

88082-1

3/11/2013

1/18



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

88082-R(1)

Date of Issuance:

March 11, 2013

NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Smart Guard for Dogs

Name and Address of Registrant (include ZIP Code):

**Belcher Pharmaceuticals, LLC**  
**6911 Bryan Dairy Road**  
**Largo, FL 33777**

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/reregistered 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 registered in accordance with FIFRA section 3(c)(7) provided that you:

EPA

Submit and/or cite all data required when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for registration review.

(continued on page 2)

Signature of Approving Official:

Refer to Page 4 of 4

Richard J. Gebken, Product Manager (10)  
Insecticide Branch, Registration Division (7505P)

Date:

March 11, 2013

EPA Form 8570-6

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.

1. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
2. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on April 1, 2013.

The quarterly reports are due two months after the quarter ends. 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, Immediate Office (attn: Kimberly Nesci).

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

3. 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.

1) **Label Revisions:**

- a) You revise the EPA Registration Number to read: "EPA Registration No. 88082-1" in all locations of the label.
- b) **Correct all of the label revisions as identified on the label and attached comment summary sheets affixed to the label.**

4. **Revisions required as part of the Spot on mitigation. Refer to the following agency web site for details: <http://www.epa.gov/pesticides/health/spot-on-meetings.html>.**

- 1) Revise the product name to "Smart Guard for DOGS", and all text must be the same size.

4/18

- 2) You must present an image of the size dog on the front panel for the weight range and package fill volume for each of the package sizes.
  - 3) A cat prohibition icon is needed on the front panel in a box at the same size as any marketing icons. The background of the box containing the cat prohibition icon must be yellow with black text. Text must read as follows: "DO NOT USE ON CATS. keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately."
  - 4) The cat prohibition icon with the statement "DO NOT USE ON CATS" is needed in other areas as identified on the label.
5. Revise the data matrix in accordance with the Efficacy Review dated March 8, 2013.

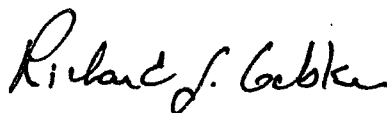
If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

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.

*Pa.* If you have any questions concerning this action, please contact Richard J. Gebken at (703) 305-6701. Submit one copy of the revised final printed label for the record before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with 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.



Richard J. Gebken  
 Product Manager (10)  
 Insecticide Branch  
 Registration Division (7505P)

*Pa.*

Enclosure: Label stamped "Accepted with Comments"

5/18

# SMART GUARD BOX INFORMATION





(Front Flap of Box)

## Smart Guard

Kills Fleas, Ticks & Chewing Lice

Fipronil 9.7%

3 Applicators

- [S] For Dogs 22 lbs 
- [M] For Dogs 23-44 lbs 
- [L] For Dogs 45-88 lbs 
- [XL] For Dogs 89-139 lbs 

Compare to Frontline® Top Spot  
Same Active Ingredient

(PICTURE OF DOG)

## Smart Guard



Kills Fleas, Ticks & Chewing Lice

Fipronil 9.7%



ACCEPTED  
With COMMENTS  
In EPA Letter Dated:


MAR 11 2013

Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg. No:


88082-1

# Summary of Comments on A9R78B.tmp


Page: 1

-  Number: 1 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:19:19 AM  
 Replace with "Smart Guard for DOGS"  
 The text size must all be the same.


---

-  Number: 2 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:20:16 AM  
 Replace with "Smart Guard for DOGS"  
 The text size must all be the same.


---

-  Number: 3 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:10:01 AM  
 Replace text with "[M] For Dogs weighing 23-44 lbs. only"


---

-  Number: 4 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:10:33 AM  
 Replace text with "[L] For Dogs weighing 45-88 lbs. only.


