



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

EPA Reg. Number:

91300-9

Date of Issuance:

8/10/18

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited  
Expires: 8/9/20

Name of Pesticide Product:

P111.03 FOR DOGS

Name and Address of Registrant (include ZIP Code):

Ann. M. Tillman, Ph.D.  
Promika, LLC  
c/o Pyxis Regulatory Consulting, Inc.  
4110 136th Street. CT NW  
Gig Harbor, WA 98332

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

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

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Catherine Aubee, Chief  
Invertebrate-Vertebrate Branch 1, Registration Division (7505P)

Date:

8/10/18

2. This registration is time-limited and expires 8/9/20.
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 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 cats and table for dogs 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, as applicable.
- 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, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- 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.

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 Order identified below:
  - a. Fipronil GDCI-129121-1305
  - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI 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. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
7. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 91300-9.”
8. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

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

- Basic CSF dated 4/23/18

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at [Breeden-Alemi.Julie@epa.gov](mailto:Breeden-Alemi.Julie@epa.gov).

Enclosure

**Primary brand name: P111.03 for Dogs**

**P111.03 for Dogs: Label for two types of 3- and/or 4-count applicators. The secondary CRP is defined as a CR outer blister in a strip of 3 and inside of each blister is the applicator (the outer blister is the CR). Primary CRP is defined as a CR applicator blister pack in a strip of 3 or 4 (the applicator blister is the CRP). {On the final printed label CRP SAUE instructions will not change in text or format from that used in testing}**

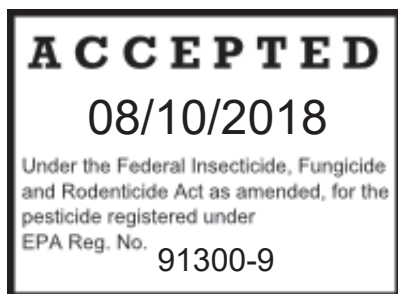
This label is for two carton configurations:

1. Carton with an Insert
2. Carton with front or back panel flap and Insert (there will be only one flap either on front or back of carton)

[text in [] denotes optional language]

{text in {} denotes location of text on packaging, notes to reviewer}

(text in () appears on label)



**{P111.03 for Dogs for 3- and 4-count applicators}**

**{Front panel of carton}**

**P111.03 for Dogs**

{On market label “Dogs” will be 75% the size of the largest letter in the primary brand name}

{One of the following statements will appear in a box on the front panel.}

Use ONLY on dogs [&] [and] puppies [5 to 22][23 to 44][45 to 88][89 to 132] lbs., over 8 weeks old {OR} ONLY For Dogs & Puppies, older than 8 weeks [&] [and] [5 to 22][23 to 44][45 to 88][89 to 132] lbs.
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{A large, clear picture of dog in the weight range will appear on front panel}

**ACTIVE INGREDIENT:**

Fipronil..... 9.7%

**OTHER INGREDIENTS:**..... 90.3%

**TOTAL** ..... 100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See Back Panel and Label Insert for First Aid, and Additional Precautionary Statements, and complete Directions for Use.

See Label Insert[and back of carton] for Storage and Disposal

[See [[Front]{or}[Back] Carton Panel Flap] [and] [Label Insert] for additional marketing claims and Warranty statements]

{There will be a 1.5 x 1.5 cm cat prohibition icon in a box located in the lower right-hand corner of the front panel in yellow with black images.}



**{For Secondary CRP}**

**Net Contents:**

[0.069 fl oz [2.01 mL]; 3 applicators each containing 0.023 fl. oz. [0.67 mL]; [3 doses][3-pack]] {OR}  
[0.135 fl oz [4.02 mL]; 3 applicators each containing 0.045 fl. oz. [1.34 mL]; [3 doses][3-pack]] {OR}  
[0.273 fl oz [8.04 mL]; 3 applicators each containing 0.091 fl. oz. [2.68 mL]; [3 doses][3-pack]] {OR}  
[0.408 fl oz [12.06 mL]; 3 applicators each containing 0.136 fl. oz. [4.02 mL]; [3 doses][3-pack]]

