



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

EPA Reg. Number:

83399-15

Date of Issuance:

9/8/15

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

C708.0 (Vectra Cat Plus Tick)

Name and Address of Registrant (include ZIP Code):

Ceva Animal Health LLC
8735 Rosehill Road
Lenexa, Kansas 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:

9/8/15

Mark Suarez, Product Manager 7
Invertebrate & Vertebrate Branch 3,
Registration Division (7505P)

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Dinotefuran GDCI-044312-1147 issued 3/1/2013
 - b. Fipronil GDCI-129121-1305 issued 3/14/2013
 - c. Pyriproxifen GDCI-129032-1299 issued 2/21/2013

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

3. 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.
4. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 83399-15."
5. This registration is time limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected release for shipment date in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.
6. Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e. no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient).
7. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information (CBI) as such Enhanced incident reporting should be submitted to the Product Manager Quarterly sales information should be submitted to the Registration Division Immediate Office.
8. 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

9. Along with the enhanced incident reporting you must submit an analysis of all incidents seen to include the following details:
- a. All minor dermal and ocular irritation reports.
 - b. 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.
 - c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
 - d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g. multi pet households).
 - e. 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.
 - f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - g. 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.
 - h. Table showing number of incidents for each dog breed.
 - i. Table showing number of incidents in dogs for each clinical sign.
 - j. Table showing number of incidents in dogs for each organ system.
 - k. Report aggregate incidents but do not combine moderate and minor incidents.

10. If EPA determines that future mitigation measures are necessary for all pet spot on products the Agency will inform all registrants concerned. If mitigation measures are necessary EPA may take regulatory action.
11. Ceva should adequately address all of the mitigation actions identified in the Agency's Generic Pet Spot On Mitigation Plan available at the following internet site
<http://www.epa.gov/pesticides/health/spot-on-meetings/html>.
12. 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 also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/30/2014

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

Enclosure

FRONT PANEL OF OUTER BOX

C708.0 (Vectra Cat Plus Tick)

Picture of Cat
according to
weight range

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]

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

Kills adult fleas, ticks, (and) chewing lice

(Optional marketing claims—front or back or side panels/continued on pages 5-7)

ACTIVE INGREDIENTS:

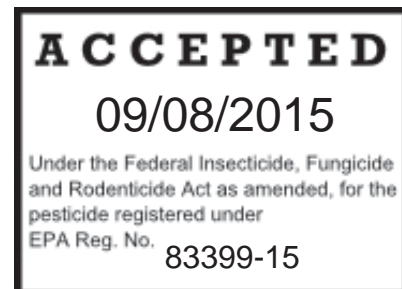
Dinotefuran.....	22.00%
Fipronil.....	8.92%
Pyriproxyfen.....	3.00%
OTHER INGREDIENTS.....	<u>66.08%</u>
TOTAL.....	100.00%

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
3 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

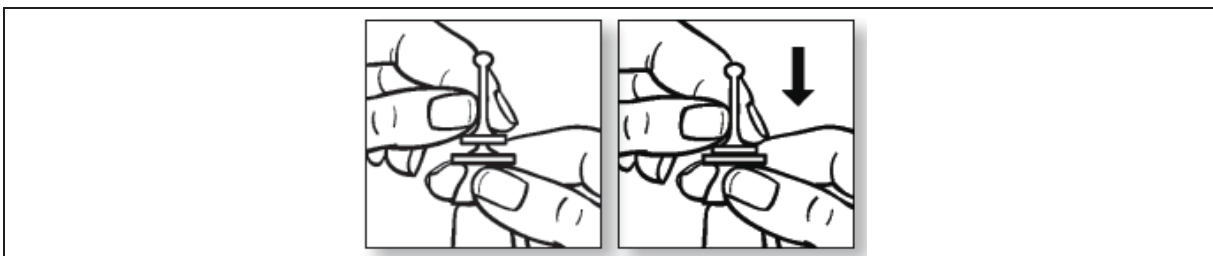
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [Precaución al consumidor: si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente. (To the User: If you cannot speak English, do not use this product until the 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, (flea) pupae, ticks (and) chewing lice year-round treatment is recommended.
-

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)]
[3 (doses)(applications)(applicators)]
[each 0.017 fl oz (0.5 ml)]

EPA Reg. No. XXXX
EPA Est. No. XXXX

[Sold by:]
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 for one month
- For cats and kittens over 1.5 lbs and (over) 8 weeks of age (or older), three (single) dose(s) (applicators)
- Effective monthly treatment of (against) fleas
- Protects from fleas for one month
- Protects cats and kittens from the development of anemia associated with (severe) flea infestation
- 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)
- Flea control (for cat and kittens)
- C708.0 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect.
- 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) on your (cat) (kitten) 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)
- 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)

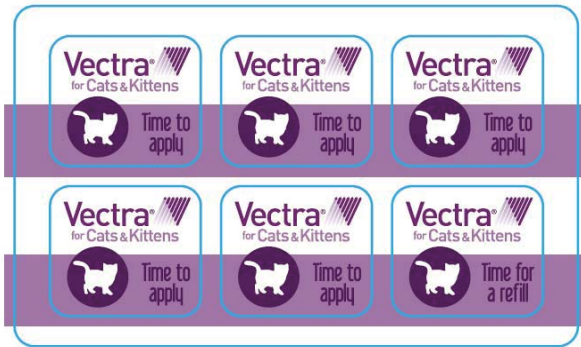
- Available from (licensed) veterinarians
- C708.0 provides ongoing protection against fleas for (cats)(and) (kittens) for one month
- After application, C708.0 spreads over the cat's body to provide (full body) (all-over) protection against fleas
- C708.0 kills fleas within 6 hours
- Questions or comments—please 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
- Easy to apply, effective control of fleas that lasts 1 month (30 days) (4 weeks)
- Kills fleas that may transmit bartonellosis and tapeworm disease
- Starts working with the first application and continues to kill 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.
- Proven treatment technology for (problem) flea infestations on (cats)(and)(kittens)
- A single dose effectively stops flea infestation and prevents re-infestation on (cats)(and) (kittens) for one month (30 days, 4 weeks)
- For both indoor and outdoor cats and kittens
- Single spot control for fleas
- 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 that may cause flea allergy dermatitis (FAD)
- Patented applicator makes it easier to apply and minimizes risk of skin abrasion
- Controls and stops flea infestations on (cats)(and) (kittens)
- Prevents (flea) re-infestation on (cats)(and) (kittens)
- Kills fleas and prevents infestation on (cats)(and) (kittens) for one (1) month
- Apply monthly for long lasting flea control and year round protection for your (cat) (kitten)
- Fleas do not have to bite to die

- C708.0 kills fleas by contact
- Eliminates existing flea infestations on your cat (or kitten)
- Kills adult fleas with two effective ingredients (dinotefuran and fipronil)
- 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 fleas, ticks and chewing lice)
- Kills fleas before they lay eggs
- Kills fleas that may cause anemia
- Protect your cat from flea infestation that may cause anemia
- Kills ticks that may transmit Lyme disease, haemobartonellosis, ehrlichiosis, babesiosis, and anaplasmosis.
- 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.
- Effective monthly treatment of fleas (ticks) (and 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]

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. XXX
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)