#### 'NVIRONMENTAL PROTECTION AGENCY EPA Registration No Date of Issuance Office of Pesticide Programs Registration Division (7505P) August 30 2012 1200 Pennsylvania Ave NW 88051-1 Washington D C 20460 Term of Issuance NOTICE OF PESTICIDE Unconditional ☑ Registration ☐ Reregistration (under the Federal Insecticide Fungicide and Rodenticide Act as Name of Pesticide Product **Zeronil Spot-On Solution for Cats** amended) Name and Address of Registrant (include ZIP Code) Chanelle Pharmaceuticals Manufacturing Ltd c/o Exponent, Inc Center for Chemical Regulation and Food Safety 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 action is taken under the authority of section 3(c)(5) of the Federal Insecticide Fungicide and Rodenticide Act as amended Registration under this section does not eliminate the need for continual reassessment of pesticides EPA may require submission of data at any time to maintain the registration of your product **Terms of Registration** EPA has registered the product listed above provided that the following change is made to the label 1 before you release the product for shipment a Revise the EPA Registration Number to read EPA Registration No 88051 1 The Net Contents in all locations must be displayed in accordance with the description identified in the Labeling Consistency Committee's clarification This information may be located at the following Agency web site under miscellaneous http://www.epa.gov/opp00001/regulating/labels/label\_review\_faq.htm#miscellaneous listing net contents Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(111) and 40 CFR 156 10(a)(1)(111) EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In Signature of Approving Official Date Refer to Page 3 August 30 2012

Richard J Gebken Product Manager (10) Registration Division Insecticide Branch

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addition the label may indicate the net weight and quantity of individual units within the carton For example Net Weight 6 25 lbs (20 5oz packets) " For additional information regarding the Net Weight/Contents statement please reference Chapter 17 of the Label Review Manual at <a href="http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm">http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm</a>

- c Under the brand name Zeronil Spot-On Solution for Cats and any other alternate brand name add the following statement For use ONLY on CATS 12 weeks and older The word CAT the word cat must be the same size as the brand name
- d Pictures Chanelle Pharmaceuticals Manufacturing Ltd must place large clear pictures of the appropriate species on the front panel
- This registration is time limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date" in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected 'release for shipment date' until an actual release for shipment date is provided in writing.
- Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e. no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient)
- You must submit the following data within the timeframe described below
   Within sixteen (16) months of the date on this Notice of Registration provide to the Agency acceptable data packages for Guideline Studies OPPTS 830 6320 (Corrosion Characteristics) and OPPTS 830 6317 (Storage Stability)
   You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this
  - You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division. Immediate Office (attn. Kimberly Nesci.)

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

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

- Along with the enhanced incident reporting you must submit an analysis of all incidents seen, to include the following details
  - All minor dermal and ocular irritation reports
  - b 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

Page 3 of 3

reported as oral exposure and an incident with both ocular and oral exposure would be reported as ocular exposure

- c A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure
- d Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e g multi-pet households)
- e A summary table for s 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
- f A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label
- g 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
- h Table showing number of incidents for each cat breed

1

- 1 Table showing number of incidents in cat for each clinical sign
- Table showing number of incidents in cat for each organ system
- k Report aggregate incidents but do not combine moderate and minor incidents
- 7 If EPA determines that future mitigation measures are necessary for all pet spot-on products the Agency will inform all registrants concerned. If mitigation measures are necessary EPA may take regulatory action
- Chanelle Pharmaceuticals Manufacturing Ltd must adequately address all of the mitigation actions identified in the Agency s *Generic Pet Spot-On Mitigation Plan* available at the following internet site within 60 days following the date of this Notice of Registration <a href="http://www.epa.gov/pesticides/health/spot-on-meetings-html">http://www.epa.gov/pesticides/health/spot-on-meetings-html</a>

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data and submit acceptable responses required for registration review of your product under FIFRA

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions

A copy of your label stamped 'Accepted with Comments' is enclosed for your records. If you have any questions concerning this action please contact me Richard J. Gebken at (703) 305-6701 or gebken richard@epa.gov

