus Spot-On Solution for Dogs contains the active ingredients fipronil and S-methoprene that targets fleas, ticks, and chewing lice for one month.] [Fipronil continuously releases from hair follicles onto the skin and coat, resulting in long-lasting protection.]

[When used on a monthly basis, Zeronil Plus Spot-On Solution for Dogs breaks the flea life cycle and controls flea, tick, and chewing lice infestations. It also aids in control of the mites that may cause sarcoptic mange.]

[Zeronil Plus Spot-On Solution for Dogs can be used for the treatment of fleas, flea eggs, flea larvae, ticks, and chewing lice infestations on puppies 8 weeks old and older, and weighing [5-22][23-44][45-88][89-132] lbs]

[Zeronil Plus Spot-On Solution for Dogs provides an easy to use and effective protection against flea, tick, and chewing lice]

[Zeronil Plus Spot-On Solution for Dogs provides protection that controls fleas, flea eggs, flea larvae, 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.]

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

[Zeronil Plus Spot-On Solution for Dogs provides easy to use and effective flea, flea egg, flea larva, tick, and chewing lice control]

[Zeronil Plus Spot-On Solution for Dogs provides control and protection against fleas, ticks, and chewing lice. Controls deer ticks that may transmit Lyme disease. Controls brown dog ticks, American dog ticks, and lone star ticks. Will prevent flea reinfestation for 1 month.]

**[Fleas]**

- [Controls adult fleas, flea eggs, and flea larvae]
- [Controls fleas for 1 month]
- [Controls fleas which may cause flea allergy dermatitis]
- [Kills adult fleas, flea eggs, and flea larvae]

**[Ticks]**

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

- [Controls American Dog Ticks [(*Dermacentor variabilis*)] for 1 month]
- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may transmit Lyme disease)]

**[Multiple Infestations]**

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

**[All Others]**

- [Easy to Use]
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every month]
- [Protects against reinfestation]
- [Can be used on puppies 8 weeks of age or older and [5-22lbs.] [23-44 lbs.] [45-88 lbs.] [89-132 lbs.]]