



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:

2/8/16

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 2/8/2018

Name of Pesticide Product:

Imidacloprid and Pyriproxyfen
Spot-On Solution for Dogs

Name and Address of Registrant (include ZIP Code):

Alicia Henk
Director, Development and regulatory Affairs
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, 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:

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

Date:

2/8/16

2. This registration is time-limited and expires 2/8/2018.
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 and EDSP Orders identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Pyriproxyfen GDCI-129032-1299
 - c. Imidacloprid EDSP-129099
 - 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://www.epa.gov/oppsrrd1/contacts_prd.htm

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. 83399-17.”
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 2/4/2016

If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Enclosure: Stamped label

“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

(Market Label-

- o The word Dog will be at least 40-75% in height of the largest letter in the primary brand name.
- o 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

CAH16 for Dogs and Puppies

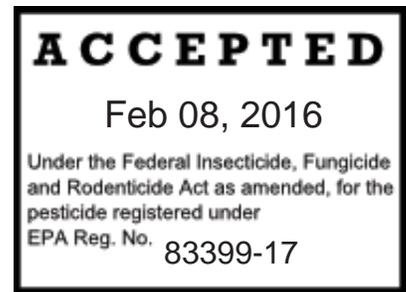
(The above brand names will be packaged in the weight ranges below:)

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)



Imidacloprid and Pyriproxyfen Spot-on Solution for Dogs Treats and Prevents Further Flea Infestation on Dogs and puppies 7 weeks and older

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—NEW

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Back Panel / Package Insert for additional Precautionary Statements, First Aid and 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 & INSERT LANGUAGE

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND PUPPIES 7 WEEKS OR OLDER WEIGHING AT LEAST 3 LBS

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 3 lbs. 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.

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 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 weekdays between 9am and 6pm EST or 1-888-426-4435 for emergency medical treatment information.	

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.

DIRECTIONS FOR USE

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

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]. [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.
- For use only on dogs [and puppies] 7 weeks and older.
- Do not use on other animals.
- Do not apply to dogs or puppies weighing less than 3 lbs. (0.014 fl. oz.) [11 lbs. (0.034 fl. oz.)] [21 lbs. (0.085 fl. oz.)] [55 lbs. (0.135 fl. oz.)]
- Weigh your dog to be sure you are using the right size product for your dog.
- 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 have contact or allow children to have contact with treated area until completely dry.

TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON DOGS ONLY. DO NOT USE ON CATS. DO NOT USE ON OTHER ANIMALS.

OPENING INSTRUCTIONS:

1 Tear through perforation



2 Fold back the safety tab

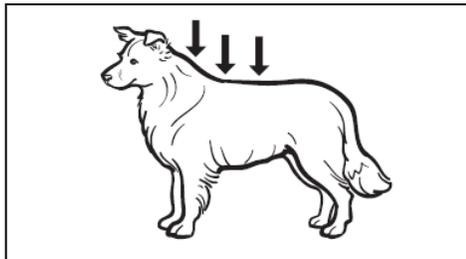


3 Cut with scissors to open applicator



HOW TO APPLY:

1. The dog should be standing or in a comfortable position for easy application. 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.
2. 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. Do not use more than one tube on dogs greater than 55 lbs.
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

EPA REG. NO. 83399-RT
INITIAL PRODUCT REGISTRATION
DATE: Feb. 08, 2016

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]

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

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

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]
- Protects against fleas for up to four [4] weeks [1 month] [30 days]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] helps prevent further flea re-infestation 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 for up to four [4] weeks [1 month] [30 days]
- Effectively kills adult fleas and prevents further infestation on dogs over 7 weeks of age weighing at least 3 pounds [lbs]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats, controls, and prevents further flea infestation
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] treats for fleas within 12 hours on dogs
- Kills fleas within [in] 12 [twelve] hours [after application]
- Kills fleas before egg laying
- Kills fleas before eggs can be laid
- Kills fleas on dogs and puppies 7 weeks of age or older weighing at least 3 pounds [lbs]
- Kills re-infesting fleas within 2 hours
- Kills fleas and their eggs
- Effectively kills flea eggs
- Disrupts the flea cycle and kills larval flea stages
- 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]
- Larval flea stages are killed after Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs is applied to dogs 7 weeks or older weighing at least 3 pounds [lbs]
- Kills re-infesting fleas within 2 hours [and protects against further flea re-infestation up to four [4] weeks [one month] [30 days]]
- Prevents further re-infestations by killing adult fleas within 12 hours for up to one month [4 weeks] [30

EPA REG. NO. 83399-RT
INITIAL PRODUCT REGISTRATION
DATE: Feb. 08, 2016

days]

- Controls fleas for dogs and puppies 7 weeks or older and weighing at least 3 pounds [lbs]
- Treats flea infestations on dogs and puppies 7 weeks or older weighing at least 3 pounds [lbs]
- Provides flea protection up to four [4] weeks [one month] [30 days]
- Controls against [problematic] flea bites
- Kills fleas that may cause Flea Allergy Dermatitis [FAD]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] offers 3-way flea protection that [kills] [controls] [prevents] adults, larvae, and eggs
- [An effective] flea adulticide, larvicide, and ovicide [that [kills][prevents][,treats] [,and] [controls] fleas]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs] offers effective multistage flea control
- Effective [once a month] [flea] [protection] [prevention and treatment]
- Effective flea treatment for your dog 7 weeks or older weighing at least 3 pounds [lbs]
- 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 pounds [lbs]
- [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 pounds [lbs]
- Monthly treatment prevents further re-infestation and treats fleas on dogs 7 weeks or older weighing at least 3 pounds [lbs]
- [Kills] [Treats] fleas which may serve as intermediate hosts for tapeworm

All Others

- For Dogs and puppies 7 weeks or older weighing at least 3 pounds [lbs]
- For Use on puppies 7 weeks or older weighing at least 3 pounds [lbs]
- For Use on Dogs Only 7 weeks or older weighing at least 3 pounds [lbs]
- Easy to Use Applicator
- Easy to Apply Applicator
- Applies Easily
- Imidacloprid and Pyriproxyfen Spot-On Solution for Dogs recommends monthly treatments
- One Step Flea Prevention 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
- Water-resistant 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 exposure to rain or sunlight
- Formulated for control of fleas 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]

APPLICATOR LABELING

{Front Label}	{Back Label}
<p>Imidacloprid and Pyriproxyfen Spot-on Solution For Dogs [insert wt range] lbs 7 weeks or older Imidacloprid 9.10% Pyriproxyfen 0.46% XXX fl. oz.</p> <p>{label code}</p>	<p>KEEP OUT OF REACH OF CHILDREN CAUTION Read entire label before use. [Use scissors to open.] EPA REG. No. 83399-NEW Lot # (<i>designation will identify producing establishment</i>)</p> <p>{label code}</p>