


70585-13

01-14-2011

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	<p align="center"><b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> Office of Pesticide Programs Registration Division (7504P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p>	<p>EPA Registration No.  <b>70585-13</b></p>	<p>Date of Issuance:  <b>JAN 14 2011</b></p>
<p align="center"><b>NOTICE OF PESTICIDE:</b></p> <p align="center"> <input checked="" type="checkbox"/> Registration  <input type="checkbox"/> Reregistration         </p> <p align="center">(under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</p>		<p>Term of Issuance: <b>Conditional Registration</b> <b>Time-limited: see conditions below</b></p> <hr/> <p>Name of Pesticide Product:  <b>NAH 3</b></p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p><b>Novartis Animal Health (c/o Pyxis Regulatory Consulting, Inc.)</b> <b>3200 Northline Avenue, Suite 300</b> <b>Greensboro, NC 27408</b></p>			
<p><b>Note:</b> 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.</p>			
<p>On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.</p> <p>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.</p> <p>This product is conditionally registered in accordance with FIFRA §3(c)(7)(a) provided that:</p> <ol style="list-style-type: none"> <li>1. 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 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.</li> <li>2. As applicable, consider limiting the formulations of each product to one basic confidential statement of formula. The Agency may require this in the future. It is possible that no additional alternate formulations or minor formulation amendments will be approved for this product in the future.</li> <li>3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on January 1, 2011. The quarterly reports are due two months after each quarter ends.</li> </ol> <p>Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division (7504P), Immediate Office (attn: Ms. Kimberly Nesci).</p>			

**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 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 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.
  - 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.

- Table showing number of incidents for each dog breed.
  - 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.
5. You must submit and/or cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA §4.
  6. Throughout the entire label, including claims, replace “treatment” with “application.”
  7. On page 1 under the header Mosquitoes, revise the following statement by adding the underlined words:  
  
“[[Kills mosquitoes] [within 24 hours for up to the first 7 days after treatment, and within 48 hours for up to 28 days].”
  8. On page 1 under the header Adult Fleas, revise the following claims to add the underlined words, or delete struck-out words, as follows:  
  
“[Kills fleas, which may be a source of flea allergy dermatitis] [or, flea bite anemia]-~~and tapeworm infestations~~”  
  
“[If dog is at high risk of flea reinfestation, apply once a month ~~monthly application may be needed.~~]”
  9. On page 1 under Multiple Bugs, revise the first claim to read as follows:  
  
“[Kills chewing lice and controls mites that may cause sarcoptic mange]”
  10. On page 1 under Multiple Bugs, delete “[Four [4] Way Protection[!]” because this is an unqualified, nebulous claim.
  11. On page 2 under All Others, delete the following claims:  
  
“Prevents reinfestation”  
“[Once a month treatment recommended]”  
“[A once monthly application is recommended for chewing lice.]”  
“{for cartons with 3 applicators}”  
“[Free] Brochure Inside!”
  12. On page 2 under All Others, revise the sarcoptic mange reference to read as follows:  
  
“Controls mites that may cause sarcoptic mange”
  13. On pages 3 and 4 under the list of claims, delete “brochure” and “images of the different kinds of

bugs killed with a line drawn through” because these have not been submitted to the Agency for review and approval.

14. On page 3 under the list of weight ranges, delete “Ingredient Statement may be on front or back label” because the ingredient statement must be printed on the front panel, and no request or rationale was received to consider an exception to this requirement, per 40 CFR 156.10(g)(2)(i).

15. On page 3 in the Ingredient Statement, correct the percentages as follows:

<b>“ACTIVE INGREDIENTS:</b>	
Fipronil.....	9.8%
Cyphenothrin.....	5.2%
<b>OTHER INGREDIENTS[*]:</b> .....	<b>85.0%</b>
<b>TOTAL</b>	<b>100.0%”</b>

16. On page 4 under the Back/Side Carton Label header, revise the last statement to read as follows:

“This product features a sustained-release formula developed for fast acting [and long lasting] control of fleas, ticks mosquitoes and chewing lice for up to 30 days on dogs.”

