

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

91090-6

Date of Issuance:

11/9/16

NOTICE OF PESTICIDE:

X Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance:

EPA Reg. Number:

Conditional, Time-Limited

Expires: 11/9/2018

Name of Pesticide Product:

Neove Spot On #002 for Cats

Name and Address of Registrant (include ZIP Code):

Shanghai Neway Animal Health Co., Ltd.

c/o Mary Hunt

Exponent, Inc.

1150 Connecticut Ave., N.W., Suite 1100

Washington, D.C. 20036

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

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

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/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Date:

11/9/16

Venus Eagle, Product Manager 01 Invertebrate & Vertebrate Branch 3 Registration Division (7505P)

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Office of Pesticide Programs

legistration Notice Conditional Time-Limited Cat Spot-On v.20150724

Page 2 of 4 EPA Reg. No. 91090-6 Decision No. 512070

#### EPA Form 8570-6

- 2. This registration is time-limited and expires 11/9/2018.
- 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 cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

Page 3 of 4 EPA Reg. No. 91090-6 Decision No. 512070

- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

- 5. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
  - a. Imidacloprid GDCI-071503-1243
  - b. Pyriproxfen GDCI-129032-1299
  - c. Imidacloprid EDSP-129099-179

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

- 6. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 91090-6."
- 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

Page 4 of 4 EPA Reg. No. 91090-6 Decision No. 512070

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

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

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

Basic CSF dated 12/5/2015

If you have any questions, please contact Marianne Lewis by phone at (703) 308-8043, or via email at lewis.marianne@epa.gov.

Enclosure

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

#### Master Label:

- 1. Carton Label (Front, back, top, bottom, right & left panels)
- 2. Package Insert
- 3. Label on Individual Tubes
- 4. Label on Back of Blister (no text or image on front of blister)
- 5. Optional Text for Carton Label/Package Insert

#### ACCEPTED

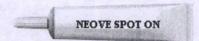
Nov 09, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 91090-6

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

{Note to EPA - The word "Cats" text size will be 75% of the height of the largest letter in the brand name.}

#### Neove Spot On #002 for Cats



[Alternate Brand Names: IMIDACARE PLUS FOR CATS; IMIDASTAR PLUS FOR CATS; PETIMIDA PLUS FOR CATS]

Picture of appropriate size of cats within the weight range for the product.

Once-A-Month Topical Flea Prevention and Treatment for Cats 0.0078 fl. oz. (0.23 mL)

For Use Only on Cats and Kittens 8 Weeks and Older and Weighing 2 - 5 lbs OR

0.014 fl. oz. (0.4 mL)

For Use Only on Cats and Kittens 8 Weeks and Older and Weighing 5 - 9 lbs

OR

0.027 fl. oz. (0.8 mL)

For Use Only on Cats and Kittens 8 Weeks and Older and Weighing Over 9 lbs

[Contains the active ingredients used in Advantage® II. This product is not manufactured or distributed by Bayer, the maker of Advantage® II. Advantage® is a registered trademark of Bayer.]

#### **ACTIVE INGREDIENTS**

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS	90.44%
TOTAL	100.00%

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

{1. Carton Label: Front Panel Continued}

## KEEP OUT OF REACH OF CHILDREN CAUTION

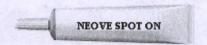
See back panel and insert for First Aid, Precautionary Statements, Storage and Disposal statements and Directions for Use.

NET CONTENTS: Each blister contains [3][4] tubes.

[0.0078 fl oz (0.23 mL) for Cats and Kittens 8 weeks and older and Weighing 2-5 lbs] or [0.014 fl oz (0.4 mL) for Cats and Kittens 8 weeks and older and Weighing 5-9 lbs] or [0.027 fl oz (0.85 mL) for Cats and Kittens 8 weeks and older and Weighing over 9 lbs]

{1. Carton Label: Back Panel}

Neove Spot On #002 for Cats



#### **FIRST AID**

Swallowed	Call a poison control center or doctor immediately for treatment advice.
-	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to 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. 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 for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.

#### PRECAUTIONARY STATEMENTS

#### **HAZARDS TO HUMANS**

Caution. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

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

#### HAZARDS TO DOMESTIC ANIMALS

For External Use Only. Do NOT use on cats or kittens under eight weeks of age or weighing less than [2 lbs][5 lbs][9 lbs]. Do NOT use on any other animals. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

#### **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. READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. USE ON CATS ONLY AND DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. DO NOT USE ON ANY OTHER ANIMALS.

#### **HOW TO APPLY**

- · REMOVE and OPEN the child resistant package according to the instructions on package insert.
- For cats and kittens 8 weeks and older and weighing [2-5 lbs][5-9 lbs][over 9 lbs] To APPLY Neove Spot On #002 for Cats: Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the chance for the cat to lick the product. Do not allow the product to run off.

