

83399-12

2/7/2014

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U.S. ENVIRONMENTAL PROTECTION
 AGENCY
 Office of Pesticide Programs
 Registration Division (7505C)
 Ariel Rios Building
 1200 Pennsylvania Ave., NW
 Washington, D.C. 20460

EPA Reg.
 Number:
 83399-12

Date of Issuance:
FEB - 7 2014

NOTICE OF PESTICIDE:
 Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance: **Conditional**

Name of Pesticide Product:
CAH12

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/reregistered 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 sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data. You must comply with DCI ID# GDCI 044312-1147 issued on 3/1/2013. If you have questions about the Generic DCI issued, you may contact Steven Snyderman from the Pesticide Re-evaluation Division.
2. Submit one year storage stability (830.6317) and corrosion characteristics (830.6320) studies. These studies can be run concurrently. Observation must be made at 0, 3, 6, 9, and 12 months period and the results must be submitted to the Agency upon completion. These studies must be submitted within 18 months from today's date.
3. Make the following label change:
 Add the phrase "EPA Registration Number 83399-12" to the front panel.

Signature of Approving Official:

Meredith Laws

Meredith Laws, Chief
 Insecticide Rodenticide Branch
 Registration Division

Date:

02/07/2014

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EPA Reg. No. 83399-12

4. For future submissions, make the following changes to your Confidential Statement(s) of Formula (EPA Form 8570-4):

In Box 4, revise the EPA Reg. No. so it reads, "EPA Reg. No. 83399-12".

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Submit one copy of the revised final printed label before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Copies of product chemistry, acute toxicity, and efficacy reviews have been sent to you by e-mail. If you have any questions, contact Rita Kumar at (703) 308-8291, or kumar.rita@epa.gov.

Sincerely,

Meredith Laws, Chief
Insecticide Rodenticide Branch
Registration Division (7505P)

Enclosure

"Master Label"

(This master label includes label text)

[Label Front Panel]

CAH12

Alternate Brand Names:

- Vectra Flea Spray**
- FirstShield Flea Spray**
- SimpleGuard Flea Spray**
- Vectra Pro Flea Spray**
- FirstShield Pro Flea Spray**
- SimpleGuard Pro Flea Spray**
- Vectra Flea Strike**
- FirstShield Flea Strike**
- SimpleGuard Flea Strike**

Picture Dog & Cat

ACCEPTED
FEB - 7 2014

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 83399-12

- Effective (efficacious) flea control
- For (use on) Dogs, Puppies, Cats and Kittens over 8 weeks of age
- Convenient, easy to apply, odor free

(Optional marketing claims on pages 6-9)

Active Ingredient

Dinotefuran.....	0.46%
Other Ingredients.....	99.54%
Total.....	100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**See insert (Peel back label) (Unfold label) for directions for use, precautionary statements,
(and) first aid, (and other information)**

Net Contents:

**10 fl oz, 300mL
(17 fl oz, 500ml)**

**EPA Registration No. 83399-RE
EPA Establishment No. xxxx-xx**

[Label Panel]

READ ENTIRE LABEL BEFORE EACH USE

For external use only on dogs over 5 lbs and cats over 3 lbs and 8 weeks of age or older

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Harmful if swallowed. Avoid contact with skin, eyes and clothing. Avoid breathing spray. Wash hand thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

CAUTION: External use only. Use only on dogs and cats. May cause eye irritation. Take care not to spray in the animal's eyes or nose area. Do not use on kittens less than 3 lbs or puppies less than 5 lbs or under 8 weeks of age. Do not use on irritated skin. Individual sensitivities, while rare, may occur after using any pesticide product. If signs persist or become severe, consult a veterinarian. Do not use this product on debilitated, aged, medicated, pregnant or nursing dogs or cats. Dogs and cats known to be sensitive to pesticide products should only use after first consulting a veterinarian. Do not re-treat before 14 days.

PHYSICAL OR CHEMICAL HAZARDS Flammable: Keep away from heat and open flame. Do not mix or allow coming into contact with oxidizing agents. Hazardous chemical reaction may occur.

FIRST AID	
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, and then continue rinsing. Call a poison control center or doctor for treatment advice.
If swallowed:	Call a poison control center or doctor 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 inhaled:	Move person to fresh air. If person is not breathing call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call poison control center or doctor for further treatment advice.
If on skin or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. If skin appears irritated after rinsing call a poison control center or doctor 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 weekdays between 9am and 6pm EST or 1-888-426-4435 for emergency medical treatment information.	

