

70585-11

04/21/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

APR 21 2011

Novartis Animal Health
c/o Pyxis Regulatory Consulting, Inc.
4110 136th St. NW
Gig Harbor, WA 98332

SUBJECT: Label Amendment – Addition of Symbols, Graphics, New Primary Brand Name,
per PR Notice 98-10, and Labeling Deletions
NAH1/EasySpot, EPA Reg. No. 70585-11
Decisions: D445730, D446412, and D447026

Dear Mr. Ross Gilbert:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. Please note that this registration is still subject to the conditions of registration, as described in the Notice of Registration, dated January 28, 2011.

Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records. If you have any questions, please call me directly at 703-305-6701 or Rosanna Louie-Juzwiak of my staff at 703-308-0037.

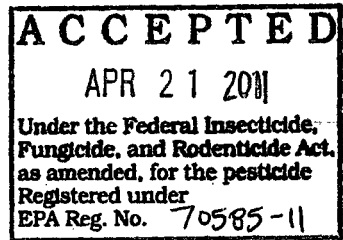
Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

Richard Gebken
Product Manager 10, Insecticide Branch
Registration Division (7504P)
Office of Pesticide Programs

[Optional text appears in brackets -the final label may include some or all of the optional text on front, back, side, or inside label panels]

EasySpot™



[apply to kittens more than 8 weeks old]
[apply to kittens 8 weeks or older]

[Mosquitoes]

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

[Adult Fleas]

- [Kills adult fleas [for up to six weeks] [!]]
- [Kills newly emerged adult fleas before they lay eggs]
- [Kills fleas, a source of flea allergy dermatitis] [, flea bite anemia]
- [If cat is a high risk for flea reinfestation, apply a once a month application]
- [Kills fleas [for] up to [4 weeks] [1 month] [30 days] [!]]

[Ticks]

- [Kills ticks, including those that may carry Lyme disease]
- [Kills ticks for up to [[4] [four] weeks] [1 month] [30 days]!]
- [Kills deer ticks [that may carry Lyme disease,] for up to [[4] [four] weeks] [1 month] [30 days]]
- [Kills ticks]
- [Kills ticks (including deer ticks) for up to [[4] [four] weeks] [1 month] [30 days]]
- [Kills [brown], [American dog,] [and] [lone star,] ticks [(*Rhipicephalus sanguineus*)] for up to [4] [four] weeks] [1 month] [30 days]]
- [Kills American dog ticks [(*Dermacentor variabilis*)] for up to [[4] [four] weeks] [1 month] [30 days]!]

[Multiple Infestations]

- [Kills chewing lice and [controls mites that may cause sarcoptic mange [infestations]]
- [Flea [&] [and] tick control for cats [&] [and] kittens [8 weeks old and older] [more than 8 weeks old]]
- [Kills [fleas], [ticks], [chewing lice] [&] [and] [mosquitoes]]
- [Kills [fleas], [ticks], [mosquitoes] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito], and [chewing lice] [treatment]]
- [[Four] [Three] [4] [3] [-] way[s] [to kill] [control] [kills [fleas], [ticks], [mosquitoes] and [chewing lice]]]
- [[4] [four] [-] week] [1 month] [30 day] [flea] and [tick] [&] [and] treatment]
- [[4] [four] [-] week] [1 month] [flea], [tick], [mosquito] and [chewing lice] control]
- [Once-a-month [flea] and [tick] treatment]
- [Use EasySpot™ monthly to control [fleas] [ticks] and [chewing lice]]
- [Monthly [flea], [tick], [mosquito] and [chewing lice].]

- [Kills [fleas] and [ticks] for up to [4] [four] weeks] [1 month] [30 days]!]]
- EasySpot™ provides [convenient] and [effective] [flea], [tick] [,] [&] [and] [chewing lice] [and mosquito] control for cats and kittens 8 weeks and older.]

[All Others]