17. On page 4 under the Back/Side Carton Label header, delete “[diagram with visual of fipronil collecting and being released from hair follicle].”

18. On page 4, delete the reference to a “[diagram with visual of fipronil collecting and being released from hair follicle].”

19. On page 4 under Precautionary Statements, revise the paragraph as follows:

“Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.”

20. On page 5 in the Directions for Use, delete “Insert Copy” from the reference to the Outer Packaging because this insert was not submitted to the Agency for review and approval.

21. On page 5 in the How to Apply section, revise the reapplication interval from “4 weeks” to “30 days” to be consistent with the interval stated under Frequency of Application.

22. On page 5 under the Frequency of Application, add the underlined words and delete the struck-out text in the following statement:

“[Brand name] kills mosquitoes within 24 hours for up to the first 7 days after application ~~treatment~~, then within 48 hours for up to 28 days].”

23. On page 6 under the Frequency of Application for dogs weighing between 23-44 pounds, delete “[Apply two tubes (0.67 mL)(0.023 fl. oz) as a spot on the dog’s back between the shoulder blades] [or]” because each application must be made only using one tube, per the child-resistant packaging test data used to support this product.

24. On page 7 under the EPA Reg. No., delete “Optional Insert” and “Insert Copy” as an option because all language under the Directions for Use must remain together on the labeled package.

- 25. On page 7 under How to Apply, delete "topical" from the 6 Step Checklist statement.
- 26. On page 8 on the Front Label tube text, correct the cyphenothrin percentage to 5.2%.
- 27. Note that should you wish to add a reference to the company's website on your label, then the website becomes labeling under FIFRA and is subject to review by the Agency/ If the website content is false or misleading, the product would be deemed misbranded and unlawful to sell or distribute under FIFRA § 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 may be referred to the EPA's Office of Enforcement and Compliance Assurance.
- 28. Revise the EPA Registration Number to read: "EPA Registration No. 70585-13."

If the Agency determines that future mitigation measures are necessary for all pet spot-on products, you will be informed, and be expected to comply. If mitigation measures are necessary, the Agency may take appropriate regulatory actions. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please contact Rosanna Louie-Juzwiak at (703) 308-0037 with any questions.

Enclosure: NAH 3 Label, Stamped *Accepted with Comments*

Signature of Approving Official:



Date:

JAN 14 2011

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

for

[CARTON LABEL - MASTER LABEL COPY]

NAH 3

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

JAN 14 2011

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
70585-13

[ABNs]

- [Apply to puppies over 12 weeks old]
- [Apply to puppies 12 weeks or older]

[Mosquitoes]

- [• [Kills mosquitoes] [within 24 hours for the first 7 days after treatment, and within 48 hours for up to 28 days]

[Adult Fleas]

- [•Kills adult fleas]
- [•Kills newly emerged adult fleas before they lay eggs]
- [•Kills fleas, source of flea allergy dermatitis] [, flea bite anemia] ~~and tapeworm infestations~~
- [•Kills fleas]
- [• Kills fleas Up to [4 weeks] [1 month] [30 days]!]
- [•If dog is at high risk of flea reinfestation a once monthly application may be needed]

[Multiple Bugs]

- [•Kills [chewing] lice and aids in the control of sarcoptic mange]
- [• Flea [&] [and] Tick Control for Dogs [&] [and] Puppies 12 weeks old and older]
- [•Kills Fleas, Ticks [and] chewing lice [&] [and] [mosquitoes]
- [•Kills Fleas, Ticks [and kills Mosquitoes]
- [•Kills [and] Fleas, Ticks, [and kills chewing lice] [and] [mosquitoes]
- [•Monthly flea, tick, mosquito, and lice treatment]
- [• ~~Four~~ [4] ~~Way Protection~~ [Kills Fleas, Ticks, mosquitoes, and lice]]
- [• [4 Week] [1 month] [30 day] [Flea and Tick & Treatment]
- [• [Four (4) Week] [1 month] [30 day] [Flea, Tick, Mosquito and Lice Treatment]
- [• Kills Fleas and Ticks for up to [4 weeks] [1 month] [30 days]!]
- [Once A Month Flea and Tick Treatment]
- [•Use NAH 3 monthly to control Ticks and chewing lice]
- [•Monthly flea, tick, mosquito, and chewing lice protection.]



