



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 19, 2016

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

Subject: PRIA Label Amendment – Add growth regulator claims and other label revisions
&
Notification for alternate brand name: Catego for Cats
Product Name: C708.0 (Vectra Cat Plus Tick)
EPA Registration Number: 83399-15
Application Date: 9/21/2015
Decision Numbers: 509427; 514108

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.

Alternate brand name Catego for Cats is also acceptable.

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.

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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 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.

Enclosure

Sincerely,

A handwritten signature in black ink, appearing to read 'MS', with a horizontal line extending to the right from the end of the signature.

Mark Suarez
Product Manager 07
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

FRONT PANEL OF OUTER BOX

Picture of Cat
according to
weight range

C708.0 (Vectra Cat Plus Tick)

Alternate Brand Names:

[Vectra Cat Plus Tick] [Vectra Plus for Cats] [Vectra Trio for Cats] [Vectra 3C for Cats] [Vectra III for Cats] [Vectra 3 for Cats] [SimpleGuard 3 for Cats] [FirstShield Trio for Cats] [Catego for Cats]

FOR CATS & KITTENS – Use only on cats and kittens weighing over 1.5 lbs and over 8 weeks of age

Kills adult fleas, (flea) eggs, (flea) larvae, ticks, (and) chewing lice

(Optional marketing claims—front or back or side panels/continued on pages 4-8)

ACTIVE INGREDIENTS:

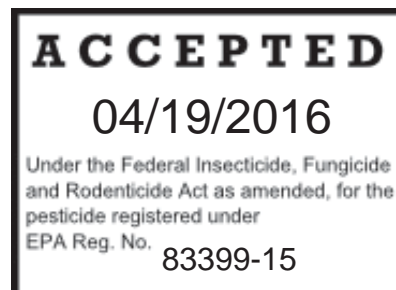
Dinotefuran.....	22.00%
Fipronil.....	8.92%
Pyriproxyfen.....	3.00%
OTHER INGREDIENTS.....	66.08%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

See package insert for directions for use, precautionary statements, [and] first aid [and other information].

**Net Contents: (0.051 fl oz) (0.102 fl oz)
(3)(6) Doses [each dose, 0.017 fl oz (0.50 mL)]**



Front, back, side and/or insert language**READ ENTIRE LABEL BEFORE EACH USE****PRECAUTIONARY STATEMENTS****HAZARDS TO HUMANS**

WARNING: May be fatal if swallowed. Causes moderate eye irritation. Harmful if absorbed through the skin. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco products, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats and kittens weighing over 1.5 lbs and over 8 weeks of age (0.5 mL dose).

Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or animals known to be sensitive to pesticide products without first consulting a veterinarian.

FIRST AID	
If swallowed:	Call a poison control center or 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 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. Call a poison control center, doctor for treatment advice
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center, doctor, or 1-800-999-0297 or after 6pm EST 1-888-426-4435 immediately for treatment advice
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 or after 6pm EST 1-888-426-4435 for emergency medical information.	

Side Effects: Monitor your cat after application. Individual sensitivity, such as slight transitory redness, erythema, scratching, pruritus or other signs of discomfort at the site of application, may occur after using ANY pesticide product for cats. If signs of sensitivity occur, bathe your cat with mild soap or shampoo and rinse with large amounts of water. If signs of individual animal sensitivity occur and persist, contact your veterinarian. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call us at 1-800-999-0297. Have the product container or label with you when calling your veterinarian for advice.

DIRECTIONS FOR USE

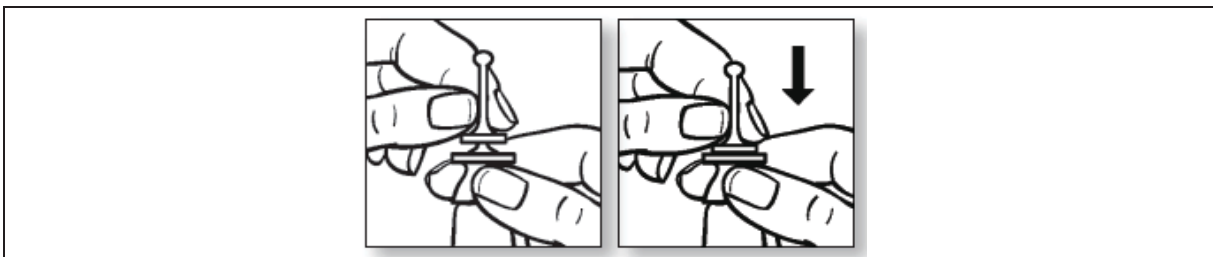
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [Precaución al consumidor: si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the User: If you cannot speak English, do not use this product until the label has been fully explained to you).] Use Restriction: Use only on cats. Do not have contact or allow children to have contact with treated areas until treatment is completely dry.

