



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 10, 2016

Alicia Henk
Director, Development and regulatory Affairs
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

Subject: Label Amendment – Clarification about package size and animal weight range
Product Name: Imidacloprid and Pyriproxifen Spot-On Solution for Cats
EPA Registration Number: 83399-16
Application Date: 4/13/2016
Decision Number: 516636

Dear Ms. Henk:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Rita Kumar by phone at (703) 308-8291, or via email at kumar.rita@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Rita Kumar" followed by a stylized flourish.

Venus Eagle, Product Manager 01
Insecticide-Rodenticide Branch 3
Registration Division (7505P)
Office of Pesticide Programs

“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)

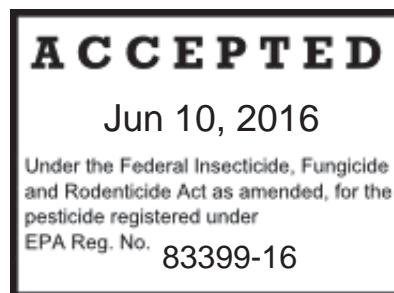
(Market Label-

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

Imidacloprid and Pyriproxyfen Spot-On Solution for Cats

Alternate Brand Names include:

- Combiva II For Cats**
- Combiva II For Cats and Kittens**
- CrossBlock II For Cats**
- CrossBlock II For Cats and Kittens**



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

[2-5 lbs., 8 weeks or older (0.0078 fl oz)]

5- 9 lbs., 8 weeks or older (0.014 fl oz)

Over 9 lbs. (0.027 fl oz)

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

Imidacloprid and Pyriproxyfen Spot-On Solution for Cats treats and prevents further flea infestation on cats and kittens 8 weeks and older

(Optional marketing claims –see pages 9-10)

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. 83399-16

**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 cats [and] [kittens] weighing (insert product weight range) lbs. and 8 weeks of age or older

(BACK PANEL OF OUTER BOX)

Imidacloprid and Pyriproxyfen Spot-On Solution for Cats

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CrossBlock II For Cats

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Over 9 lbs. (0.027 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 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. | |

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 CATS ONLY. DO NOT USE ON DOGS.

Do not use on kittens under 8 weeks of age or weighing less than (*mimimum weight based on the package size*) [2 lbs (0.0078 fl oz)] [5 lbs (0.014 fl oz)] [9 lbs (0.027 fl oz)]. Do not treat your cat with more than one pesticide product at a time. As with any product, consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY

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pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any pesticide product.

Side Effects: Monitor your cat after application. Although side effects are rare, some cats may experience some temporary irritation at the site of the product application such as redness, scratching or other signs of discomfort. If these or other side effects occur, consult your veterinarian or call 1-800-999-0297. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have been reported.

[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)

Imidacloprid and Pyriproxyfen Spot-On Solution for Cats

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Combiva II For Cats

Combiva II For Cats and Kittens

CrossBlock II For Cats

CrossBlock II For Cats and Kittens

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

[2-5 lbs., 8 weeks or older (0.0078 fl oz)]

5- 9 lbs., 8 weeks or older (0.014 fl oz)

Over 9 lbs. (0.027 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



RESTRICTIONS:

- Do not allow children to apply product.
- Do not apply more than one [1] tube per treatment, even for larger cats.
- Do not split one tube between two cats.
- Do not treat your cat with more than one pesticide product at a time. Over dosing your cat 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 Cats

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Over 9 lbs. (0.027 fl oz)

(Package Insert will list only one weight range based on the package dose volume.)

Imidacloprid and Pyriproxyfen Spot-On Solution for Cats treats and prevents further flea infestation on cats and kittens 8 weeks and older

(Optional marketing claims –see pages 9-10)

ACTIVE INGREDIENTS:

Imidacloprid..... 9.10%

Pyriproxyfen 0.46%

OTHER INGREDIENTS: 90.44%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
 CAUTION**

| 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. | |

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 CATS ONLY. DO NOT USE ON DOGS.

