

## Page 2 of 3

addition the label may indicate the net weight and quantity of individual units within the carton For example Net Weight 625 lbs (20 50 z packets) " For additional information regarding the Net Weight/Contents statement please reference Chapter 17 of the Label Review Manual at http //www epa gov/oppfead 1/labeling/lrm/chap-17 him
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 product for the quarter that begins on August 12012 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 ( $\mathrm{mm} / \mathrm{dd} / \mathrm{yyyy}$ )
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 MF 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
a 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

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reported as oral exposure and an mcident 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
1 d Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (eg multı-pet households)
e A summary table for s showing number of incidents for each severity code for these age ranges <3 months 36 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 $12 \mathrm{yr} 13 \mathrm{yr} 14 \mathrm{yr} 15 \mathrm{yr}>15 \mathrm{yr}$
$f$ 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
1 h Table showing number of incidents for each cat breed
1 Table showing number of incidents in cat for each clinical sign
J 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 8 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 http //www epa gov/pesticides/health/spot on meetings html

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) 3056701 or gebken rıchard@epa gov


Enclosures

## \{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

| Fipronıl | $\mathbf{9 7 0 \%}$ |
| :--- | ---: |
| OTHER INGREDIENT | $\mathbf{9 0 3 0 \%}$ |
| TOTAL | $\mathbf{1 0 0 0 0 \%}$ |

## KEEP OUT OF REACH OF CHILDREN

 CAUTIONREAD 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


## 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 1

## 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
[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 $77^{\circ} \mathrm{F}[/]\left[25^{\circ} \mathrm{C}\right]$ ) 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

Read the entire Label, including the Precautionary Statements First Aıd, 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 claıms based on contract, negligence, strict liability, or other legal theories) shall be limited to, at Chanelle Pharmaceuticals Manufacturing Ltd selection, 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 Manufacturıng 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]

## Chanelle Pharmaceutıcals 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]']
- [Protects against remfestation]
- [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]
- [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

| Fipronıl | $970 \%$ |
| :--- | ---: |
| OTHER INGREDIENT | $\mathbf{9 0 3 0 \%}$ |
|  | TOTAL |
| $\mathbf{1 0 0 0 0 \%}$ |  |

KEEP OUT OF REACH OF CHILDREN CAUTION
See [Side] [Back] Panel For Additional Precautionary Statements
NET CONTENTS
[Three] [3][three] $0017 \mathrm{fl} \mathrm{oz} \mathrm{(050} \mathrm{mL)} \mathrm{applicators}$
\{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 ] <br> [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 ]

1

## 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 vetermarian immediately Certain medications can interact with pesticides Consult a veterinarian before using on medicated, debilitated or aged cats

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

## 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


(3)


## DIRECTIONS FOR APPLICATION OF PRODUCT

1 Place pipette tip through the animal's hair to the skin level between the shoulder blades
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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<br>Do not contaminate water, food, or feed by storage and disposal<br>PESTICIDE STORAGE Do not remove tube from the pack until ready to use Store in a cool (below $\left.77^{\circ} \mathrm{F} / /\right]\left[25^{\circ} \mathrm{C}\right]$ ) dry place inaccessible to children and pets Do not refrigerate Protect from direct sunlight<br>\section*{CONTAINER DISPOSAL}<br>If empty Non-refillable container Do not reuse or refill this container Place in trash or offer for recycling if available<br>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

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\{END - BACK / SIDE PANEL \}

## \{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 1 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]']
- [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]
- [Fipronıl (97\%)]
- [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]

\{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 $\mathbf{1 2}$ weeks or older] | CAUTION Read directions and |
| Fipronıl $97 \%$ w/w | precautions before using |
| $00017 \mathrm{fl} \mathrm{oz} \mathrm{\{label} \mathrm{code}\}$ | EPA REG No 88051-NEW |

\{ END - APPLICATOR INFORMATION\}