HOW TO OPEN:

Separate one unit from the others.
Cut on both dotted lines with scissors.
Open plastic lid.
Remove tube.

HOW TO APPLY:

1. Remove applicator (tube) from package.
2. The cat should be standing or in a comfortable position for easy application.
3. Holding the (tube) applicator upright, pointing away from your face, place your thumb and index finger around the applicator tip under the large disk. With the other hand, grasp the stem of the applicator tip above the small disk. Press down firmly on the small disk until both disks meet, piercing the seal. (See illustration)



4. Part the hair down to the level of the skin and slowly apply the product at the base of the cat or kitten's head until the applicator (tube) is (completely) empty, as shown in the diagram below. [Do not make superficial application to the cat/kitten's hair.]



[Avoid superficial application to the cat's hair.][Do not get the product in your cat's eyes or mouth.]

5. Discard the empty applicator (tube) as outlined in the Storage and Disposal section.
 6. Repeat every month (30 days, 4 weeks), or as recommended by your veterinarian.
 7. For optimal treatment, control and prevention of (adult) fleas, flea eggs, flea larvae, ticks (and) chewing lice year-round treatment is recommended.
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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry place. Protect from freezing.

PESTICIDE DISPOSAL AND CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partially filled:** call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[NET CONTENTS: (0.051 fl oz (1.5 ml)) (0.102 fl oz (3 mL))
[(3)(6) (doses)(applications)(applicators)]
[each 0.017 fl oz (0.5 mL)]

EPA Reg. No. 83399-15

EPA Est. No. XXXX

[Sold by:] [Manufactured for:]

Ceva Animal Health, LLC

8735 Rosehill Road

Lenexa, KS 66215

[For additional information, contact us at 1-800-999-0297 or contact.us@ceva.com]

PACKAGE INSERT (full label language plus additional text)

LIMITED WARRANTY AND LIMITATION OF DAMAGES

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

ALTERNATE MARKETING TEXT *(for use on front, side, or back panels or package insert)*

- Protects cats and kittens (over 1.5 lbs and 8 weeks of age or older) from fleas, flea eggs and flea larvae for one month

- For cats and kittens over 1.5 lbs and (over) 8 weeks of age (or older), three (six) (single) dose(s) (applicators)
- Effective monthly treatment of (against) fleas, flea eggs, and larvae
- Protects (your cat and kitten) from all stages of fleas for one month
- Prevents development of fleas, flea eggs, and flea larvae
- Protects from fleas for one month
- Protects cats and kittens from the development of anemia associated with (severe) flea infestation
- Kills newly emerged fleas before they lay eggs
- Kills fleas within 6 hours
- Flea treatment formulated for cats and kittens over 1.5 lbs.
- Easy, spot-on (topical) application
- (Patented) applicator tip (Trademark) for easy application directly to the skin
- Satisfaction guaranteed or your money back (Ceva ICON) ((Please) call our professional staff at xxx-xxx-xxxx or e-mail us at contact.us@ceva.com if you have any questions or comments about [Trade Name])
- Kills fleas that may cause flea allergy dermatitis(FAD)
- Treatment of cat kills fleas that may cause FAD
- Flea control (for cats and kittens)
- Pyriproxyfen is an insect growth regulator which controls development of immature fleas.
- Picture of cat
- Picture of kitten
- Satisfaction guaranteed or Ceva Animal Health, LLC will supply replacement product
- Persistent efficacy through 30 days
- Prevents (re-)infestation (of fleas) for one month
- Monthly treatment (all year) is recommended for optimal control and prevention of fleas
- Once monthly application
- 3 applicators (doses)
- 3 monthly doses (applications) (treatments)
- 6 applicators (doses)
- 6 monthly doses (applications) (treatments)
- Quick drying, non-greasy
- Easy to apply spot-on (patented) applicator
- Easy to apply spot-on (patented) applicator (allows the product to be applied directly to the skin)
- Convenient, easy to apply
- Fragrance (odor) free
- No noticeable (lingering) odors
- Convenient to use
- Convenient (easy to apply) topical treatment
- Convenient (easy to apply) topical treatment [with (patented) applicator tip] (that allows application down to the skin)