---

-  Number: 5 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:11:14 AM  
 Replace with "[XL] For Dogs weighing 89-139 lbs. only"


---

-  Number: 6 Author: rgebken Subject: Comment on Text Date: 3/11/2013 11:15:26 AM  
 Comparative claims must adhere to agency guidance in the following document:  
<http://www.epa.gov/pesticides/regulating/labels/pdf/metoo.pdf>


---

-  Number: 7 Author: rgebken Subject: Sticky Note Date: 3/11/2013 12:40:55 PM  
 Place the agency Cat Prohibition icon and the following text on the front panel:  
 "DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately"

---

-  Number: 8 Author: rgebken Subject: Sticky Note Date: 3/11/2013 11:45:58 AM  
 Add the following text to the front panel:  
 "Refer to inside for Precautionary Statements and Directions for Use on the bottom of the box"

---

-  Number: 9 Author: rgebken Subject: Sticky Note Date: 3/11/2013 11:45:22 AM  
 The following statements must appear on the front panel:  
**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

(Sides of Box)

# Smart Guard <sup>1</sup>

Kills Fleas, Ticks & Chewing Lice

Fipronil 9.7%

For Dogs

22 lbs <sup>2</sup>

23-44 lbs <sup>3</sup>

45-88 lbs <sup>4</sup>

89-132 lbs <sup>5</sup>

3 Applicators

## (Front Bottom of Box (Below Front Flap))

Treatment and control of fleas, ticks, chewing lice, ~~car~~carceptic mites and mosquitoes. <sup>7</sup>

- Fast-acting
- Long-lasting
- Waterproof



**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA Reg 88082-R EPA Est xxxxx-xx-xxxx

<sup>8</sup>This product is NOT manufactured or distributed by Merial, the makers of Frontline® Top Spot

**For Dogs and Puppies 8 <sup>9</sup>weeks and older**

**<sup>10</sup>ACTIVE INGREDIENTS:**

Fipronil .....	9.7%
OTHER INGREDIENTS .....	90.3%
TOTAL .....	100.0%

- <sup>11</sup>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



Page: 2

- Number: 1 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:19:43 AM  
 Replace with "Smart Guard for DOGS"  
 The text size must all be the same.

---

- Number: 2 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:20:30 AM  
 Replace with "Smart Guard for DOGS"  
 The text size must all be the same.

---

- Number: 3 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:20:52 AM  
 Replace text with "[M] For Dogs weighing 23-44 lbs. only"

---

- Number: 4 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:21:18 AM  
 Replace text with "[L] For Dogs weighing 45-88 lbs. only.

---

- Number: 5 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:21:39 AM  
 Replace with "[XL] For Dogs weighing 89-139 lbs. only"

---

- Number: 6 Author: rgebken Subject: Cross-Out Date: 3/11/2013 11:15:48 AM

---

- Number: 7 Author: rgebken Subject: Sticky Note Date: 3/11/2013 11:16:32 AM  
 Add a subsequent sentence "Aids in the control of Sarcoptic mange mites."

---

- Number: 8 Author: rgebken Subject: Cross-Out Date: 3/11/2013 11:18:23 AM  
 This disclaimer must be placed in the same area of the label so that both the statement and disclaimer can be viewed together.

---

- Number: 9 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:22:12 AM  
 Replace 8 with 10.

---

- Number: 10 Author: rgebken Subject: Cross-Out Date: 3/11/2013 11:43:25 AM  
 The ingredient statement must appear on the front Panel of the package.

---

- Number: 11 Author: rgebken Subject: Comment on Text Date: 3/11/2013 11:24:02 AM  
 Net weight or contents must be stated on a pesticide label in accordance with FIFRA (2)(q)(2)(C)(iii) and 40 CFR 156.10(a)(1)(iii). EPA interpretation of the statutory and regulatory requirements is that the label must state the total weight for the entire contents as sold and distributed. In addition, the label may indicate the net weight and quantity of individual units within the carton. For example, "Net Weight 6.25 lbs. (20 - 5oz. packets)." For additional information regarding the Net Weight/Contents statement, please reference Chapter 17 of the Label Review Manual at <http://www.epa.gov/oppfead1/labeling/lrm/chap-17.htm>.