Sincerely,

Product Manager 10
Insecticide Branch

Registration Division (7505C)

& Cabke

**Enclosures** 

1

[] - Denotes optional statements and/or images

## {Master Label}

## **Zeronil Spot-On Solution for Cats**

#### USE ONLY ON CATS AND KITTENS OVER 12 WEEKS OF AGE

[[Brand Name] provides protection that controls adult fleas ticks mosquitoes 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]

[[Brand Name] provides an easy to use spot treatment for quick-acting long-lasting control of adult fleas, ticks, chewing lice and mosquitoes]

[[Brand Name] for cats [&] [and] kittens 12weeks or older Easy to use spot treatment for quick-acting, long lasting control of adult fleas, ticks, chewing lice and mosquitoes]

[[Brand Name] provides easy to use and effective flea tick chewing lice and mosquito control for cats and kittens over 12 weeks of age ]

**ACTIVE INGREDIENT** Fipronil

OTHER INGREDIENT TOTAL 9 70%

90 30 % 100 00%

# KEEP OUT OF REACH OF CHILDREN CAUTION READ ENTIRE LABEL BEFORE EACH USE

#### 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 kittens under 12 weeks of age Individual sensitivities, while rare, may occur after using ANY pesticide product Some cats 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 or aged cats.

ACCEPTED With COMMENTS In EPA Letter Dated

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No

88051-1

**PAGE 1 OF 16** 

FIRST AID			
If swallowed	<ul> <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> <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> <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>		
1	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

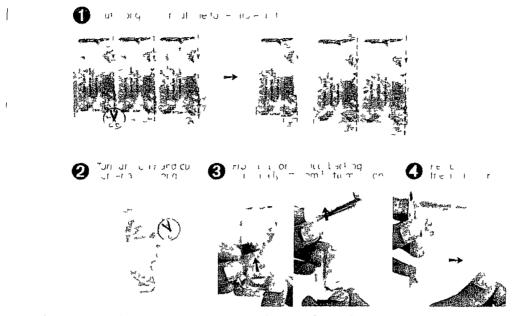
#### **DIRECTIONS FOR USE**

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 TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY FOR EXTERNAL USE ON CATS ONLY DO NOT USE ON RABBITS DO NOT USE ON OTHER ANIMALS

To control adult fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply on cats and kittens (12 weeks or older) as follows

#### DIRECTIONS FOR OPENING PACKAGING



#### DIRECTIONS FOR APPLICATION OF PRODUCT

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

Only one pipette per treatment is necessary

#### FREQUENCY OF APPLICATION

When used as directed on a monthly basis, [Brand Name] will completely control flea, tick and chewing lice infestations

Fleas – Studies show that [Brand Name] Controls adult fleas for up to six weeks Although [Brand Name] can protect against adult fleas for up to six weeks, if there is a high risk of reinfestation or if the pet has fleas which can cause flea allergy dermatitis, a once a month application may be necessary

**Ticks** – [**Brand Name**] Controls ticks for up to one month A once a month application is recommended where tick control is desired

**Mosquitoes** – [**Brand Name**] Controls mosquitoes within 24 hours for up to two weeks and within 48 hours for up to one month

Chanelle Cat Fipronil Only Spot On ver 4 (30 Aug 2012)

[Brand Name] continues to work even after bathing, water immersion, or exposure to sunlight Avoid contact with treatment area until dry Do not reapply [Brand Name] for at least one month

#### STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and 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

#### **CONTAINER DISPOSAL**

If empty Non-refillable container Do not reuse or refill this container 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

1

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.]