- [• Flea & Tick Control for Dogs & Puppies 12 weeks old and older]
- [•Kills Fleas, Ticks, and kills chewing lice & mosquitoes]

[Ticks]

- [•Kills Ticks including those that may transmit Lyme disease]
- [• Kills Ticks for Up to [4 weeks] [1 month] [30 days]!]
- [• Kills] Deer Ticks [that may transmit Lyme Disease,] for up to [4 weeks] [1 month] [30 days]]
- [• Kills Ticks]

- [•Kills Deer Ticks for up to [4 weeks] [1 month] [30 days]]
- [• Kills [Brown Dog Ticks], [American Dog Ticks,] [and Lone Star Ticks] [(*Rhipicephalus sanguineus*)] for up to [4 weeks] [1 month] [30 days]]
- [• Kills [Brown Dog Ticks], [(*Rhipicephalus sanguineus*)] for up to [4 weeks] [1 month] [30 days]]
- [• Kills American Dog Ticks [and] [(*Dermacentor variabilis*)] for up to [4 weeks] [1 month] [30 days]!]

[All Others]

- [•For Dogs and Puppies 12 weeks of age or older]
- [•For Dogs [up to 22 lbs], [23-44 lbs], [45-88 lbs], [89-132 lbs]
- [•Fast Acting]
- [•Dogs can be bathed 24 hours after treatment]
- [•Long Lasting]
- [•~~Prevents reinfestation~~]
- [•Convenient spot treatment]
- [•~~Once a month treatment recommended~~]
- [•~~A once monthly application is recommended for chewing lice.~~]
- [•Fast Action against chewing lice infestations]
- [•Aids in Control of Sarcoptic Mange [infestations]]
- [• Three Applications ~~{for cartons with 3 applicators}~~] and/or [3 Month Supply] or [12 Week Supply]
- [• Best if used year round!]
- [• (ICON Showing 4 Week Protection)]
- [• 4 Week Dose!]
- [• 1 Month Dose!]
- [• Easy to Use [Application]]
- [• Specially Formulated for Dogs and Puppies]
- [• [Free] Calendar Stickers Inside!]
- [• ~~[Free] Brochure Inside!~~]



- [• [Free] ~~Brochure~~ and Calendar Stickers Inside]
- [• Apply once every [4 weeks] [month] [30 days]!]
- [• Dogs can be bathed 24 hours after squeeze-on is applied]
- [• Waterproof]
- [• Can be used on puppies 12 weeks of age and older]
- [• Monthly application reminder card inside]
- [• ~~Images of the different kinds of bugs killed with a line drawn through~~]

[For Dogs & Puppies] ~~[12 weeks or older] [and] [up to] 22 lbs.]~~  
 [For Dogs 23-44 lbs.]  
 [For Dogs 45-88 lbs.]  
 [For Dogs 89-132 lbs.]

[ ] - Denotes Optional Statements and/or Images that May be Used on Front, Back or Side Label Panels

~~[Ingredient Statement may be on front or back label]~~

EPA Reg. No. 70585-XX  
 EPA Establishment No.

