



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

EPA Reg. Number:

88051-5

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 FOR
 CATS

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 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. 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 GDCIs 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. 88051-5.”
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 09/18/2018
- Alternate CSF #1 dated 09/18/2018

If you have any questions, you may contact Dr. Breeden-Alemi at 703-347-0511 or via email at Breedon-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 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 & Kittens over 1.5 lbs and 8 weeks of age and older

{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 Cats and kittens 8 weeks of age or older and over 1.5 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..... | 11.8% |
| OTHER INGREDIENTS:..... | 78.4% |
| TOTAL | 100.0% |

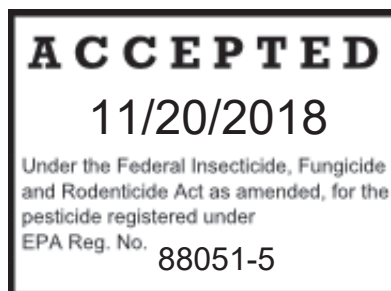
**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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

NET CONTENTS: {total} fl oz (0.50 mL)
Y – 0.017 fl oz (0.50 mL) tubes

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

{End - Front Panel of Carton}



{Back Panel of Carton}

Zeronil Plus 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.}

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 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:

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 Plus Spot-On Solution for Cats once a month to control fleas, flea eggs, flea larvae, all stages of ticks, 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 Carton}

Zeronil Plus 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 & Kittens over 1.5 lbs and 8 weeks of age and older

ACTIVE INGREDIENTS:

Fipronil.....9.8%

S-Methoprene.....11.8%

OTHER INGREDIENTS:..... 78.4%

TOTAL

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. 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 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:

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 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 Plus Spot-On Solution for Cats once a month to control fleas, flea eggs, flea larvae, all stages of ticks, and chewing lice infestations.

Zeronil Plus Spot-On Solution for Cats can also be used for the treatment and protection from fleas, flea eggs, flea larvae, ticks, and chewing lice infestations on kittens 8 weeks of age and older and over 1.5 lbs.

Zeronil Plus 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 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.]

EPA Reg. No. 88051-L
Application for Registration April 2, 2018
[BAR CODE AREA]

Zeronil Plus Spot-On Solution for Cats
Revised November 19, 2018

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

EPA Reg. No. 88051-new
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 Cats
8 weeks & older, over 1.5 lbs
9.8% fipronil, 11.8% S-methoprene
Keep Out of Reach of Children
CAUTION
Read Entire Label Before Use
EPA Reg. No. 88051-L

{END – INDIVIDUAL POUCH}

{START - APPLICATOR}

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

{END – TUBE}

{Optional claim}

[Zeronil Plus Spot-On Solution for Cats 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.]

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

[Zeronil Plus Spot-On Solution for Cats provides protection that controls fleas, flea eggs, flea larvae, ticks, and chewing lice. Prevents flea reinfestation.]

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

[Zeronil Plus Spot-On Solution for Cats provides control and protection against fleas, ticks, and chewing lice. Controls deer ticks that may transmit Lyme disease. Will prevent flea reinfestation for one month.]

[Zeronil Plus Spot-On Solution for Cats can also be used for the treatment and control of fleas, flea eggs, flea larvae, ticks, and chewing lice infestations on kittens 8 weeks of age and older and over 1.5 lbs]

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

[When used on a monthly basis, Zeronil Plus Spot-On Solution for Cats breaks the flea life cycle and controls flea, tick, and chewing lice infestations.]

[Fleas –Zeronil Plus Spot-On Solution for Cats controls adult fleas, flea eggs, and flea larvae for one month. Zeronil Plus Spot-On Solution for Cats can protect against adult fleas which can cause flea allergy dermatitis.]

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

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

[Fleas]

- [[Controls][Kills] adult fleas, flea eggs, and flea larvae for one month]

- [[Controls][Kills] fleas]
- [Controls fleas which may cause flea allergy dermatitis]
- [Breaks the flea life cycle]
- [Kills adult fleas, flea eggs, and flea larvae]

[Ticks]

- [[Controls][Kills] ticks including those that may transmit Lyme disease]
- [[Controls][Kills] Ticks for one month]
- [[Controls][Kills] Deer Ticks (that may transmit Lyme disease) for one month]
- [Controls Ticks (Including Deer Ticks) for one month]
- [[Controls][Kills] [brown dog ticks] [(*Rhipicephalus sanguineus*)][,] [American dog ticks] [and] [lone star ticks][.] [for one month.]
- [Controls [Brown][,] [American][,] [and] [Lone Star] Dog Ticks[.] [for one month.]]
- [[Controls][Kills] 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 one month]

[Multiple Infestations]

- [Eliminates chewing lice]
- [Quickly halts chewing lice infestations]
- [Flea [&] [and] Tick Control for Cats [&] [and] Kittens 8 weeks old & older and over 1.5 lbs]
- [Controls fleas, ticks, and chewing lice]
- [Once a month flea, tick, and chewing lice treatment]
- [Three] [3] Way [Action][Controls] [fleas, ticks, and chewing lice]
- [1 month Flea and Tick Application]
- [Monthly Protection against Flea, Tick, and Chewing Lice]
- [Monthly Flea and Tick Treatment]
- [Use Zeronil Plus 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 Fleas and Ticks for 1 month]

[All Others]

- [For use on Cats & Kittens 8 weeks of age & 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]
- [Controls fleas which may cause flea allergy dermatitis]
- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may transmit Lyme disease)]
- [Can be used on kittens 8 weeks of age and older and over 1.5 lbs]
- [For use on Cats over 1.5 lbs and 8 weeks of age]
- [Contains Fipronil (9.8%) and S-Methoprene (11.8%)]