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Dublin Road
Loughrea, Co, Galway
Ireland
EPA Reg No 88051-NEW
EPA Est No 74720-DEU-001

[CHANELLE BRAND LOGO]

[BAR CODE AREA]

## Chanelle Pharmaceuticals Manufacturing Ltd:

## **Zeronil Spot-On Solution for Cats**

## FOR USE ONLY ON CATS AND KITTENS OVER 12WEEKS OF AGE

[[Brand Name] provides an easy to use and effective flea, tick, chewing lice and mosquito protection for cats and kittens 12 weeks or older]

- [Easy to Use]
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every [4 weeks] [month] [30 days]<sup>1</sup>]
- [Protects against reinfestation]
- [Controls adult fleas which may cause flea allergy dermatitis]
- [Controls newly emerged adult fleas before they lay eggs]
- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks, and deer ticks (which may carry Lyme disease)]
- Controls mosquitoes
- [Quickly halts chewing lice infestations]

#### [Mosquitoes]

- [[Controls] [Kills] mosquitoes within 24 hours for up to [14 days][2 weeks]]] [and within 48 hours for up to [28 days][one month]]
- [[Controls] [Kills] mosquitoes]]

#### [Adult Fleas]

- [Controls adult fleas [for up to six weeks]]
- [Controls adult Fleas [Up to 4 weeks] [1 month] [30 days]']
- [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 [4 weeks] [1 month] [30 days]']
- [Controls Deer Ticks (that may carry Lyme disease) for up to [4 weeks] [1 month] [30 days]]
- [Controls Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
- [Controls [brown dog ticks], [American dog ticks,] [and lone star ticks] [for up to [4 weeks] [1 month] [30 days]]]
- [Controls [Brown], [American,] [and Lone Star] Dog Ticks] [for up to [4 weeks] [1 month] [30 days]]]
- [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 [4 weeks] [1 month] [30 days]']

#### [Multiple Infestations]

- [Controls chewing lice]
- [Quickly halts chewing lice infestations]
- [Flea [&] [and] Tick Control for Cats [&] [and] Kittens 12 weeks old and older]
- [Controls adult fleas, ticks, mosquitoes [&] [and] chewing lice]
- [Controls adult fleas, ticks, chewing lice, and mosquitoes]
- [Once a month flea, tick, mosquito and chewing lice protection]
- [Four] [4] Way [Action] [Control] [adult fleas, ticks, mosquitoes, and chewing lice]
- [[4 Week] [1 month] [30 day] [Flea and Tick [&] [and] Application]
- [[Four (4) Week] [1 month] [Flea, Tick, Mosquito and Chewing Lice Protection]
- [Monthly Flea and Tick Treatment]
- [Use [Full Brand Name] once a month to protect from ticks and chewing lice]
- [Once a month flea, tick, mosquito, and chewing lice protection]
- [Controls adult Fleas and Ticks for up to [4 weeks] [1 month] [30 days]']

#### [All Others]

- [For use on Cats and Kittens 12weeks of age or older]
- [Fipronil (9 7%)]
- Use ONLY on cats (and kittens) OF ALL WEIGHTS over 12 weeks of age
- Use ONLY on cats (and kittens)] [of ALL weights] [over 12 weeks of age
- [Apply on kittens over 12 weeks old]

Chanelle Cat Fipronil Only Spot On ver 4 (30 Aug 2012)

• [Apply on kittens 12 weeks or older]

#### **(START - FRONT PANEL OF PACKAGING)**

[[Full Brand Name] for cats [&] [and] kittens 12 weeks or older Easy to use spot treatment for quick-acting, long lasting protection from adult fleas, ticks chewing lice and mosquitoes]

#### **ACTIVE INGREDIENT**

Fipronil 9 70%

OTHER INGREDIENT 90 30 %

TOTAL 100 00%

## KEEP OUT OF REACH OF CHILDREN CAUTION

See [Side] [Back] Panel For Additional Precautionary Statements

**NET CONTENTS** 

1

[Three] [3][three] 0 017 fl oz (0 50 mL) applicators

**(END - FRONT PANEL OF PACKAGING)** 

#### **(START - BACK/SIDE PANEL OF PACKAGING)**

[[Brand Name] contains the active ingredient fipronil that targets adult fleas, ticks, chewing lice and mosquitoes ][Fipronil pools in the oils of the skin and hair follicles, and continuously releases from hair follicles onto the skin and coat, resulting in long-lasting protection ]