**ACTIVE INGREDIENTS:**

Fipronil.....	9.8%
Cyphenothrin.....	5.0%
<b>OTHER INGREDIENTS:</b> .....	<u>85.2%</u>
<b>TOTAL:</b> .....	100.0%

**KEEP OUT OF REACH OF CHILDREN  
 WARNING**

See [Back][or][Side] [Label Panel[s] ~~[or]~~ ~~[insert]~~ for Additional Precautionary Statements

**NET CONTENTS:**

- Contains (3) 0.023 fl oz (0.67 ml) applicators
- Contains (3) 0.045 fl oz (1.34 ml) applicators
- Contains (3) 0.091 fl oz (2.68 ml) applicators
- Contains (3) 0.136 fl oz (4.02 ml) applicators





**[BACK/SIDE CARTON LABEL - MASTER LABEL]**

NAH 3 contains Fipronil and Cyphenothrin to effectively kill Fleas, Ticks [(including those that may transmit Lyme Disease)], and kills mosquitoes and (chewing) lice. [The active ingredients in NAH 3 works by collecting in the hair follicles and skin oils. This product features a sustained-release formula ~~that discharges from the animal's hair follicles using the natural skin oils, resulting in~~ fast acting [and long lasting] control of Fleas and Ticks , [and kills mosquitoes] and chewing lice [for 30 days].]

~~[diagram with visual of fipronil collecting and being released from hair follicle]~~

**READ ENTIRE LABEL BEFORE EACH USE.  
USE ONLY ON DOGS AND PUPPIES OVER 12 WEEKS OF AGE.**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS. WARNING.** Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Harmful if swallowed. Harmful if absorbed through skin. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

<b>FIRST AID</b>	
<b>If In Eyes</b>	<ul style="list-style-type: none"> <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 further treatment advice.</li> </ul>
<b>If On Skin Or Clothing</b>	<ul style="list-style-type: none"> <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>
<b>If Swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or 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>
<b>HOT LINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For more information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-637-0281.	
<b>NOTE TO PHYSICIAN OR VETERINARIAN</b>	
Treat patient symptomatically	

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. READ ENTIRE LABEL [AND ENCLOSED DIRECTIONS] BEFORE EACH USE.

DO NOT USE ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Weigh your dog to be sure you are applying the right dose formulated for the weight of your pet. Do not treat your pet with more than one pesticide product at a time. Over dosing your animal can result in serious illness and even death. **Best if used year round.** Certain medications can interact with pesticides. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. DO NOT USE ON CATS or animals other than dogs. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Cats and dogs that actively groom or engage in close physical contact with treated dog may be at risk of serious harmful effects. The most common signs of ingestion are excessive salivation and foaming at the mouth. If these symptoms occur immediately feed your dog and continue to monitor your pet for the next 24 hours. If symptoms persist call 1-800-637-0281 to talk to a veterinarian. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. If your dog is exhibiting signs of and/or are being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

**Sensitivities may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your dog with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately by calling 1-800-637-0281.**

[{Outer Packaging or Insert Copy}]

**How to open:** Remove product tubes [vial] from the package. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**How to apply:** Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin, as directed below. Repeat application may be made if necessary, but do not apply more often than once every 4 weeks.

**FREQUENCY OF APPLICATION**

Use NAH 3 monthly for complete control of flea, tick [and] chewing lice [and to kill mosquitoes] [infestations]. [ [Studies show that] NAH 3 kills fleas for up to 30 days]. If your pet is at high risk of flea reinfestation [, or in a highly infested environment], apply monthly. Apply monthly to control ticks, mosquitoes and chewing lice. NAH 3 kills mosquitoes within 24 hours for the first 7 days after treatment, then within 48 hours for up to 28 days. NAH 3 remains effective, even after bathing, water immersion, or exposure to sunlight. Allow treated area to dry thoroughly. Do not reapply for 30 days.

**For Dogs Weighing up to 22 lbs.**

{For cartons containing .67ml (0.023 fl. oz.) applicator tubes}

Apply one tube (.67ml)(0.023 fl. oz.) [as a spot to the dog's back between the shoulder blades]

[from the back of the neck to a point midway between the neck and tail].