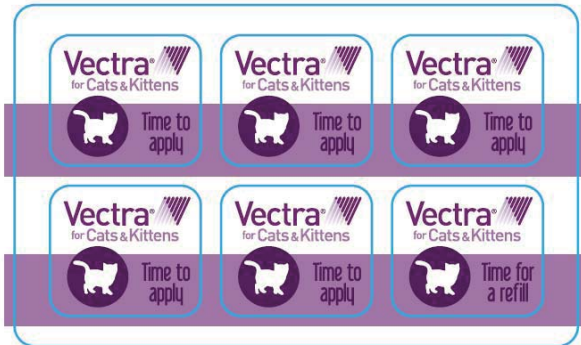
- Formulated for cats and kittens (over 1.5 lbs and over 8 weeks of age)
- Available from (licensed) veterinarians
- Sold by veterinarians
- Available from licensed veterinarians
- C708.0 provides ongoing protection against fleas for one month
- Effective monthly control of all stages of fleas (flea stages)
- After application, C708.0 spreads over the cat's body to provide (full body) (all-over) protection against all stages of fleas
- C708.0 kills fleas within 6 hours
- Questions or comments—please call (tel. no.) or e-mail us at contact.us@ceva.com
- For more information call (tel. no.)
- C708.0 protects cats and kittens from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
- C708.0 protects cats and kittens from fleas and ticks that may carry and transmit *Francisella tularensis*
C708.0 kills fleas that may carry and transmit *Rickettsia felis*, *Rickettsia typhi* and *Francisella tularensis*
- For emergencies call (tel. no.)
- Kills fleas that may transmit bartonellosis , tapeworm and tularemia
- Controls (fleas) (all stages of fleas)
- Easy to apply, effective control of fleas that lasts 1 month (30 days) (4 weeks)
- Kills fleas within 6 hours
- Kills fleas that may transmit bartonellosis and tapeworm
- Regular use breaks the flea life cycle
- Starts working with the first application and continues to kill fleas and immature fleas for up to one month
- Starts with first application, killing fleas in 6 hours
- Recommended for use in an integrated flea management system
- Treatment of cats and kittens with C708.0 kills fleas that may cause flea allergy dermatitis (FAD)
- Kills fleas that may cause flea allergy dermatitis (FAD) and anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats with C708.0 kills fleas that may cause FAD.
- C708.0 contains the insect growth regulator pyriproxyfen that acts to prevent the development of immature fleas for one month (30 days) (4 weeks)
- Regular use (of C708.0) protects your cat and kitten against all stages of the flea life cycle
- Proven treatment technology for problem flea infestations
- Proven treatment technology for flea infestations
- Pyriproxyfen (the insect growth regulator) found in C708.0 stops the development of immature fleas
- Pyriproxyfen controls immature fleas