[Use ONLY on cats or kittens OF ALL WEIGHTS over 12 weeks of age]

## READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON CATS AND KITTENS OVER 12WEEKS OF AGE

[[Brand Name] provides control and protection that Controls adult fleas, ticks mosquitoes 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]

#### **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 kittens under 12 weeks of age Individual sensitivities, while rare, may occur after using any pesticide product Some cats 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 or aged cats

FIRST AID			
If swallowed	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	Hold eye open and rinse slowly and gently with water for 15-20 minutes		
i .	• 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	• Rinse skin immediately with plenty of water for 15-20 minutes		
	Call a poison control center or doctor for treatment advice		
	HOTLINE NUMBER		
~	t container or label with you when calling a poison control center or doctor, or ent. For emergency information concerning this product, call 1-800-XXX-		

[[Brand Name] provides easy to use and effective flea, tick, chewing lice and mosquito protection for cats and kittens 12 weeks or older]

XXXX

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#### **DIRECTIONS FOR USE**

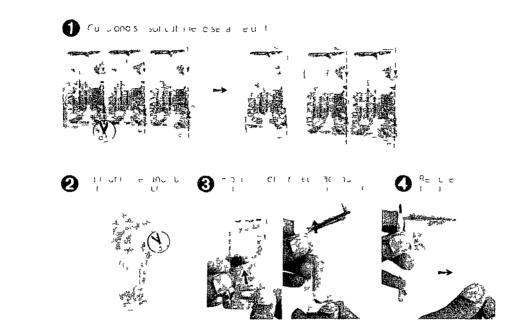
It is a violation of Federal law to use this product in a manner inconsistent with its labeling

DO NOT ALLOW CHILDREN TO APPLY PRODUCT TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND ENCLOSED DIRECTIONS BEFORE EACH USE FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY FOR EXTERNAL USE ON CATS ONLY DO NOT USE ON RABBITS DO NOT USE ON OTHER ANIMALS

To control adult fleas, all stages of brown dog ticks, American dog ticks, lone star ticks, deer ticks (which may carry Lyme disease), chewing lice and mosquitoes, apply on cats and kittens

(12 weeks or older) as follows

#### DIRECTIONS FOR OPENING PACKAGING



#### **DIRECTIONS FOR APPLICATION OF PRODUCT**

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

Only one pipette per treatment is necessary

#### FREQUENCY OF APPLICATION

When used as directed on a monthly basis, [Brand Name] will completely control flea, tick and chewing lice infestations

Fleas – Studies show that [Brand Name] Controls adult fleas for up to six weeks Although [Brand Name] protects cats from adult fleas for up to six weeks, if there is a high risk of reinfestation, or if the pet has fleas which may cause flea allergy dermatitis, apply once a month

Ticks – [Brand Name] Controls ticks for at least up to one month A once a month application is recommended where tick protection is desired

**Mosquitoes** – [**Brand Name**] Controls mosquitoes within 24 hours for up to two weeks and within 48 hours for up to one month

[Brand Name] continues to work even after bathing, water immersion, or exposure to sunlight Avoid contact with treatment area until completely dry Do not reapply [Brand Name] for at least one month

#### STORAGE AND DISPOSAL

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

#### CONTAINER DISPOSAL

**If empty** Non-refillable container Do not reuse or refill this container 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

#### PHYSICAL OR CHEMICAL HAZARDS

FLAMMABLE Keep away from heat and open flame

#### **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

Chanelle Cat Fipronil Only Spot On ver 4 (30 Aug 2012)

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.]