Do not use on kittens under 8 weeks of age or weighing less than (*minimum weight based on package size*) [2 lbs (0.0078 fl. oz.)] [5 lbs (0.014 fl. oz.)] [9 lbs (0.027 fl. oz.)]. As with any product, consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing cats. Individual sensitivities, while rare, may occur after using ANY pesticide product for cats. If signs persist, or become more severe, consult a veterinarian immediately. If your cat is on medication, consult your veterinarian before using this or any pesticide product.

Side Effects: Monitor your cat after application. Although side effects are rare, some cats may experience some temporary irritation at the site of the product application such as redness, scratching or other signs of discomfort. If these or other side effects occur, consult your veterinarian or call 1-800-999-0297. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. Gastrointestinal signs such as hypersalivation, vomiting or diarrhea have been reported.

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 Cats [This product] kills fleas within 12 hours, and re-infesting fleas are killed within 2 hours. **Imidacloprid and Pyriproxyfen Spot-On Solution for Cats** prevents further flea infestation for four [4]weeks [1 month][30 days].

OR

[The active ingredients in] Imidacloprid and Pyriproxyfen Spot-On Solution for Cats [this product] are formulated for control of fleas for 1 month[4 weeks][30 days] on cats. Imidacloprid and Pyriproxyfen Spot-On Solution for Cats is an effective flea adulticide, larvicide, and ovicide [that [kills] [prevents]][,treats] [,and][controls] fleas.]

RESTRICTIONS:

- Do not allow children to apply product.
- Weigh your cat to be sure you are using the right size product for your cat.
- For use only on cats [and kittens] 8 weeks and older weighing [2-5lbs (0.0078 fl. oz.)] or [5-9 lbs (0.014 fl. oz.)] or [over 9lbs (0.027 fl. oz.)]
- Do not use on other animals.
- Do not apply more than one [1] tube per treatment, even for larger cats.
- Do not split one tube between two cats.

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- Do not treat your cat with more than one pesticide product at a time. Over dosing your cat 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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. FOR EXTERNAL USE ON CATS ONLY. DO NOT USE ON OTHER ANIMALS.

OPENING INSTRUCTIONS:

1 Tear through perforation



2 Fold back the safety tab

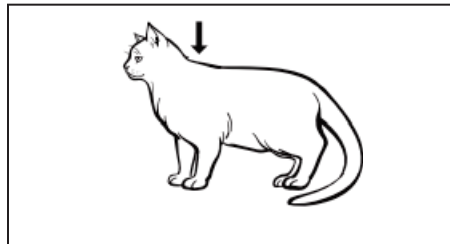


3 Cut with scissors to open applicator



HOW TO APPLY:

1. The cat should be standing or in a comfortable position for easy application.
2. Part the hair down to the level of the skin, and slowly apply the product at the base of the cat's head until the applicator is completely empty. (Avoid superficial application to the cat's hair).



3. Do not get the product in the cat's eyes or mouth. Do not allow your cat to ingest this product. Salivation may occur if the cat ingests the product immediately after treatment. Do not use more than one tube on cats greater than 9 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

The presence of fleas on cats may cause a sensitive skin disorder due to the feeding activity of fleas. This is called flea allergy dermatitis [FAD]. Imidacloprid and Pyriproxyfen Spot-On Solution for Cats kills fleas that may cause flea allergy dermatitis [FAD]. Treatment of Imidacloprid and Pyriproxyfen Spot-On Solution for Cats will kill fleas on cats [and][kittens] within twelve [12] 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 Cats monthly [every 30 days][every 4 weeks] for the control of fleas.

OR

[Studies have shown that] Imidacloprid and Pyriproxyfen Spot-On Solution for Cats kills fleas on cats 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 Cats remains effective even after exposure to sunlight. Imidacloprid and Pyriproxyfen Spot-On Solution for Cats 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.

