



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

EPA Reg. Number:

83399-17

Date of Issuance:

2/8/18

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 02/08/2020

Name of Pesticide Product:

Imidacloprid and Pyriproxyfen
 Spot-on Solution for Dogs

Name and Address of Registrant (include ZIP Code):

Alicia Henk
 Ceva Animal Health, LLC
 8735 Rosehill Road
 Lexington, KS 66215

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:

Date:

2/8/18

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

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited, expires 02/08/2020.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the initial registration notice dated 2/8/2016
4. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. Imidacloprid GDCI-129099
 - b. Imidacloprid EDSP-129099
 - c. Pyriproxyfen GDCI-129032
 - d. Pyriproxyfen EDSP-129032

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

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 2/4/2016

If you have any questions, please contact Jacquelyn Herrick by phone at 703-347-0559, or via email at herrick.jacquelyn@epa.gov.

Enclosure

“Master Label”

This master label includes label text for different size packages and application rates specific to the pet’s age and body weight. Text that appears in parenthesis are informational to the EPA, but will not be printed. Text that appears in brackets are optional.

(FRONT PANEL OF OUTER BOX)

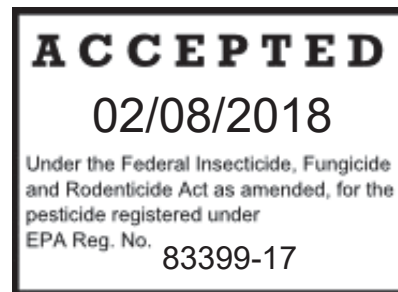
(Market Label-

- The word Dog will be at least 40-75% in height of the largest letter in the primary brand name.
- A large clear picture of a dog in the respective weight range will be on the front panel of the label.)

Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs

Alternate Brand Names include:

Combiva II For Dogs and Puppies
CrossBlock II For Dogs and Puppies



(The above brand names will be packaged in the weight ranges below:)

- 3-10 lbs, 7 weeks or older (0.014 fl oz)**
- 11-20 lbs, 7 weeks or older (0.034 fl oz)**
- 21-55 lbs, 7 weeks or older (0.085 fl oz)**
- Over 55 lbs, 7 weeks or older (0.135 fl oz)**

(Outer box will list only one weight range based on the package dose volume)

Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs treats and prevents further flea infestation on dogs

(Optional marketing claims –see pages 9-11)

ACTIVE INGREDIENTS:

Imidacloprid..... 9.10%
Pyriproxyfen 0.46%

OTHER INGREDIENTS: 90.44%

TOTAL 100.00%

NET CONTENTS: XXX fl oz [XXX mL]
[XX Doses [each dose XXX fl oz]]

EPA Est. No. TBD

EPA Reg. No. 83399-17

KEEP OUT OF REACH OF CHILDREN
CAUTION

See Back Panel / Package Insert for additional Precautionary Statements, First Aid and complete Directions for Use.

Use only on dogs [and puppies] weighing (insert product weight range) lbs. and 7 weeks of age or older



(“Do Not Use on Cats” icon 1.5cm x 1.5cm) (placed on front panel)

(BACK PANEL OF OUTER BOX)

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21-55 lbs, 7 weeks or older (0.085 fl oz)

Over 55 lbs, 7 weeks or older (0.135 fl oz)

(Outer box will list only one weight range based on the package dose volume)

(Optional marketing claims –see pages 9-10)

FIRST AID	
IF SWALLOWED:	Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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 OR CLOTHING:	Wash with plenty of soap and water. Remove and wash contaminated clothing before reuse.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact 1-800-999-0297 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Keep out of reach of children.

HAZARDS TO DOMESTIC ANIMALS

FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS.

Do not use on puppies under 7 weeks of age or weighing less than (*minimum weight based on the package size*) [3 lbs (0.014 fl oz)][11 lbs (0.034 fl oz)][21 lbs (0.085 fl oz)][56 lbs (0.135 fl oz)]. As with any product, consult your veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing dogs. If your dog is exhibiting signs or is being treated for skin dermatitis, talk to your vet before applying any topical flea and tick control product.

Side Effects: Monitor your dog after application. Side effects, although rare, 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, consult your veterinarian or call 1-800-999-0297. Have the product container or label with you when calling your veterinarian for advice.