- A single dose effectively stops flea infestation and prevents re-infestation for one month (30 days, 4 weeks)
- For both indoor and outdoor cats and kittens
- Single spot control for all flea stages
- C708.0 may be used to prevent infestation in flea free cats and kittens
- C708.0 prevents infestation in flea free cats and kittens and protects animals in flea contaminated environments
- Kills adult fleas which may cause flea allergy dermatitis (FAD)
- Patented applicator makes it easier to apply and minimizes risk of skin abrasion
- Controls and stops flea infestations
- Prevents (flea) re-infestation
- Kills fleas and prevents infestation for one month
- Apply monthly for long lasting flea control and year round protection
- C708.0 kills more than the adult fleas you see, it controls immature fleas
- Fleas do not have to bite to die
- C708.0 kills fleas by contact
- C708.0 kills not only adult fleas, it breaks the flea life cycle (flea life cycle diagram)
- Eliminates existing flea infestations on your cat (or kitten)
- Kills adult fleas and controls immature fleas with three effective ingredients (dinotefuran, fipronil, and pyriproxyfen)
- Proven effective topical flea control containing dinotefuran, fipronil, and pyriproxyfen
- After application, C708.0 spreads over the cat's body to provide (full body) (all-over protection against all flea stages)
- Kills fleas before they lay eggs
- Proven treatment technology for flea infestation
- Contains pyriproxyfen an insect growth regulator
- Kills fleas that may cause anemia
- Protect your cat from flea infestation that may cause anemia
- Pyriproxyfen provides ovicidal activity
- Kills all life stages of ticks (larva, nymph and adult), including brown dog ticks (*Rhipicephalus sanguineus*), American dog ticks (*Dermacentor variabilis*), lone star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*).
- Kills ticks that may transmit Lyme disease, cytauxzoonosis, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis.
- Kills ticks that may carry and transmit the causative agent of cytauxzoonosis.
- Kills ticks through contact so they do not have to bite (feed) to die.
- Ticks do not have to bite to die
- Effective monthly prevention and treatment of fleas, ticks, and chewing lice
- Easy, fast, effective control of fleas, ticks, and chewing lice that lasts 1 month.
- Kills ticks that may carry and transmit the organism which causes Lyme disease.
- Kills ticks that may carry and transmit babesiosis.
- Kills ticks that may carry and transmit Ehrlichia.
- C708.0 kills ticks that may carry and transmit *Cytauxzoon felis* (*C felis*).
- Effective monthly treatment of fleas, ticks, and chewing lice.

- Effective monthly treatment of fleas (ticks)(chewing lice)
- Kills fleas (ticks)(chewing lice)
- Available from (Ceva authorized) (Seller authorized)(approved) (endorsed) (certified) (qualified) (licensed) veterinarians.
- This product has been authorized for sale (by) (Ceva) (Seller) (through) veterinarians (in the context of an established veterinarian/client/patient relationship). (Ceva) (Seller) may pursue appropriate (legal) action against any person not so authorized involved in the sale of this product.
- Sold by (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (We)(Ceva)(Seller) (company name) may take appropriate (legal) action if the product is sold by an unauthorized person.
- Sold by (authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (Seller) (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Available from (authorized) (approved) (endorsed) (certified) (qualified) veterinarians. Seller markets this product to (authorized) (approved) (endorsed) (certified) (qualified) veterinarians, who have established (veterinary client relationship) (veterinary patient relationship) (veterinary client patient relationship). Sale or marketing of this product by (unauthorized) (not approved) (non -qualified) persons could result in appropriate action by the (manufacturer) (Ceva) (company name)
- Available from (Ceva authorized) (Seller authorized)(approved) (endorsed) (certified) (qualified) veterinarians.
- Available from licensed veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Sold by veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Sale or marketing of this product by (unauthorized) (not approved) (non -qualified) persons could result in appropriate action by the (manufacturer) (Ceva) (company name)
- Authorized for sale by licensed veterinarians

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:



After applying the first dose, place a sticker on your calendar 30 days from that day for a simple reminder.

Visit VectraPet.com for more information

APPLICATOR LABELING

C708.0 (Vectra Cat Plus Tick)

Alternate Brand Names:

[Vectra Cat Plus Tick] [Vectra Plus for Cats] [Vectra Trio for Cats] [Vectra 3C for Cats] [Vectra III for Cats] [Vectra 3 for Cats] [SimpleGuard for Cats] [FirstShield Trio for Cats] [Catego for Cats] [Catego]

ACTIVE INGREDIENTS:

Dinotefuran.....	22.00%
Fipronil.....	8.92%
Pyriproxyfen.....	3.00%
OTHER INGREDIENTS.....	66.08%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

READ ENTIRE LABEL BEFORE USE

Use only on cats and kittens over 8 weeks of age, weighing 1.5 lbs. and over

0.017 fl. oz. (0.50 mL)

EPA Reg. No. 83399-15

EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)