



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

EPA Reg. Number:

91090-5

Date of Issuance:

08/05/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 08/05/2018

Name of Pesticide Product:

Neove Spot On #003 for Cats

Name and Address of Registrant (include ZIP Code):

Ann M. Tillman
 Shanghai Neway Animal Health Co., Ltd.
 c/o Pyxis Regulatory Consulting Inc.
 4110 136th St. NW
 Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03
 Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

08/05/16

2. This registration is time-limited and expires 08/05/2018.
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 DCI Orders identified below:
 - a. Fipronil GDCI-129121-1305
 GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-pesticide-re-evaluation-division>

6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 91090-5.”
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 10/21/2015

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at Ciarlo.Timothy@epa.gov.

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and {braces indicate notes to review}.

- Master Label:**
- 1. Carton Label (Front, back, top, bottom, right & left panels)**
 - 2. Package Insert**
 - 3. Label on Individual Tube**
 - 4. Label on Back of Blister**
 - 5. Optional Text for Carton Label/Package Insert**

{1. Carton Label: Front Panel}

{Note to Reviewer: The word “Cats” will be at least 75% in height of the largest letter in the primary brand name.}

Neove Spot On #003 for Cats

[Alternate Brand Names: FIPRENE PLUS FOR CATS, FIPMETH PLUS FOR CATS]

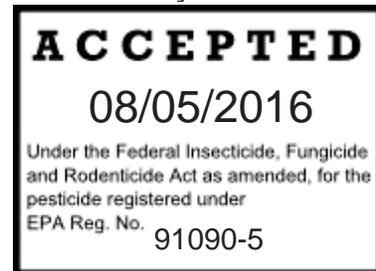
{Drawing of tube}

{Picture of appropriate size of cats}

Kills Fleas, Flea Eggs and Larvae

Kills Ticks, including those that may transmit Lyme disease

- [Fast acting]
- [Long lasting]
- [Waterproof]
- [Contains the same active ingredients used in FRONTLINE® Plus for Cats. This product is not manufactured or distributed by Merial, the maker of FRONTLINE® Plus for Cats. FRONTLINE® Plus is a registered trademark of Merial]



For Use ONLY on CATS & KITTENS 8 Weeks and Older and Weighing Over 1.5 lbs

ACTIVE INGREDIENTS

Fipronil	9.8%
(S)-methoprene	11.8%
OTHER INGREDIENTS	<u>78.4%</u>
TOTAL	100.0%

NET CONTENT: [X fl. oz. (Y mL)]

[[3]][4][6][8] - 0.017 fl. oz. (0.50 mL) tubes]

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

{1. Carton Label: Front Panel}

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSERT AND BACK PANEL FOR FIRST AID AND PRECAUTIONARY STATEMENTS

{1. Carton Label: Back Panel}

Neove Spot On #003 for Cats

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 CAT, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY AND DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. DO NOT USE ON RABBITS OR ANY OTHER ANIMALS.

Neove Spot On #003 for Cats contains fipronil and (S)-methoprene that effectively kill and control fleas and ticks for use **ONLY** on cats & kittens 8 weeks and older and weighing over 1.5 lbs.

Neove Spot On #003 for Cats remains effective after bathing, water immersion, or exposure to sunlight. Apply this product ONLY on cats/kittens 8 weeks of age or older to kill fleas, flea eggs and ticks. Do not use on cats weighing less than 1.5 lbs or younger than 8 weeks. If your cat weighs more than 20 lbs, consult with your veterinarian before use. Do not use more than one tube per cat per month, even on cats larger than 20 lbs.

HOW TO APPLY

- REMOVE and OPEN the child resistant package according to the instructions on package insert.
- To APPLY Neove Spot On #003 for Cats: Part the cat's hair and place the tip of the tube through the cat's hair to the skin level at the base of neck and between the shoulders. Squeeze the tube thoroughly to ensure the entire contents are applied in a single spot on the cat's skin. Do not apply the product superficially to the hair coat and avoid contact with the treated area until dry.