Keep cats away from treated dog for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[Product of]

[Distributed by:] [Manufactured for:]

Ceva Animal Health, LLC

8735 Rosehill Road

Lenexa, KS 66215

[Made in Germany]

lot#, date &/or label code [UPC CODE]

[MWI, Boise, ID 83705]

[Combiva is a registered trademark of Ceva Santé Animale]

[Recyclable Packaging][recycling symbol]

(SECTION UNDER FRONT PANEL- appears after lifting the front panel of the box)

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Over 55 lbs, 7 weeks or older (0.135 fl oz)

(Outer box will list only one weight range based on the package dose volume)

1 Tear through perforation



2 Fold back the safety tab



3 Cut with scissors to open applicator



DIRECTIONS FOR USE

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

RESTRICTIONS:

- Do not allow children to apply product.
- Do not apply more than one [1] tube per treatment.
- Do not split one tube between two dogs.
- 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.

See package insert for complete directions for use.

(PACKAGE INSERT)

Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs

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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.
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Keep cats away from treated dog for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

DIRECTIONS FOR USE

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

CONSUMER INFORMATION

Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs kills fleas within 12 hours. **Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs** prevents flea infestation for four (4) weeks [1 month] [30 days].

OR

The active ingredients in Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs [this product] are formulated for control of fleas for 1 month [4 weeks] [30days] on dogs.

RESTRICTIONS:

- Do not allow children to apply product.
- Weigh your dog to be sure you are using the right size product for your dog.
- For use only on dogs and puppies 7 weeks and older weighing [3-10 lbs (0.014 fl.oz.)] or [11-20 lbs (0.034 fl. oz.)] or [21-55 lbs (0.085 fl. oz.)] or [Over 55 lbs (0.135 fl. oz.)]
- Do not apply more than one [1] tube per treatment.

- Do not split one tube between two dogs.
- 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.
- Do not use on other animals.
- Do not have contact or allow children to have contact with treated area until completely dry.
- For external use only.
- Do not allow your dog to ingest this product.

TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE.
FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

OPENING INSTRUCTIONS:

1 Tear through perforation



2 Fold back the safety tab

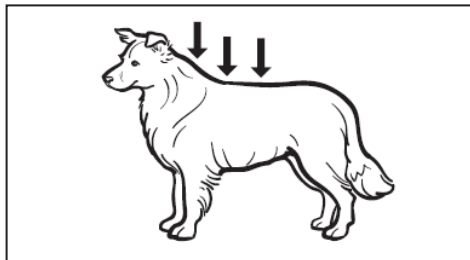


3 Cut with scissors to open applicator



HOW TO APPLY:

1. Ensure your dog is dry before applying the product, and ensure your dog remains dry for 24 hours after application. The dog should be standing or in a comfortable position for easy application.
2. Apply the entire contents of the applicator evenly to three spots along the dog's back, from the shoulder to the middle of the back. At each spot, part the hair down to the level of the skin and gently squeeze the applicator to apply the product. [Avoid superficial application to the dog's hair.]



3. Do not apply an excessive amount of solution to any one spot. This could cause the product to run

off the dog. Do not get the product in the dog's eyes or mouth or allow your dog to ingest the product.

4. Discard the empty applicator as outlined in the Storage and Disposal section.
5. Repeat every month, or as recommended by your veterinarian.

FREQUENCY OF APPLICATION

Treatment of Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs will kill fleas on dogs [and][puppies] within 12 hours and re-infesting fleas within 2 hours. It is possible pre-existing pupae in the environment may continue to emerge for six [6] weeks [or longer] depending on climatic conditions. Use Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs monthly [every 30 days] [every 4 weeks] for the control and prevention of flea re-infestations.

OR

[Studies have shown that] Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs kills fleas on dogs within 12 hours for up to four [4] weeks [1 month] [30 days]. To prevent flea re-infestation, apply monthly. Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs remains effective even after exposure to sunlight. Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is water resistant and is still effective, after bathing or water immersion. Allow treated area to dry thoroughly.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry place. Keep out of reach of children.

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.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that the material conforms to the chemical parameters of the US EPA registration and the label. To the extent consistent with applicable law, seller makes no warranty, express or implied, other than indicated on the label. Buyer and user assume all risk of use and handling of this material. To the extent consistent with applicable law, any damages arising from use of this product or a breach of this warranty shall be limited to direct damages and shall not include consequential or incidental damages such as loss of profit or values.

[Made in Germany]

[Product of] [Distributed by:] [Manufactured for:]
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

EPA Reg. No. 83399-17
EPA Est. No. TBD
lot#, date &/or label code [UPC CODE]

[MWI, Boise, ID 83705]
[Combiva is a registered trademark of Ceva Santé Animale]

[Recyclable Packaging][recycling symbol]

(OPTIONAL MARKETING CLAIMS)

(for use on the front, side, or back panels of the outer box or on the package insert)