**Side Effects:** Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort such as hypersalivation. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects such as lethargy occur, consult your veterinarian.

# RESTRICTIONS □ DO NOT apply to cats weighing less than [2 lbs][5 lbs][9 lbs]. □ USE ONLY on cats or kittens 8 weeks and older. □ DO NOT use on other animals. □ DO NOT apply more than one (1) tube per treatment. □ DO NOT have contact or allow children to have contact with treated area until completely dry. □ FOR EXTERNAL USE ONLY. □ Cat is to be dry prior to application and remain dry for 24 hours after application [for product to work effectively].

3

11/07/2016

☐ Do not allow children to apply the product.

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

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

Manufactured/Distributed by:

SHANGHAI NEWAY ANIMAL HEALTH CO., LTD

[PRODUCT BAR CODE]

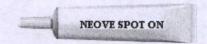
Rm 509, 1438 Shan Xi Bei Road, Shanghai, 200060 P. R. China

Made in [China]. All rights reserved.

EPA Reg. No. EPA Est. No.:

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

Neove Spot On #002 for Cats



0.0078 fl oz (0.23 mL) For Use only on Cats and Kittens 8 weeks and older and Weighing 2-5 lbs

or

0.014 fl oz (0.4 mL) For Use only on Cats and Kittens 8 weeks and older and Weighing 5-9 lbs

or

0.27 fl oz (0.8 mL) For Use only on Cats and Kittens 8 weeks and older and Weighing Over 9 lbs

{1. Carton Label: Bottom Panel}

For Use on cats Only.

Lot/Batch No .:

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

#### {2. Package Insert}

## {The commercial package insert will be specific for one weight range with appropriate tube/package size:

0.0078 fl oz (0.23 mL) For Use only on Cats and Kittens 8 weeks and older and Weighing 2-5 lbs or

0.014 fl oz (0.4 mL) For Use only on Cats and Kittens 8 weeks and older and Weighing 5-9 lbs or

0.27 fl oz (0.8 mL) For Use only on Cats and Kittens 8 weeks and older and Weighing Over 9 lbs

#### Neove Spot On #002 for Cats

READ THE ENTIRE LABEL BEFORE EACH USE
USE ONLY ON CATS AND KITTENS 8 WEEKS AND OLDER AND WEIGHING [2-5 lbs][5-9 lbs][OVER 9 lbs]

#### For the Flea Prevention and Treatment for Cats

#### **ACTIVE INGREDIENTS**

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS	90.44%
TOTAL	100.00%

#### KEEP OUT OF REACH OF CHILDREN

#### **CAUTION**

#### FIRST AID

If Swallowed	Call a poison control center or doctor immediately for treatment advice.
	Have person sip a glass of water if able to swallow.
	Do not induce vomiting unless told to 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. 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 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.

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

{2. Package Insert Continued}

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS

RESTRICTIONS

effectively].

Caution. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin 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 cats or kittens under eight weeks of age or weighing less than [2 lbs][5 lbs][9 lbs]. Do NOT use on any other animals. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing cats. Individual sensitivities may occur after using ANY pesticide product for cats. If signs persist or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any other product.

**Side Effects:** Monitor your cat after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort such as hypersalivation. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects such as lethargy occur, consult your veterinarian.

#### **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. READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. USE ON CATS ONLY AND DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. DO NOT USE ON ANY OTHER ANIMALS.

## □ DO NOT apply to cats weighing less than [2 lbs][5 lbs][9 lbs]. □ USE ONLY on cats or kittens 8 weeks and older. □ DO NOT use on other animals. □ DO NOT apply more than one (1) tube per treatment. □ DO NOT allow children to have contact with treated area until completely dry. □ FOR EXTERNAL USE ONLY. □ Cat is to be dry prior to application and remain dry for 24 hours after application [for product to work

☐ Do not allow children to apply the product.

Neove Spot On #002 for Cats contains imidacloprid and an insect growth regulator, pyriproxyfen, that effectively kill multiple stages of the existing fleas (flea eggs, flea larvae and adult fleas) within 12 hours and prevents further re-infestation up to four weeks, which may reduce the incidence of Flea Allergy Dermatitis (FAD) or Flea Bite Hypersensitivity (FBH). Neove Spot On #002 for Cats remains effective after bathing. Monthly treatments are recommended for control and prevention of fleas.