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Loughrea, Co, Galway
Ireland
EPA Reg No 88051-NEW
EPA Est No 74720-DEU-001

[CHANELLE BRAND LOGO]

{END - BACK / SIDE PANEL}

[BAR CODE AREA]

### {Product Claims to be printed on packaging}

[[Brand Name] provides easy to use and effective flea, tick chewing lice and mosquito protection for cats and kittens 12 weeks or older]

- [Easy to Use]
- [Quick Acting]
- [Long Lasting]
- [Waterproof]
- [Continues to work even after bathing]
- [Apply once every [4 weeks] [month] [30 days]']
- [Protects against reinfestation]
- [Controls adult fleas which may cause flea allergy dermatitis]
- [Controls newly emerged adult fleas before they lay eggs]
- [Controls all stages of brown dog ticks, American dog ticks, lone star ticks and deer ticks (which may carry Lyme disease)]
- [[Controls] [Kills] mosquitoes]]
- [Quickly halts chewing lice infestations]

#### [Mosquitoes]

- [[Controls] [Kills] mosquitoes within 24 hours for up to [14 days][2 weeks]] [and within 48 hours for up to [28 days][one month]]
- [[Controls] [Kills] mosquitoes]]

#### [Adult Fleas]

- [Controls adult fleas [for up to six weeks]]
- [Controls adult Fleas [Up to 4 weeks] [1 month] [30 days]']
- [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 [4 weeks] [1 month] [30 days]<sup>1</sup>]
- [Controls Deer Ticks (that may carry Lyme disease) for up to [4 weeks] [1 month] [30 days]]
- [Controls Ticks (Including Deer Ticks) for up to [4 weeks] [1 month] [30 days]]
- [Controls [brown dog ticks] [American dog ticks] [and lone star ticks] [for up to [4 weeks] [1 month] [30 days]]]
- [Controls [Brown] [American,] [and Lone Star] Dog Ticks] [for up to [4 weeks] [1 month] [30 days]]]
- [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 [4 weeks] [1 month] [30 days]']

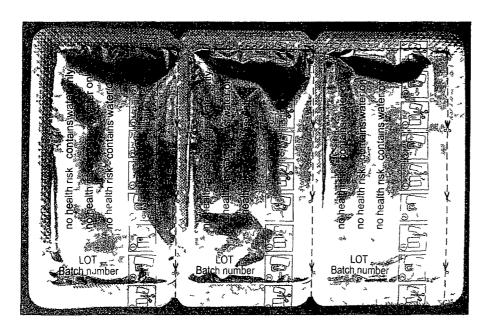
#### [Multiple Infestations]

- [Controls chewing lice]
- [Quickly halts chewing lice infestations]
- [Flea [&] [and] Tick Control for Cats [&] [and] Kittens 12 weeks old and older]
- [Controls adult fleas, ticks, mosquitoes [&] [and] chewing lice]
- [Controls adult fleas, ticks, chewing lice, and mosquitoes]
- [Once a month flea tick mosquito and chewing lice protection]
- [Four] [4] Way [Action] [Control] [adult fleas, ticks, mosquitoes, and chewing lice]
- [[4 Week] [1 month] [30 day] [Flea and Tick [&] [and] Application]
- [[Four (4) Week] [1 month] [Flea, Tick, Mosquito and Chewing Lice Protection]
- [Monthly Flea and Tick Treatment]
- [Use [Brand Name] once a month to protect from ticks and chewing lice]
- [Once a month flea, tick mosquito and chewing lice protection]
- [Controls adult Fleas and Ticks for up to [4 weeks] [1 month] [30 days]']

#### [All Others]

- [For use on Cats and Kittens 12 weeks of age or older]
- [Fipronil (9 7%)]
- [Use ONLY on cats (and kittens) OF ALL WEIGHTS over 12 weeks of age]
- [Use ONLY on cats (and kittens)] [of ALL weights] [over 12 weeks of age]
- [Apply on kittens over 12 weeks old]
- [Apply on kittens 12 weeks or older]

## **(START – BLISTER PACK INFORMATION)**



## $\{ END-BLISTER\ PACK\ INFORMATION \}$

### **(START - APPLICATOR INFORMATION)**

Front Label		Back Label
	{Brand Name} [Use only on cats and	KEEP OUT OF REACH OF CHILDREN
	kittens 12 weeks or older]	CAUTION Read directions and
	Fipronil 9 7% w/w	precautions before using
	0 017 fl oz {label code}	EPA REG No 88051-NEW

### { END – APPLICATOR INFORMATION}