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

EPA Reg. No. 83399-16
EPA Est. No. TBD
lot#, date &/or label code [UPC CODE]

[Made in Germany]

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

(OPTIONAL MARKETING CLAIMS)

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

- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] contains the active ingredient imidacloprid,[and an/the] [insect growth regulator][IGR] pyriproxyfen
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] contains [insect growth regulator] [IGR] that effectively kills flea eggs
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] prevents further flea infestation for four[4] weeks [1 month][30 days]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] prevents further flea infestation for up to four [4] weeks [1 month][30 days]
- Protects against fleas
- Protects against further flea infestation up to four[4] weeks [1 month][30 days]
- Imidacloprid and Pyriproxyfen Spot-On Solution for Cats helps prevent further flea infestation for up to four [4] weeks [1 month][30 days]
- Imidacloprid and Pyriproxyfen Spot-On Solution for Cats [continually] works to prevent further flea infestation for up to four [4] weeks [1 month][30 days]
- [Effectively] [stops][controls] existing flea infestation by killing adult fleas][and prevents further re-infestation]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] treats, controls, and prevents further flea re-infestation
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] treats fleas [within 12 hours] on cats and kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)]or [9 lbs (0.027 fl oz)]
- Kills fleas within [in] 12 [twelve] hours [after application]
- Kills fleas before egg laying
- Kills fleas before eggs can be laid
- Kills fleas on cats and kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
- Kills fleas and their eggs
- Effectively kills flea eggs
- Disrupts the flea cycle and kills larval flea stage
- Breaks the flea life cycle [and][prevents][stops] flea eggs from developing into adult [biting] fleas
- Kills flea eggs from hatching[and][developing into biting adults]
- Kills larval flea stages
- Kills flea larvae
- Kills re-infesting fleas within 2 hours [and][Protects against further flea infestations [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 days]
- Controls fleas for cats and kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
- Treats flea infestation on cats and kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
- Provides flea protection [up to [[four][4] weeks][a month][30 days]]
- Controls against problematic fleas
- Kills fleas that may cause flea allergy dermatitis (FAD)
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] offers 3-way flea protection that

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- [kills][[controls][prevents] against] adults, larvae, and eggs
- [An effective] flea adulticide, larvicide, and ovicide [that [kills][prevents][,treats][,and][controls] against fleas]
- [Imidacloprid and Pyriproxyfen Spot-On Solution for Cats] offers effective multistage flea control
- Effective once a month flea [protection][prevention and treatment]
- Effective flea treatment for your cat 8 weeks of age or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
- Monthly topical treatment of Imidacloprid and Pyriproxyfen Spot-On Solution for Cats kills fleas and treats flea infestation for cats and kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
- Monthly treatment prevents further reinfestation and treats fleas on cats and kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
- Formulated to target every stage of flea development [to treat and prevent further flea infestations]

All Others

- For Cats and Kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
 - For use on kittens 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
 - For use on cats 8 weeks or older weighing at least [2 lbs (0.0078 fl oz)] or [5 lbs (0.014 fl oz)] or [9 lbs (0.027 fl oz)]
 - Easy to Use Applicator
 - Easy to Apply Applicator
 - Applies Easily
 - Imidacloprid and Pyriproxyfen Spot-On Solution for Cats recommends monthly treatments
 - One Step Flea Prevention for up to [[four][4] weeks] [a month][30 days]
 - Apply [Monthly][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 4[four] weeks[1 month][30days]
 - Water-resistant after application
 - Imidacloprid and Pyriproxyfen Spot-On Solution for Cats is waterproof after application
 - Imidacloprid and Pyriproxyfen Spot-On Solution for Cats is effective after [bathing] [shampooing]
 - Imidacloprid and Pyriproxyfen Spot-On Solution for Cats is effective [even] after exposure to rain or sunlight
 - Formulated for control of fleas for 1 month [4 weeks] on cats
 - Contains the [same] active ingredients [imidacloprid, pyriproxyfen] as in [Bayer] Advantage II for Cats
 - Contains the active ingredients found in [Bayer] Advantage II for cats
 - Imidacloprid and Pyriproxyfen Spot-On Solution for Cats is not manufactured or distributed by Bayer [Animal Health]
 - Satisfaction guaranteed [or] Ceva Animal Health, LLC will provide new product or your money back
-

(APPLICATOR LABELING)

**Imidacloprid and Pyriproxyfen Spot-On
Solution For Cats**

[insert wt range] lbs
8 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. 83399-16
Lot # (*designation will identify producing establishment*)
XXX fl. oz.

[label code]