**For Dogs Weighing Between 23 and 44 lbs.**

**{For cartons containing 1.34 ml (0.045 fl. oz.) applicator tube}**

~~[Apply two tubes (.67ml)(0.023 fl. oz.) as a spot on the dog's back between the shoulder blades]~~  
[or] [Apply one tube (1.34 ml)(0.045 fl. oz.)] [as a spot to the dog's back between the shoulder blades.] [from the back of the neck to a point midway between the neck and tail].

**For Dogs Weighing Between 45-88lbs.**

**For cartons containing 2.68 ml (0.091 fl. oz.) applicator tube}**

Apply one tube (2.68 ml)(0.091 fl. oz.) [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

**For Dogs Weighing 89-132 lbs**

**For cartons containing 4.02ml (0.136 fl. oz.) applicator tube}**

Apply one tube (4.02 ml)(0.136 fl. oz.) [as a spot on the dog's back between the shoulder blades] [from the back of the neck to a point midway between the neck and tail].

**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:** Non-refillable container. Do not reuse or refill this container.

If empty: Place in the 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**

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of NOVARTIS ANIMAL HEALTH US, Inc. (NAHUS) or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold NAHUS and Seller harmless for any claims relating to such factors.

NAHUS warrants that this product conforms to the chemical description on the label and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or NAHUS, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW NAHUS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent consistent with State law, in no event shall NAHUS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF NAHUS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF NAHUS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

[If you have questions or comments about this product, please write: Novartis Animal Health US, Inc., (address).]

In Case of Emergency, call: 1-800-637-0281 [For more information] [Visit us at:] [website address]

Non-Emergency call (number) [Made in USA]

Distributed by:  
Novartis Animal Health US, Inc.  
3200 Northline Avenue, Suite 300  
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-XX  
EPA Est. No. XXXXX-XX-XXX

[Optional Insert or package copy]

**[How to Apply - May contain graphics illustrating product use, e.g., dog with a drop falling onto its neck from a vial on front, side, or back carton label and/or applicator labeling.]**

[[Outer Packaging or Insert Copy]]

**How to open**

1. Remove product tubes [vial] from the package.
2. Separate one tube from the others. Holding the tube [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

**How to apply:**

1. Invert tube over dog and use open end to part dog's hair.
2. Squeeze tube firmly to apply all of the solution to the dog's skin [as a spot to the dog's back between the shoulder blades.] [or] [from the back of the neck to a point midway between the neck and tail.]

**[Flea life cycle diagram]  
[diagram with visual of fipronil collecting and being released from hair follicle]**

[Look at the Label (Look at the Label icon) 6 Step [Easy] [NAH 3] [Spot On] [Squeeze-On] [Topical] Checklist

- Read the label completely and follow directions

- Weigh your pet
- Do NOT use Dog products on Cats
- Do NOT treat with more than one pesticide product at a time
- Separate animals after treatment to avoid chance of ingestion
- Do NOT split tubes between pets]

**NAH 3**

[Monthly reminder card]

[Apply NAH 3 monthly for continuous protection against Fleas, Ticks, [and] chewing lice [and mosquitoes].]

[Pet's Name (Empty blank for owner to fill in name)]

[First [dose] [Treatment] (Empty blank for owner to fill in date)]

[Second [dose] [Treatment] (Empty blank for owner to fill in date)]

[Third [dose] [Treatment] (Empty blank for owner to fill in date)]

[calendar stickers with brand name] [Place stickers on your calendar as a reminder to reapply [brand name] [in 30 days.]

{END - BACK / SIDE PANEL}



Front Label

Back Label

<p><b>NAH 3</b>  Fipronil 9.8%, Cyphenothrin 5.0%  Dog 0.67 mL (or) 1.34 mL (or) 2.68 mL (or)  4.02 mL {label code}</p>	<p><b>KEEP OUT OF REACH OF CHILDREN</b>  <b>WARNING:</b> Read directions and precautions  before using. Use scissors to open.  EPA REG. No. 70585-XX {label  code}</p>
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[Optional: Example pictograms that may or may not be found on the printed label]



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