**{For Primary CRP}**

**Net Contents:**

[0.069 fl oz [2.01 mL]; 3 applicators each containing 0.023 fl. oz. [0.67 mL]; [3 doses][3-pack]] {OR}  
[0.135 fl oz [4.02 mL]; 3 applicators each containing 0.045 fl. oz. [1.34 mL]; [3 doses][3-pack]] {OR}  
[0.273 fl oz [8.04 mL]; 3 applicators each containing 0.091 fl. oz. [2.68 mL]; [3 doses][3-pack]] {OR}  
[0.408 fl oz [12.06 mL]; 3 applicators each containing 0.136 fl. oz. [4.02 mL]; [3 doses][3-pack]]  
{OR}

**Net Contents:**

[0.092 fl oz [2.68 mL]; 3 applicators each containing 0.023 fl. oz. [0.67 mL]; [4 doses [4-pack]] {OR}  
[0.18 fl oz [5.36 mL]; 3 applicators each containing 0.045 fl. oz. [1.34 mL]; [4 doses [4-pack]] {OR}  
[0.364 fl oz [10.7 mL]; 3 applicators each containing 0.091 fl. oz. [2.68 mL]; [4 doses [4-pack]] {OR}  
[0.544 fl oz [16.1 mL]; 3 applicators each containing 0.136 fl. oz. [4.02 mL]; [4 doses [4-pack]]

**{End Front Panel of Carton}**

*{Back Panel of Carton}*

<b>FIRST AID</b>	
If swallowed:	Call a poison control center or 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 15-20 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:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison center or doctor for treatment advice.
<b>HOTLINE NUMBER</b>	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also want to contact SafetyCall at 1-866-897-8050 for emergency medical treatment information.	

**READ ENTIRE LABEL BEFORE EACH USE.  
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE AND [5 to 22][23 to 44][45 to 88][89 to 132] LBS.**

[[**Brand Name**] for dogs delivers [effective] protection against fleas, ticks, [and chewing lice]. [This product aids in the control of sarcoptic mange mites.] [Brand Name kills] [Kills] deer ticks, brown dog ticks, American dog ticks, and lone star ticks, including those transmitting Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases. Controls existing flea infestation and reinfestation for [[4] [four] weeks] [[1] [one] month] [30 days].]

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS**

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

**HAZARDS TO DOMESTIC ANIMALS.**

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 a dog with more than one pesticide product at a time. Over dosing a dog can result in serious illness and even death. As with any product, use caution before using on medicated, debilitated, aged, pregnant, nursing dogs or dogs with known organ dysfunction. If the dog is exhibiting signs of and/or is being treated for skin dermatitis, use caution before applying any topical flea and tick control product. This product is not a substitute for prescribed Heartworm preventative.

**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 THE DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.**

## RESTRICTIONS

Do not use on rabbits or animals other than dogs. Do not allow the dog to ingest this product. Do not use on puppies under 8 weeks of age or on dogs or puppies weighing less than [5][23][45][89] lbs. Do not apply more than once every [4 weeks] [30 days][month]. Do not apply more than one applicator per treatment for one dog regardless of the dog's weight. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Allow the area to dry before touching treated dog. Do not bathe or allow the dog to swim for 24 hours after application. The dog needs to be dry at the time of application and remain dry for 24 hours after application.

{A box labeled "Side Effects" will be located in the lower right corner of the back panel immediately above the cat warning box.}

**Side Effects:** Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, advise dog owner to consult with veterinarian or SafetyCall at 1-866-897-8050.

{There will be a 1.5 x 1.5 cm cat prohibition icon and warning text in a box located in the lower right-hand corner of the back panel in yellow with black images.}

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



[BAR CODE AREA]

{Storage and Disposal will be found on the label Insert and may be found on back of carton as space permits}

### [STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Keep product in its original container. Do not repackage. Store in a cool (below 77°F [/[25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight. **PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this 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.]

*{End Back Panel of Carton}*

*{Bottom Panel of carton}*  
Lot or Batch No.

*{Side Panel of carton}*  
For Use ONLY on Dogs 8 Weeks and Older and Weighing [5 to 22][23 to 44][45 to 88][89 to 132] lbs.



*{Package Insert for Primary or Secondary CRP (3- or 4-Count)}*

**P111.03 for Dogs**

{On market label “Dogs” will be 75% the size of the largest letter in the primary brand name}

**DO NOT USE ON CATS**

{One of the following statements will appear on the front panel.}

Use ONLY on dogs [&] [and] puppies [5 to 22][23 to 44][45 to 88][89 to 132] lbs., over 8 weeks old  
{OR}  
ONLY For Dogs & Puppies, older than 8 weeks [&] [and] [5 to 22][23 to 44][45 to 88][89 to 132] lbs.