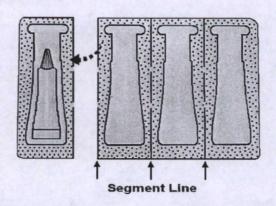
[Brackets indicate alternate language] and {braces indicate notes to reviewer}

{2. Package Insert Continued}

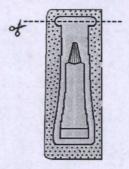


#### HOW TO REMOVE AND OPEN THE CHILD RESISTANT PACKAGE

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**

To APPLY Neove Spot On #002 for Cats: Part the hair on the neck at the base of the skull until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. Do not get this product in your cat's eyes or allow your cat to ingest this product. The product is bitter tasting and salivation may occur for a short time if the cat licks the product immediately after treatment. Treatment at the base of the skull will minimize the chance for the cat to lick the product. Do not allow the product to run off.



[Brackets indicate alternate language] and {braces indicate notes to reviewer}

{2. Package Insert Continued}

#### 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 in a cool dry place; keep out of reach of 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.

EPA Reg. No.

EPA Est. No.:

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

{3. Label on Individual Tubes}

#### Neove Spot On #002 for Cats

Imidacloprid 9.10%

Pyriproxyfen 0.46%

0.0078 fl oz (0.23 mL)

Use only on 2-5 lbs Cats and Kittens 8 weeks and older

or

0.014 fl oz (0.4 mL)

Use only on 5-9 lbs Cats and Kittens 8 weeks and older

or

0.27 fl oz (0.8 mL)

Use only on Cats and Kittens over 9 lbs, 8 weeks and older

#### KEEP OUT OF REACH OF CHILDREN

#### **CAUTION**

Read entire label before each use

[NEWAY]

EPA Reg. No. 91090-XXX

Lot No. 0000000

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

{4. Label on Back of Blisters}

{The blister pack(s) containing tubes are placed inside the carton for market}

#### Neove Spot On #002 for Cats

Imidacloprid......9.10% Pyriproxyfen.....0.46% Other Ingredients....90.44%

0.0078 fl oz (0.23 mL)

For Use only on Cats and Kittens 8 weeks and older and Weighing 2-5 lbs

01

0.014 fl oz (0.4 mL)

For Use only on Cats and Kittens 8 weeks and older and Weighing 5-9 lbs

or

0.27 fl oz (0.8 mL)

For Use only on Cats and Kittens 8 weeks and older and Weighing Over 9 lbs

One blister card contains [3][4] tubes [1][2] blister card(s) per carton

### KEEP OUT OF REACH OF CHILDREN CAUTION

Read entire label before each use

[NEWAY] EPA Reg. No. 091090-XXX Lot No. 0000000

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

- Neove Spot On #002 for Cats contains imidacloprid, and [an/the][insect growth regulator][IGR]
   Pyriproxyfen
- For use on cats and kittens 8 weeks of age and older and weighing [2-5 lbs] or [5-9 lbs] or [over 9 lbs]
- · A single topical application remains effective for [4 weeks][1 month]
- · Convenient, easy-to-apply and fragrance-free [monthly][topical solution]
- Once a month topical flea prevention and treatment for cats 8 weeks of age or older and [2-5 lbs] or [5-9 lbs] or [over 9 lbs]
- Neove Spot On #002 for Cats is for the prevention and treatment of fleas on cats 8 weeks of age and older and weighing 2-5 lbs or 5-9 lbs or over 9 lbs.
- · For the treatment and prevention of flea infestations
- One treatment prevents further flea re-infestations for up to [4 weeks][1 month][30 days]
- · Kills flea life stages
- · Kills fleas within 12 hours of application
- · Re-infesting fleas on cats are killed within 12 hours of application
- · Stops existing flea infestations by killing adult fleas
- · Prevents re-infestations by killing adult fleas before they lay eggs
- · Re-infesting fleas are killed within 2 hours with protection against further flea infestation
- · [Prevents][Stops] flea eggs from hatching [into biting adults]
- · Effectively breaks the flea life cycle
- · [Kills][controls] flea life stages
- · Comprehensive flea prevention and treatment
- · 3-way flea protection ([kills][controls]) adults, larvae, and eggs

[Brackets indicate alternate language] and {braces indicate notes to reviewer}

- · [Prevents][Stops] flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
- Treatment with [Neove Spot On #002 for Cats] kills fleas and may reduce the incidence of flea allergic dermatitis [FAD] or flea bite hypersensitivity
- · Flea adulticide, larvicide, and ovicide
- · Kills flea eggs
- · Controls existing flea infestations on your cat and prevents further re-infestations
- · Contains an insect growth regulator (IGR) to kill flea eggs and prevent re-infestation
- · Monthly use of Neove Spot On #002 for Cats kills fleas and may prevent ([flea allergy dermatitis][flea bite hypersensitivity])
- Start working through contact
- · Remains effective after [bathing][shampooing]
- · Fragrance-free