FOR EXTERNAL USE ONLY
DO NOT RE-APPLY FOR 30 DAYS

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

{1. Carton Label: Back Panel}

FREQUENCY OF APPLICATION

FLEAS: When used monthly, this product breaks the flea life cycle and controls flea, flea eggs, and flea larvae on your cat.

TICKS: This product kills all stages of ticks for at least one month. For best control of ticks, apply once every month.

Side Effects: Monitor your cat after application. Cats may experience some temporary irritation at the site of application. If signs persist or become more severe with a few days of application, consult a veterinarian immediately. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

FOR CAT USE ONLY

If ingested by a cat, contact your veterinarian immediately.

Made in [China]

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

[PRODUCT BAR CODE]

RM509, 1438 Shan Xi Bei Road,

Shanghai, 200060

P. R. China

All rights reserved.

EPA Reg. No.: 091090-

EPA Est. No.:

{1. Carton Label: Top, Left and Right Panels}

Neove Spot On #003 for Cats

{Drawing of tube}

For Use **ONLY** on **CATS and KITTENS 8 Weeks or Older and Over 1.5 lbs**

{1. Carton Label: Bottom Panel}

For Cat Use Only

Lot/Batch No.: XXXXXX

{2. Package Insert}

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

Neove Spot On #003 for Cats

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS & KITTENS OVER 8 WEEKS OF AGE OR OLDER AND
WEIGHING OVER 1.5 LBS**

Neove Spot On #003 for Cats provides a fast-acting, long-lasting and waterproof treatment to:

- Kill Fleas, Flea Eggs and Larvae
- Kill Ticks, including those that may transmit Lyme disease and other tick-borne diseases

ACTIVE INGREDIENTS

Fipronil	9.8%
(S)-methoprene	11.8%
OTHER INGREDIENTS	<u>78.4%</u>
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor for treatment advice immediately• Have person sip a glass of water if able to swallow• Do not induce vomiting unless told to do so by the poison control center or doctor• Do not give anything 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.• Call a poison control center or doctor for treatment advice
If on Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water and soap 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. Call 1-XXX-XXX-XXXX for emergency treatment information.	

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS - CAUTION**

Harmful if swallowed. Causes moderate 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.

{2. Package Insert}

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

HAZARDS TO DOMESTIC ANIMALS

FOR EXTERNAL USE ONLY. Do NOT use on kittens under 8 weeks of age or weighing less than 1.5 lbs. Do NOT use on rabbits or any other animals. Sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

Side Effects: Monitor your cat after application. Cats may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

PHYSICAL OR CHEMICAL HAZARDS

Flammable: Keep away from heat or open flame.

Do not mix or allow to come into contact with oxidizing agents. Hazardous chemical reaction may occur.

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

{2. Package Insert}

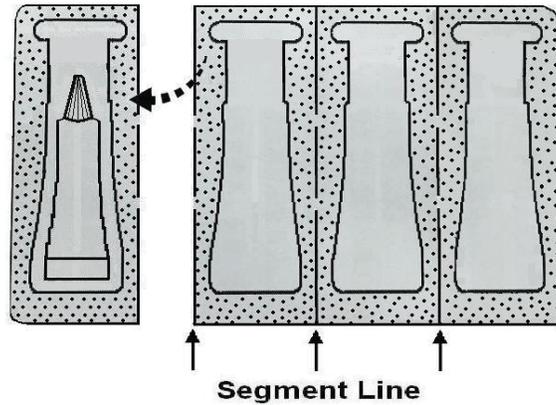
DIRECTIONS FOR USE

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 CAT, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY AND DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. DO NOT USE ON RABBITS OR ANY OTHER ANIMALS.