**ACTIVE INGREDIENT:**

Fipronil..... 9.7%

**OTHER INGREDIENTS:**.....90.3%

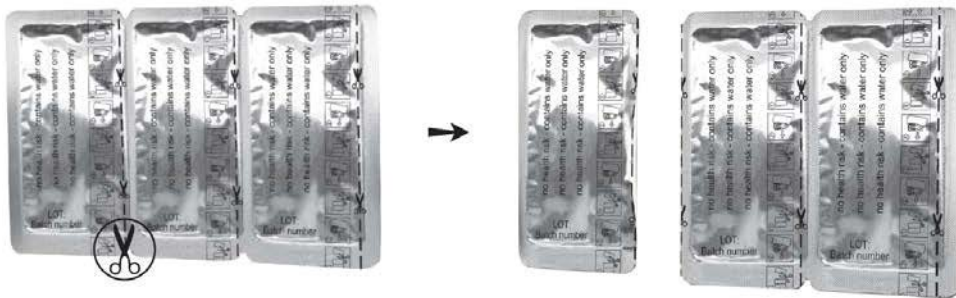
**TOTAL** 100.0%

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

How to Open:

**{Secondary CRP - applicator inside CR blister pack}**

**1** Cut along scissor cut line to separate unit



**2** Turn unit over and cut corner at bulb end



**3** From cut corner, peel backing completely off from bottom to top



**4** Remove the applicator



**How to Apply {Secondary CRP}**

Remove applicator[s] from packaging. Separate one applicator from the others using scissors.

{One of the following directions will be included}

[Hold upright with foil side away from you and snap the applicator tip back to open.]{OR}

[Hold the applicator with the narrow end pointing up. Snap the outline of the tip back to allow access to the applicator]. {OR}

[Hold the applicator with the narrow end pointing up. Snap the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip][notches][applicator]]. {OR}

[Holding applicator away from your and your dog's eyes, snap the applicator tip [at notched line] to open.]

{One of the following directions will be included}

[Part the hair and place the open end of the applicator just above the skin.]{OR}

[Invert applicator over dog and use open end to part dog's hair.]

{One of the following directions will be included}

[Apply [this product] at a spot between the dog's shoulder blades directly onto the dog's skin.]

[Squeeze the entire contents of the applicator and direct the solution in one spot and onto the dog's skin.]

Allow the area to dry before touching treated dog. Use only one applicator per treatment.

Do not apply more frequently than once every [30 days][4 weeks][month].

[Optional pictogram for Secondary CRP, may be used in addition to SAUE instructions]



**{Primary CRP – CR applicator in blister pack (3-Count)}**

**1** Tear through perforation



**2** Fold back the safety tab



**3** Cut with scissors to open applicator



### {Primary CRP – CR applicator in blister pack (4-Count)}

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



### How to Apply {Primary CRP}

Remove applicator[s] from packaging. Separate one applicator from the others using scissors.

{One of the following directions will be included}

[Hold upright with foil side away from you and cut the applicator tip back to open.] {OR}

[Hold the applicator with the narrow end pointing up. Cut the outline of the tip back to allow access to the [dotted tip] [applicator]]. {OR}

[Hold the applicator with the narrow end pointing up. Cut the applicator tip [backwards] [across the marked line] [to allow access to the] [dotted tip][notches][applicator]]. {OR}

[Holding applicator away from your and your dog's eyes, cut the applicator tip [at notched line] to open.]

{One of the following directions will be included}

[Part the hair and place the open end of the applicator just above the skin.] {OR}

[Invert applicator over dog and use open end to part dog's hair.]

{One of the following directions will be included}

[Apply [this product] at a spot between the dog's shoulder blades directly onto the dog's skin.]

[Squeeze the entire contents of the applicator and direct the solution in one spot and onto the dog's skin.]

Allow the area to dry before touching treated dog. Use only one applicator per treatment.

Do not apply more frequently than once every [30 days][4 weeks][month].

[Optional pictogram for Primary CRP, may be used addition to SAUE instructions]



### FREQUENCY OF APPLICATION

[**Brand Name**] [This product] should be applied once every [30 days] [4 weeks] [month]. Treatment remains effective, even after bathing, water immersion, or exposure to sunlight. Do not reapply [**Brand Name**] for [30 days][4 weeks] [1 month].

### STORAGE AND DISPOSAL

**PESTICIDE STORAGE:** Keep product in its original container. Do not repackage. Store in a cool (below 77°F [/][25°C]) dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this 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.

