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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: 4/18/18		
NOTICE OF PESTICIDE:	Term of Issuance:			
<u>X</u> Registration	Conditional, Time-Limited			
Reregistration Conditional, Time-Limited Expires: 04/18/2020				
(under FIFRA, as amended)	Name of Pesticide Produ	ıct:		
	NEOVE SPOT O CATS			
Name and Address of Registrant (include ZIP Code):				
Ann Tillman Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting Inc. 4110 136 <sup>th</sup> St. Ct. 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.				
<ol> <li>The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 04/18/2020.</li> </ol>				
Signature of Approving Official:	Date:			
XB+	4/18/18			
Kable Bo Davis, Product Manager 03 Invertebrate-Vertebrate Branch I, Registration Division (7505P)				
EPA Form 8570-6	•			

Registration Notice Conditional Time-Limited Dog Spot-On Extension v.20151203

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- 3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated 8/5/2016.
- 4. You are required to comply with the data requirements described in the DCI or EDSP Orders identified below:
  - a. Fipronil GDCI-129121-1305
  - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

5. 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 Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Enclosure

## 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

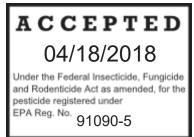
- · [Long lasting]
- [Waterproof 24 hours after application]
  - [Contains the same active ingredients used in FRONTLINE<sup>®</sup> Plus for Cats. This product is not manufactured or distributed by Merial, the maker of FRONTLINE<sup>®</sup> Plus for Cats. FRONTLINE<sup>®</sup> Plus is a registered trademark of Merial]

	For Use ONLY on CATS & KITTENS 8 Weeks and Older and Weighing Over 1.5 lbs	
A	CTIVE INGREDIENTS	
	Fipronil 9.8%	)

Fipronil	9.8%
(S)-methoprene	11.8%
OTHER INGREDIENTS	78.4%
TOTAL	100.0%

**NET CONTENT:** [X fl. oz. (Y mL)] {Total net contents, X fl oz (Y mL) in carton is determined by the xx fl oz per tube and the number of tubes in carton}

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



Note: [Brackets indicate alternate language] and {braces indicate notes to review} (text in parentheses will appear on label).

#### **{1. Carton Label: Front Panel}**

#### KEEP OUT OF REACH OF CHILDREN

# CAUTION

# SEE INSERT FOR COMPLETE DIRECTIONS FOR USE, 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. FOR EXTERNAL USE ONLY. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

#### Restrictions

- Do not allow children to apply product.
- Use ONLY on cats.
- Do not allow your cat to ingest this product.
- Do not use on rabbits or animals other than cats.
- Do not use on cats weighing less than 1.5 lbs or younger than 8 weeks.
- Do not use more than one tube per treatment per cat regardless of the cat's weight.
- Do not re-apply for [30 days][one month][4 weeks]

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 when applied 24 hours before bathing, water immersion, or exposure to sunlight. Apply this product <u>ONLY</u> on cats/kittens 8 weeks of age or older to kill fleas, flea eggs and ticks.

#### 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.

## **{1. Carton Label: Back Panel}**

## FREQUENCY OF APPLICATION

**FLEAS:** When used [monthly][every 30 days][every 4 weeks], 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][30 days][4 weeks]. For best control of ticks, apply once every [month][30 days][4 weeks].

{Side Effects box will appear at the lower right-hand corner of the back panel}

**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.: 91090-5 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** 

Note: [Brackets indicate alternate language] and {braces indicate notes to review} (text in parentheses will appear on label).

## {1. Carton Label: Bottom Panel}

For Cat Use Only Lot/Batch No.: XXXXXX

## **{2. Package Insert}**

## 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 long-lasting treatment and is waterproof 24 hours after 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	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	• 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	• 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}

## HAZARDS TO DOMESTIC ANIMALS

**FOR EXTERNAL USE ONLY**. Do <u>NOT</u> use on kittens under 8 weeks of age or weighing less than 1.5 lbs. Do <u>NOT</u> use on rabbits or animals other than cats. Sensitivities, while rare, may occur after using ANY pesticide product for cats. 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.

{The side effects box will be placed on the package insert}

**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.

## **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 PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

## Restrictions

- Do not allow children to apply product.
- Use ONLY on cats.
- Do not allow your cat to ingest this product.
- Do not use on rabbits or animals other than cats.
- Do not use on cats weighing less than 1.5 lbs or younger than 8 weeks.
- Do not use more than one tube per treatment per cat regardless of the cat's weight.
- Do not re-apply for [30 days][one month][4 weeks]

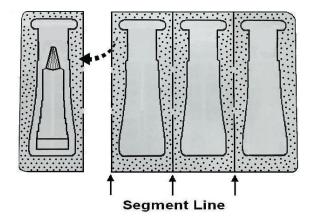
Note: [Brackets indicate alternate language] and {braces indicate notes to review} (text in parentheses will appear on label).

#### **{2. Package Insert}**

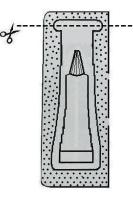


## HOW TO REMOVE AND OPEN THE CHILD RESISTANT PACKAGE

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.

## 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][30 days][4 weeks]. Do not apply more than one tube per treatment for one cat regardless of the cat's weight.

## **{2. Package Insert}**

## [Visual Depicting Application To Skin of 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][every 30 days][every 4 weeks], 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][30 days][4 weeks]. For best control of ticks, apply once every [month][30 days][4 weeks].

## STORAGE AND DISPOSAL

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

**Pesticide Storage:** Store this product in a cool, dry (preferably locked) place in the original child-resistant package. Keep away from heat and open flame in an area inaccessible to children and animals.

**Pesticide Disposal and Container Handling:** Non-refillable container. Do not reuse or refill the 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

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.

Note: [Brackets indicate alternate language] and {braces indicate notes to review} (text in parentheses will appear on label).

#### **{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.: 91090-5 Lot No.: 0000000

**{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. 91090-5 [Lot No. 0000000]

Note: [Brackets indicate alternate language] and {braces indicate notes to review} (text in parentheses will appear on label).

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

#### {NON-PESTICIDE RELATED TEXT}

- · [[Convenient/Easy] to use]
- · [[3][4][6][8] month supply]
- · [Best results when used [monthly][every 30 days[every 4 weeks]]
- · [Remains effective when applied 24 hours before [bathing][swimming][exposure to sunlight]]
- [Apply directly to your cat's skin]

## {PESTICIDE RELATED TEXT}

- · [Provides [Easy] and [effective] control of flea and tick for cats & kittens]
- · [Effective [monthly][once every 30-days][once every 4-weeks] treatment of [fleas] and [ticks]]
- · [[Monthly][30 Days][4 Weeks] [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][every 30 days][every 4 weeks] application may be needed if cat is at a high risk for flea reinfestation]
- [[Kills] ticks that may transmit [Lyme disease], [haemobartonellosis], [babesios], [ehrlichiosis], [anaplasmosis] and other tick-borne diseases]
- · [Kills ticks for up to [1 month][30 days] [4 weeks]]