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- Number: 12 Author: rgebken Subject: Sticky Note Date: 3/11/2013 12:40:07 PM  
 Add the agency's required Prohibition icon with the following text "DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately."



(Inside Flap)

# Smart Guard <sup>1</sup>

~~Compare to Frontline® Top Spot Same Active Ingredient~~

## Kills Fleas, Ticks & Chewing Lice

Smart Guard contains the active ingredient fipronil that effectively targets fleas, ticks, chewing lice and mosquitoes. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity.

**KEEP OUT OF REACH OF CHILDREN CAUTION**

(Graphic) Fleas | (Graphic) Ticks | (Graphic) Lice | (Graphic) Mites | (Graphic) Mosquitoes

~~For Dogs 22 lbs.~~ <sup>3</sup>

~~For Dogs 23-44 lbs.~~ <sup>4</sup>

~~For Dogs 45-88 lbs.~~ <sup>5</sup>

~~For Dogs 89-132 lbs.~~ <sup>6</sup>

### FLEAS

- Kills fleas
- Kills newly emerged adult fleas before they lay eggs
- Stops existing infestation and prevents establishment of new infestations
- Kills fleas which may cause flea allergy dermatitis

### TICKS

- Kills all life stages of ticks (larva, nymph and adult), including deer ticks, brown dog ticks, American dog ticks, and lone star ticks.
- Kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne disease.

### LICE

- Rapidly eliminated chewing lice infestations.

### MITES

- Aids in control of sarcoptic mange <sup>7</sup> infestations.

### MOSQUITOES

- Kills mosquitoes.

Page: 3

- Number: 1 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:24:25 AM  
Replace with Smart Guard for DOGS

---
- Number: 2 Author: rgebken Subject: Cross-Out Date: 3/11/2013 11:26:00 AM  
Comparative claims must be in the same section of the label as the disclaimer.

---
- Number: 3 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:26:47 AM  
Replace with "Smart Guard for DOGS"  
The text size must all be the same.

---
- Number: 4 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:27:16 AM  
Replace text with "[M] For Dogs weighing 23-44 lbs. only"

---
- Number: 5 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:27:53 AM  
Replace text with " For Dogs weighing 45-88 lbs. only"

---
- Number: 6 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:28:16 AM  
Replace text with "For Dogs weighing 89-132 lbs. only"

---
- Number: 7 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:28:51 AM  
replace "manage" with "mange"

---

11/18

## (Bottom of Box)

Manufactured By:  
Belcher Pharmaceuticals, LLC  
6911 Bryan Dairy Road  
Largo, FL 33777  
For animal use only

Lot No xxxxxx

## BARCODE

Smart Guard is a registered trademark of Belcher Pharmaceuticals, LLC.  
© 2012 Belcher Pharmaceuticals, LLC, Largo FL.

## (Back of Box)

### Smart Guard <sup>2</sup>

For Dogs 25-45 lbs <sup>3</sup>

For Dogs 23-44 lbs <sup>4</sup>

For Dogs 45-88 lbs <sup>5</sup>

For Dogs 89-139 lbs <sup>6</sup>

## (Left Back Side of Box)



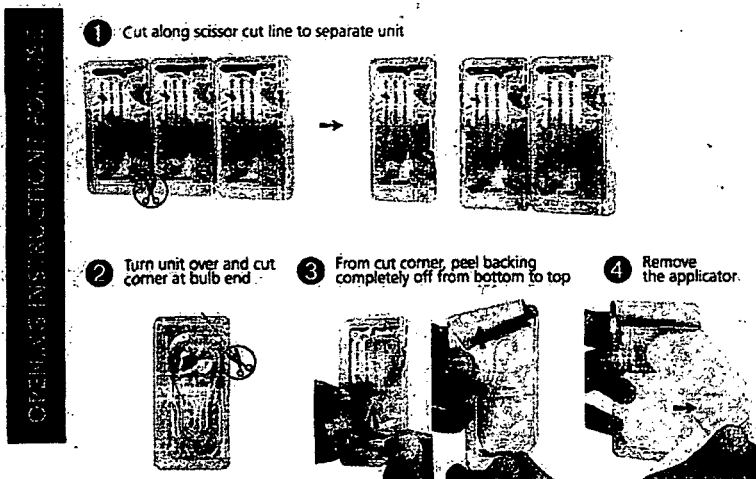
### DIRECTIONS FOR USE READ THE ENTIRE LABEL BEFORE EACH USE.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.  
**KEEP OUT OF REACH OF CHILDREN. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS.**