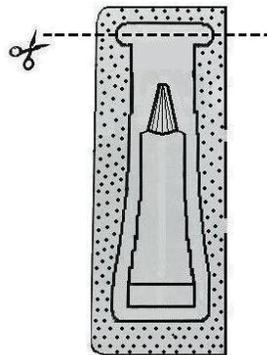


HOW TO REMOVE AND OPEN THE CHILD RESISTANT PACKAGE

1. Snap off **ONE** blister pack along the segment line.



2. Use scissors to cut across the top bubble section (Do not harm the tube inside).



3. Peel off the foil from the cut line and take out the tube.

{2. Package Insert}

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

HOW TO APPLY

Remember, your cat needs to be dry at the time when this product is applied and must remain dry for 24 hours after application.

1. Hold the tube in an upright position facing away from you and your cat's face and eyes. Screw the cap off the tube.
2. The cat should be standing for easy application. Part the cat's hair and place the tip of the tube through the cat's hair to the skin level at the base of neck and between the shoulders. Squeeze the tube thoroughly to ensure the entire contents are applied in a single spot on the cat's skin. Do not apply the product superficially to the hair coat and avoid contact with the treated area until dry. Do not use more than one tube per cat per month, even on cats larger than 20 lbs.

[Visual Depicting Application To Cats]

3. Make sure the tube is empty after application and discard empty tube as described in the Storage and Disposal section.

FREQUENCY OF APPLICATION

FLEAS: When used monthly, this product breaks the flea life cycle and controls flea, flea eggs, and flea larvae on your cat.

TICKS: This product kills all stages of ticks for at least one month. For best control of ticks, apply once every month.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store unused tubes in the original child-resistant package; keep out of reach of children and animals.

Pesticide Disposal:

If Partly Filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Container Handling: Non-refillable container. If Empty: Do not reuse or refill the container. Place in trash or offer for recycling if available.

WARRANTY

To the extent consistent with applicable law, Sellers makes no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

USE ON CATS ONLY

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

All rights reserved.

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

{3. Label on Individual Tube}

Neove Spot On #003 for Cats

9.8% Fipronil
11.8% (S)-methoprene

0.017 fl. oz. (0.5 mL)

ONLY for CATS & KITTENS 8 Weeks or Older and Over 1.5 lbs

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read entire label before each use

[NEWAY]

EPA Reg. No.: 091090-

Lot No.: 0000000

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

{4. Label on Back of Blisters}

Neove Spot On #003 for Cats

9.8% Fipronil
11.8% (S)-methoprene

0.017 fl. oz. (0.5 mL)

ONLY for CATS & KITTENS 8 Weeks or Older and Over 1.5 lbs

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read entire label before each use

[NEWAY]

EPA Reg. No. 091090-

[Lot No. 0000000]

**Neove Spot On #003 for Cats
MASTER LABEL**

Note: [Brackets indicate alternate language] and
{braces indicate notes to review}.

{5. Optional Text for Carton Label/Package Insert}

{NON-PESTICIDE RELATED TEXT}

- [Buy “X” get “Y” free]
- [X% more free]
- [[Value Pack]][Great Value]][Bonus Pack]]
- [[Convenient/Easy] to use]
- [[X] month supply]
- [Best results when used monthly (30 days)]
- [Remains effective after [bathing]][swimming]][exposure to sunlight]]
- [Apply directly to your cat’s skin]

{PESTICIDE RELATED TEXT}

- [Provides [Easy], [Fast] and [effective] control of flea and tick for cats & kittens]
- [Effective monthly treatment of [fleas] and [ticks]]
- [Monthly [flea] and [tick] protection]
- [[Prevents] all stages of flea [eggs, larvae, pupae] from developing]
- [Effective [against] all stages of the flea life cycle]
- [Controls flea reinfestation]
- [Contains (S)-methoprene, an Insect Growth Regulator which breaks flea life cycle]
- [[Breaks] the flea life cycle]
- [Dual action: Fipronil & (S)-methoprene IGR]
- [A once a month application may be needed if cat is at a high risk for flea reinfestation]
- [[Kills] ticks that may transmit [Lyme disease], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis] and other tick-borne diseases]
- [Kills ticks for up to [4 weeks]][1 month]][30 days]]