- [For cats and kittens [more than 8 weeks old]]
- [For cats and kittens [8 weeks old and older]]
-
- [Waterproof]
- [Fast-acting] [Fast acting]
- [Long-lasting] [Long lasting]
- [Prevents [flea] reinfestation]
- [Convenient spot treatment]
- [Once-a-month treatment]
- [A once monthly application for chewing lice]
- [Fast action against [chewing] lice infestations]
- [Three applications] and/or [3-month supply] or [12-week supply] or [3 applications]
- [Best if used year round!]
-
- [4[-]week dose[!]] [in Child Resistant Packaging]
- [1[-]month dose[!]] [in Child Resistant Packaging]
- [30[-]day dose[!]] [in Child Resistant Packaging]
- [Easy-to-use [application]]
- [Specially formulated for cats and kittens older than 8 weeks]
- [fipronil (9.7%)]
- [A fipronil product]
- [Contains fipronil[,] [-] the active ingredient in [Frontline Top Spot®*]
- [*EasySpot™] is not manufactured by or distributed by Merial. Frontline® Top Spot® is a registered trademark of Merial.]
- [Fast-acting, long-lasting that's also waterproof.]
- [3 Easy-to-Use Applications!] [in Child Resistant Packaging]
- [Cats can be bathed 24 hours after [application] [treatment] [EasySpot™] is applied]]
-
- [Easy-to-use [application]]
- [[Free] calendar stickers inside!]
- [[Free] calendar stickers inside]
- [Apply once every [4 weeks] [month] [30 days]!]]
- [Can be used on breeding, pregnant and lactating [cats] [queens] [female cats]]
- [[Free with purchase] [Free inside] [Monthly application reminder magnet]
- [clip] [insert] [inside]
- [Can be used on kittens [more than 8 weeks of age]]
- [Can be used on kittens [8 weeks of age and older]
- [Optional graphics: picture of all controlled pests with line through them]

EPA Reg. No. 70585-11
EPA Establishment No.

ACTIVE INGREDIENTS:

Fipronil 9.7 %

INERT INGREDIENTS: 90.3%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back][or][Side][or][Interior Panel][Label Panel[s] for Additional Precautionary Statements [and First Aid Statements].

NET CONTENTS:

[Three] [3] [-] 0.017 fl oz (0.50ml) applicators

[EasySpot™] contains fipronil to effectively kill fleas and ticks [(including those that may transmit Lyme disease)].

READ ENTIRE LABEL BEFORE EACH USE

[EasySpot™] for cats provides [four-] [three-] way protection that kills [fleas], [ticks], [mosquitoes] and [chewing lice]. Kills deer ticks [that may transmit Lyme disease]. Kills brown dog ticks, American dog ticks and lone star ticks. Prevents flea reinfestation.]

PRECAUTIONARY STATEMENTS

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

HAZARDS TO DOMESTIC ANIMALS. For external use only. Do not use on kittens under 8 weeks of age. Individual sensitivities, while rare, may occur after using any pesticide product. Cats may experience some temporary irritation at the site of product applications. If signs persist, or become more severe within a few days of application, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

FIRST AID	
If swallowed	Call a poison control center for a doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so 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 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue

	rinsing eye. Call a poison control center or doctor for treatment advice.
If on skin	Wash with plenty of soap and water. Get medical attention if irritation persists.
HOTLINE NUMBER	
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.	

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to apply product. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY. DO NOT USE ON RABBITS. DO NOT USE ON OTHER ANIMALS.

Do not use on kittens under 8 weeks of age. Best if used year round. Consult a veterinarian before using this product on debilitated, aged, medicated cats. Can be used on breeding, pregnant, or nursing [cats] [female cats] [queens]. Consult a veterinarian before using on cats with known organ dysfunction. Pets may experience some temporary irritation at the site of product application. Certain medications can interact with pesticides. Sensitivities may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your cat with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

[(INSERT DIAGRAM THAT DEPICTS APPLICATION OF PRODUCT ON THE CAT)]

How to Open: Remove product [tubes] [vials] 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, use scissors to cut off the narrow end at the notches.

How to apply: While holding the cat with one hand, use the other hand to apply the solution. Invert the [tube] [vial] and use the open end to part the cat's hair. Apply contents of one [tube] [vial] of EasySpot™ [as a spot between the shoulder blades] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades]. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat. When finished, wrap the [tube] [vial] in paper and put into the trash. Only one applicator per treatment is needed. Repeat application may be made if necessary, but do not apply more often than once every 30 days.

[Optional drawings of application process that may or may not appear on finished label]

FREQUENCY OF APPLICATION

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

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not remove tube from the pack until ready to use. Store in a cool (below 77°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.

[[Outer Packaging or Interior Carton Panel]]

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 to: Novartis Animal Health US, Inc., (address).]

For Technical Information call: 1-800-637-0281 [hours of service]
[Made in USA]

Distributed by [Manufactured for][Available exclusively from]:
Novartis Animal Health US, Inc.
3200 Northline Avenue, Suite 300
Greensboro NC 27408

[BAR CODE AREA]

EPA Reg. No. 70585-11
EPA Est. NO. XXXXX-XX-XXX

[Optional Exterior or Interior package copy]

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

How to Open:

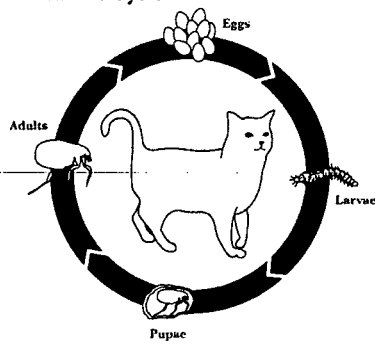
1. Remove product [tube] [vial] from package.
2. Separate one [tube] [vial] from the others. Holding the [tube] [vial] with notched end pointing up and away from the face and body, cut off the narrow end at the notches with scissors.