Smart Guard is approved for use on all dogs, including: Breeding, pregnant, lactating bitches and puppies as young as 8 weeks. <sup>9</sup> To kill fleas, ticks, chewing lice and mosquitoes apply Smart Guard <sup>10</sup> follows:

### See Insert Opening Instructions



Page: 4

- Number: 1 Author: rgebken Subject: Cross-Out Date: 3/11/2013 11:30:59 AM  
 Replace "For animal use only." with For external use on DOGS only.
- Number: 2 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:31:28 AM  
 Replace "Smart Guard" with "Smart Guard for Dogs"
- Number: 3 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:31:47 AM  
 Replace text with "For Dogs weighing 23-44 lbs. only"
- Number: 4 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:32:02 AM  
 Replace text with "For Dogs weighing 23-44 lbs. only"
- Number: 5 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:32:33 AM  
 Replace text with "For Dogs weighing 45-88 lbs. only"
- Number: 6 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:32:58 AM  
 Replace text with "For Dogs weighing 89-139 lbs. only"
- Number: 7 Author: rgebken Subject: Sticky Note Date: 3/11/2013 12:37:49 PM  
 Add the agency "DO NOT USE ON CATS" ICON and text here.
- Number: 8 Author: rgebken Subject: Sticky Note Date: 3/11/2013 11:49:39 AM  
 Within the Directions for Use, add the following text inside of a box:  
 "Side Effects: Monitor your dog after application. 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 dog for the next 24 hours. Some dogs may experience temporary startle effects when any product is applied. Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If signs persist or become more severe within a few days of application, consult a veterinarian immediately by calling 1-800-XXX-XXX. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application."
- Number: 9 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:34:28 AM  
**DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR DOG. READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.** Do not use on rabbits or animals other than dogs. Do not allow your dog to ingest this product. Cats exhibiting these same symptoms from ingestion should be taken to the veterinarian immediately. Do not use on puppies under 10 weeks of age. Use entire contents of tube vial on each dog. Do not split one tube between dogs. Do not use multiple tubes on one dog. Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Number: 10 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:35:00 AM  
 Replace with "Smart Guard for DOGS"

**OPEN:**

Hold applicator upright position and snap off applicator tip.

**APPLY:**

Apply product by parting the hair on the dog's back, between shoulder blades, until the skin is visible. Place the tip of the on the dog's skin and gently squeeze the entire contents of the tube directly on the skin. The entire contents should be applied to a single spot directly on to the skin. The product should be applied directly on to the skin and not on the hair coat itself. Try to avoid contact with treated area until dry. The dog should be standing for easy application.

**FREQUENCY OF APPLICATION**

Smart Guard completely controls flea, tick and chewing lice infestation. Smart Guard is for monthly use and should not be reapplied for 30 days from last use.

- Smart Guard kills adult fleas for up to 3 months. If there is a risk of high infestation, re-infestation or if the dog has fleas which may cause flea allergy dermatitis (FAD), use Smart Guard once-a-month.
- Smart Guard kills ticks (ALL Life Stages: larva, nymph and adult) for at least 1 month. If tick control is needed, use Smart Guard once-a-month.
- Smart Guard kills chewing lice for at least 1 month. If chewing lice control is needed, use Smart Guard once-a-month.
- Smart Guard kills mosquitoes for up to 7 days within 24 hours and 28 days within 48 hours with a monthly treatment of Smart Guard.
- Smart Guard aids in the control of mite infestations.