[For Chemical Emergency, Spills, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night within USA and Canada: 1-800-424-9300 CCN712312 or +1 703-527-3887 (collect calls accepted)]

[Optional recycling graphic]



### [WARRANTY}

#### [LIMITATION OF WARRANTY AND LIABILITY]

[IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS:** The directions for use of this product must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, and other unknown factors, all of which are beyond the control of [Distributor Company]. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, [Distributor Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, neither [Distributor Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

[In Case of Emergency, call: XXX-XXX-XXXX]

[Non-Emergency, call XXX-XXX-XXXX]

[Formulated for the USA]

[Manufactured For][Distributed By]:

[Promika, LLC

5000 CentreGreen Way, Suite 100

Cary, NC 27513]

EPA Reg. No. 91300-O

EPA Est. No. XXXX-XXX-XXX

*{End Package Insert for Primary or Secondary CRP (3- or 4-Count)}*

*{Carton Panel Flap text options - only if this type carton is used}*

### **P111.03 for Dogs**

{On market label “Dogs” will be 75% the size of the largest letter in the primary brand name}

#### **DO NOT USE ON CATS**

{One of the following statements will appear on the carton panel flap.}

Use ONLY on dogs [&] [and] puppies [5 to 22][23 to 44][45 to 88][89 to 132] lbs., over 8 weeks old

{OR}

ONLY For Dogs & Puppies, older than 8 weeks [&] [and] [5 to 22][23 to 44][45 to 88][89 to 132] lbs.

[[**Brand Name**] for dogs delivers [effective] protection against fleas, ticks, [and chewing lice]. [This product aids in the control of sarcoptic mange mites.] [Brand Name kills] [Kills] deer ticks, brown dog ticks, American dog ticks, and lone star ticks, including those transmitting Lyme disease, Rocky Mountain spotted fever, ehrlichiosis, babesiosis, anaplasmosis and other tick-borne diseases. Controls existing flea infestation and reinfestation for [[4] [four] weeks] [[1] [one] month] [30 days].]

{Restrictions will be found on the back panel of the carton and may or may not be repeated on the carton flap.}

#### **[RESTRICTIONS**

Do not use on rabbits or animals other than dogs. Do not allow the dog to ingest this product. Do not use on puppies under 8 weeks of age or on dogs or puppies weighing less than [5][23][45][89] lbs. Do not apply more than once every [4 weeks] [30 days][month]. Do not apply more than one applicator per treatment for one dog regardless of the dog’s weight. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. Allow the area to dry before touching treated dog. Do not bathe or allow the dog to swim for 24 hours after application. The dog needs to be dry at the time of application and remain dry for 24 hours after application.]

{Optional pictogram for Secondary CRP, may be used in addition to SAUE instructions on label insert}



{Optional pictogram for Primary CRP, may be used in addition to SAUE instructions on label insert}



**{Optional marketing claims may be added to this carton panel flap}**

**[WARRANTY]  
[LIMITATION OF WARRANTY AND LIABILITY]**

[IMPORTANT: READ BEFORE USE. Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness, injury, and other unintended consequences may result because of such factors as manner of use or application (including misuse), the presence of other materials, and other unknown factors, all of which are beyond the control of [Distributor Company]. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, [Distributor Company] makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, neither [Distributor Company], the manufacturer, nor the Seller shall be liable for any indirect, special, incidental or consequential damages resulting from the use, handling, application, storage, or disposal of this product. To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use, handling, application, or storage of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid.]

[Promika, LLC  
5000 CentreGreen Way, Suite 100  
Cary, NC 27513]

*{End Carton Panel Flap– only if this type carton is used}*

*{Text for secondary CRP back of each blister and back of each applicator; text for primary CRP on back of each blister applicator}*

P111.03 for Dogs Fipronil 9.7% [0.023 fl. oz. [0.67 mL]] {OR} [0.045 fl. oz. [1.34 mL]] {OR} [0.091 fl. oz. [2.68 mL]] {OR} [0.136 fl. oz. [4.02 mL]] {OR} EPA Reg. No. 91300-O [Use ONLY on dogs [&] [and] puppies [5-22][23-44][45-88][89-132] lbs., over 8 weeks old]{OR} [ONLY For Dogs & Puppies, older than 8 weeks [&] [and] [5-22][23-44][45-88][89-132] lbs.]	KEEP OUT OF REACH OF CHILDREN CAUTION: Read entire label before each use.  <i>{Lot code will be printed on or molded into the applicator}</i>
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*{IMAGE ON OUTER BLISTER LABEL – for secondary CRP}*