Fleas

- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] contains the active ingredient [imidacloprid,][and an/the] [insect growth regulator][IGR] [pyriproxyfen]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] contains an [insect growth regulator] [IGR] that effectively kills flea eggs
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] prevents further flea infestation for four [4] weeks [1 month] [30 days] on dogs [puppies]
- Protects against fleas on dogs [puppies] for up to four [4] weeks [1 month] [30 days]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] helps prevent further flea infestation on dogs for up to four [4] weeks [1 month] [30 days]
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs [continually] works to prevent further flea infestation on dogs [puppies] for up to four [4] weeks [1 month] [30 days]
- Effectively kills adult fleas and prevents further re-infestation on dogs [puppies]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats, controls, and prevents further flea re-infestation on dogs [puppies]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats for fleas within 12 hours on dogs
- Kills fleas on dogs [puppies] within [in] 12 [twelve] hours [after application]
- Kills fleas so they can't lay eggs on your dog
- Kills fleas on dogs and puppies 7 weeks of age or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Kills re-infesting fleas on dogs [puppies] within 2 hours
- Kills fleas and their eggs on dogs [puppies]
- Effectively kills flea eggs
- Disrupts the flea cycle and kills larval flea stages on dogs [puppies]
- Breaks the flea life cycle and [prevents] [stops] flea eggs [and larvae] from developing into adult [biting] fleas
- Stops flea eggs from hatching [and] [developing into biting adults]
- Kills larval flea stages on dogs [puppies]
- Kills re-infesting fleas on dogs [puppies] within 2 hours [and protects against further flea re-infestation up to four [4] weeks [one month] [30 days]]
- Prevents further re-infestations on dogs [puppies] by killing adult fleas within 12 hours for up to one month [4 weeks] [30 days]
- Controls fleas for dogs and puppies 7 weeks or older and weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Treats flea infestations on dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Provides dogs [puppies] with protection against fleas for up to four [4] weeks [one month] [30 days]]
- Controls against flea bites on dogs [puppies]
- Kills fleas that may cause Flea Allergy Dermatitis [FAD] on dogs [puppies]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] offers 3-way flea protection that [kills] [controls] [prevents] adults, larvae, and eggs on dogs [puppies]
- [An effective] flea adulticide, larvicide, and ovide [that [kills][prevents][,treats] [,and] [controls] fleas] on dogs
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] offers effective multistage flea control on dogs

EPA REG. NO. 83399-17
LABEL AMENDMENT
DATE: February 07, 2018

- Effective [once a month] flea prevention and treatment for dogs [puppies]
- Effective flea treatment for your dog 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Monthly topical treatment of Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs kills fleas and treats flea infestation for dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats for fleas in 12 hours on dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Monthly treatment prevents further re-infestation and treats fleas on dogs 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- [Kills] [Treats] fleas on dogs [puppies] which may serve as intermediate hosts for tapeworm

All Others

- For Dogs and puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- For Use on puppies 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- For Use on Dogs Only 7 weeks or older weighing at least [3 lbs (0.014 fl. oz.)] or [11 lbs. (0.034 fl. oz.)] or [21 lbs. (0.085 fl. oz.)] or [55 lbs. (0.135 fl. oz.)]
- Easy to Use Applicator
- Easy to Apply Applicator
- Applies Easily
- Monthly treatment recommended
- One Step Flea Prevention for dogs [puppies] for up to four [4] weeks [one month][30 days]
- For Best Results Apply Monthly [every 30 Days] [every [4] [four] weeks]
- For year round protection apply monthly [every [[four] [4] weeks] [30 days]]
- Use Monthly [Every [30 Days] [4] [Four] Weeks] for best results
- Only one treatment needed every month [30 Days] [[4] [Four] Weeks]
- One treatment remains effective for four [4] weeks [1 month] [30days]
- Convenient
- Waterproof after application
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is waterproof after application
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is effective after [bathing] [shampooing]
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is effective [even] after your dog is exposed to rain or sunlight
- Formulated for control of fleas on dogs [puppies] for 1 month [4 weeks] on dogs
- Contains the [same] active ingredients as in [Bayer] Advantage II for Dogs*
- Contains the active ingredients [imidacloprid, pyriproxyfen]found in [Bayer] Advantage II for dogs*
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is not manufactured or distributed by Bayer [Animal Health]*
- Satisfaction guaranteed [or] Ceva Animal Health, LLC will provide new product or your money back

**{When a claim is used comparing the product to Bayer's Advantage II For Dogs, the disclaimer for manufacturing and distributing will be used also.}*

(APPLICATOR LABELING)

**Imidacloprid and Pyriproxyfen Spot-on
Solution For Dogs**

[insert wt range] lbs
7 weeks or older

Imidacloprid 9.10%
Pyriproxyfen 0.46%

KEEP OUT OF REACH OF CHILDREN
CAUTION

Read entire label before use.
[Use scissors to open.]

EPA REG. No. 83399-17
Lot # (*designation will identify producing establishment*)
XXX fl. oz.

[label code]