**STORAGE AND DISPOSAL**

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

**STORAGE:** Store unused product in original container only, out of reach of children and animals.

**PESTICIDE DISPOSAL:** If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**CONTAINER DISPOSAL:** If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

**(Right Back Side of Box)**

Treatment and control of fleas, ticks, chewing lice, sarcoptic mites and mosquitoes.

Smart Guard is waterproof and remains effective following shampoo treatment, swimming or after exposure to rain or sunlight. Multiple monthly treatments are recommended if there is a risk of high infestation.

19/18

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■ Number: 1 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:36:57 AM  
Replace "sarcoptic mites" with "sarcoptic mange mites"

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15/18

<b>FIRST AID</b> Have the product container or label with you when calling poison control center or doctor or going for treatment.	
<b>IF SWALLOWED:</b>	Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not include vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
<b>IF IN EYES</b>	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 eye. Call a poison control center or doctor for treatment advice.
<b>IF ON SKIN</b>	<del>Wash with plenty of soap and water. Get medical attention if irritation persists.</del>

**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.~~

**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. Pets may experience some temporary irritation at the site of product application. 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 animals.  
Call 1-800-xxx-xxxx for assistance.

**PHYSICAL OR CHEMICAL HAZARDS**

**FLAMMABLE:** Keep away from heat and open flame.

**WARRANTY**

~~Seller make no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and handling of this material when such use and handling are contrary to label instructions.~~

Number: 1 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:38:43 AM  
 Revise the "If on skin" subsection within the First Aid section on page 4 to read as follows:  
 "If on skin or clothing: 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."

Number: 2 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:39:49 AM  
 Replace washing instructions with "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."

Number: 3 Author: rgebken Subject: Inserted Text Date: 3/11/2013 11:40:37 AM  
 1) Revise the Hazards to Humans and Domestic Animals section as follows:  
 "HAZARDS TO DOMESTIC ANIMALS. Do not use on dogs less than 10 weeks of age. For external use on dogs only. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over dosing your dog can result in serious illness and even death. Consult a veterinarian before using on medicated, debilitated, aged, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product."

Number: 4 Author: rgebken Subject: Cross-Out Date: 3/11/2013 11:51:47 AM  
 The Warranty section of the label must adhere to the Guidance on Warranty Statements October 17, 2006 located at the following agency web address: <http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf>



17/18

**The following text must be present on the applicator tube:]**

**[Applicator Tube Text]**

**SMART GUARD for DOGS**

[Only for use on dogs weighing 22. lbs ]

0.023 fl oz. / .67 mL

[Only for use on dogs weighing 23-44 lbs.]

0.045 fl oz. /1.34 mL

[Only for use on dogs weighing 45-88 lbs.]

0.091 fl oz. /2.68 mL

[Only for use on dogs weighing 89-139 lbs.]

0.136 fl oz. /4.2 mL

Contains fipronil (9.7%)

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See full label for additional directions

**DO NOT USE ON CATS**

EPA Reg. No. 88082-1

**CAT PROHIBITION ICON**

17/18



Number

tick c

Number

tick c

**In addition to the Directions on how to open the foil pouch (exactly as presented with the CRP testing, the text for foil on the blister package must also contain the following information on each tube's blister package:]**

**[Blister package]**

**Smart Guard For Dogs**

- [Only for use on dogs weighing 22 lbs]  
0.023 fl oz. /0.67 mL
- [Only for use on dogs weighing 23-44 lbs]  
0.045 fl oz. /1.34 mL
- [Only for use on dogs weighing 45-88 lbs]  
0.091 fl oz. /2.68 mL
- [Only for use on dogs weighing 89-132 lbs.]  
0.136 fl oz. /4.20 mL

Contains fipronil 9.7%  
**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
See full label for additional directions  
Lot #  
EPA Reg. No. 88082-1  
**DO NOT USE ON CATS**  
CAT PROHIBITION ICON