How to Apply:

1. Invert [tube] [vial] over cat and use open end to part cat's hair.
2. Apply contents of one [tube] [vial] of EasySpot™ [as a spot between the shoulder blades] [as a stripe, starting high on the back of the cat's neck to in front of the shoulder blades].
3. Squeeze [tube] [vial] firmly to apply all of the solution to the cat's skin.

[Example Flea life cycle diagram – actual may differ slightly]

Flea Life Cycle



- [Look at the Label (Look at the Label icon)]

[[Easy] [6] [Six-] [Step] EasySpot™ [Spot-on] [Squeeze-On] Checklist

1. Read the label completely and follow directions.
2. Weigh your pet.
3. Do NOT use dog products on cats.
4. Do NOT treat with more than one pesticide product at a time.
5. Separate animals after treatment to avoid chance of ingestion.
6. Do NOT split tubes between pets.

[For year round protection, apply EasySpot™monthly.]

[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)]

[Visit [web-address] to download a free convenient application for your smartphone for an electronic calendar reminder]

[Visit [web-address] to download a convenient electronic calendar reminder]

[Calendar stickers [with EasySpot™]

[3-month] [application tracker]

[For year-round protection, apply EasySpot™ monthly. Place stickers on your calendar as a reminder to reapply EasySpot™ in 30 days.]

[It's time for EasySpot™ [!]]

[Enclosed for your convenience are [3] [three] stickers.] [Place stickers on your calendar every 30 day from initial treatment as a reminder to reapply EasySpot™ every 30 days.]

[Optional Example graphics for calendar stickers and/or magnets.]



[Monthly Application Reminder Magnet (image of reminder magnet)]

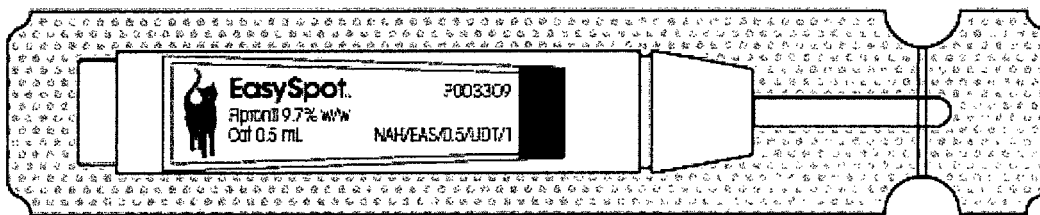
[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and

the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days the reminder light will blink, reminding you to reapply EasySpot™. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

{END - OPTIONAL EXTERIOR OR INTERIOR PANEL PACKAGE COPY}

[BEGIN TUBE LABEL]

[FRONT OF TUBE]



[BACK OF TUBE]

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read accompanying directions and precautions before using. Use scissors to open.

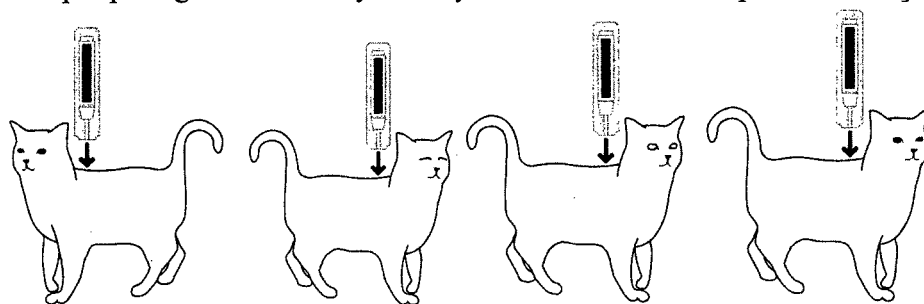
EPA REG. No. 70585-11

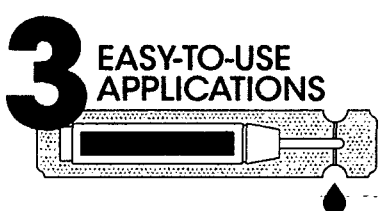
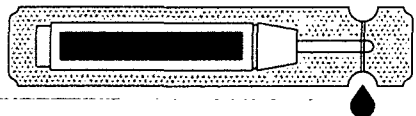
{label code}

[END TUBE LABEL]

[OPTIONAL GRAPHICS FOR EXTERIOR OR INTERIOR PANEL PACKAGE:

Example pictograms that may or may not be found on the printed label]





EPA 2011041123