*{End Text for secondary CRP back of each blister and back of each applicator; text for primary CRP on back of each blister applicator}*

{Optional Marketing Claims}

1. Convenient dosing for use on dogs

**Chewing Lice Claims**

2. Kills [chewing lice] [lice] infestations

**Flea Claims**

3. Kill Fleas
4. Kills [adult] fleas [for] [up to] [4 weeks] [30 days] [1 month]
5. Kills newly emerged adult fleas before they lay eggs
6. Kills [adult] [fleas] [causing] [responsible for] [flea allergy dermatitis] [and] [flea bite anemia]
7. Controls existing [flea] infestations [and] [prevents new infestations]
8. Monthly application may be needed for dogs with high risk for flea reinfestation

**Tick Claims**

9. Kills ticks [,] [including those transmitting Lyme disease]
10. Kills [all stages of] ticks [up to] [4 weeks] [1 month] [30 days]
11. Kills [brown dog ticks] [(Rhipicephalus sanguineus)] [,] [American dog ticks] [(Dermacentor variabilis)] [,] [lone star ticks] [,] [and] [deer ticks] [including ticks that may cause] [Lyme disease] [, Rocky Mountain spotted fever] [, ehrlichiosis] [, babesiosis] [, anaplasmosis] [and] [other tick-borne diseases]

**Multiple Pest Claims**

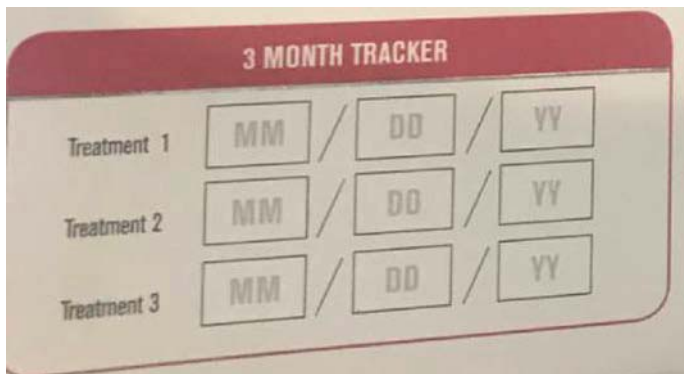
12. Kills chewing lice and ticks
13. Tick and flea control for dogs [, including puppies over 8 weeks and [5-22][23-44][45]88][88-132] lbs]
14. Kills fleas, [&] [and] ticks, [&] [and] [chewing] [lice] [monthly]
15. Once a month protection from fleas, ticks, and chewing lice
16. Once a month flea, tick, and chewing lice [application] [treatment]
17. Effectively kills ticks, [fleas] and chewing lice
18. [4 Week] [1 month] [30 day] [Flea and Tick Treatment]
19. [Four (4) Week] [1 Month] [Flea, Tick, and Chewing [Lice Control] [Treatment] [Application]
20. Use [Brand Name] monthly to [kill] ticks and chewing lice
21. Kills Fleas, [and] [&] Ticks for up to [4 weeks] [1 month] [30 days]!

**Other Pest Claims**


























22. Use on Dogs and puppies 8 weeks of age or older and [5-22][23-44][45]88][88-132] lbs
23. Apply [to] puppies over 8 weeks of age and [5-22][23-44][45]88][88-132] lbs
24. Formulated for Dogs and puppies 8 weeks of age or older and [5-22][23-44][45]88][88-132] lbs
25. Convenient [applicator] [spot-on product]
26. Easy to Use
27. Apply monthly
28. Apply once every [4 weeks] [month] [30 days]!
29. Waterproof
30. Fast-acting
31. Long-lasting
32. Effective after bathing [and] [exposure to water and sunlight]
33. As with any product, use caution before using this product on debilitated, aged, pregnant or nursing dogs



{Area for placement of reminder stickers}



{Optional graphics below may or may not appear anywhere on finished label}

	Adult Flea	
	Fleas	
	Flea eggs	
	Flea Larvae	
	Flea Pupae	
	Ticks	
	Brown Dog Tick	
	Deer Tick	
	American Dog Tick	
	Chewing Lice	
	Lone Star Tick	
	Mosquitoes	
	Mite	