(Side Effects: Monitor your pet after application. Individual sensitivity, such as slight transitory redness, erythema, pruritus or other signs of discomfort at the site(s) of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog or 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 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).]

Follow all directions and precautionary statements carefully. **Use only on dogs and cats.**

HOW TO APPLY:

Spray the entire body of the dog or cat applying from a distance of 5 to 10 inches. Ruffle the coat especially in long haired or densely coated animals. Apply against the lay of the hair; so that the product penetrates down to the skin. For head and eye area spray on cloth and rub gently into the animals hair. Avoid spraying directly on the animals' eyes or nose. Make sure the entire coat of the animal is thoroughly covered. Wash hands thoroughly with soap and water after application.

1. The dog or cat should be standing or in a comfortable position for easy application.
2. Calculate the number of spray pumps based on the weight of the dog or cat. Your veterinarian or veterinary technician (nurse) can help with calculations using the charts below if needed.
3. Application charts for Dogs and Cats are shown below.

Cats

Cat weight (lbs)	(Application Volume) (1.3ml/spray)	Actual number of sprays to be applied
3.0-5.0 lbs	(3.9ml)	3
5.1-7.0 lbs	(5.2ml)	4
7.1-10.0 lbs	(6.5ml)	5
10.1-14.5 lbs	(7.8ml)	6
> 14.5 lbs	(9.1ml)	7

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Dogs

Dog weight (lbs)	(Application Volume) (1.3ml/spray)	Actual number of sprays to be applied
5.0-7.0 lbs	(5.2ml)	4
7.1-10.0 lbs	(6.5ml)	5
10.1-14.0 lbs	(7.8ml)	6
14.1-17.0 lbs	(9.1ml)	7
17.1-22.0 lbs	(10.4ml)	8
22.1-26.0 lbs	(11.7ml)	9
26.1-29.0 lbs	(13.0ml)	10
29.1-33.0 lbs	(14.3ml)	11
33.1-35.5 lbs	(15.6ml)	12
35.6-39.0 lbs	(16.9ml)	13
39.1-44.0 lbs	(18.2ml)	14
44.1-49.0 lbs	(19.5ml)	15
49.1-54.0 lbs	(20.8ml)	16
54.1-59.0 lbs	(22.1ml)	17
59.1-65.0 lbs	(23.4ml)	18
65.1-70.0 lbs	(24.7ml)	20
> 70 lbs	(26.0ml)	21 Plus one additional spray for every 5lbs over 75 lbs

4. **Cats / Kittens:** Restrain (scruff) and apply the required number of sprays over the entire body of the cat.

Dogs/ Puppies: Restrain (scruff) and apply the required number of sprays over the entire body of the dog, including the sides, abdomen, legs, shoulders, tail and neck

OR-

Dogs / Puppies: Apply approximately one fifth of the total number of spray pumps required to each of 5 areas of the dog.

- **Area 1:** Left side of the dog. Start at the front left paw and spray up over the front leg, over the side of the chest and abdomen and the down the back leg to the paw.
- **Area 2:** Right side of the dog. Follow directions for Area 1 on right side.
- **Area 3:** Top of the chest, back and rump continuing to the tip of tail.
- **Area 4:** Top and side of the neck, and jaw.
- **Area 5:** Bottom of the jaw, neck and chest, the abdomen and groin and inside all 4 legs, over lapping the areas to ensure total cover.

As with any flea control product, wash hands and exposed skin thoroughly with soap and water after use.

STORAGE & DISPOSAL:

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

PESTICIDE STORAGE:

Store unused product in original container only. Keep out of reach of children and animals.

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 or 1-800-CLEANUP. Never place unused product down any indoor or outdoor drain.

[Package Insert] (Full label text plus additional copy)

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 damage 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 package insert and / or label back and/or side panels)]

- Vectra Spray (alternate product name) contains the insecticide Dinotefuran, a neonicotinoid with both knockdown and adulticidal activity
- Controls fleas (on dogs and cats)
- Starts killing fleas by (in) (2) hours
- Dead fleas start falling from treated animals within (2) hours (post treatment)
- Tough on fleas
- Lasts for up to 5 days
- Up to 5 day (flea) protection
- Treats (protects) for up to 5 days
- Continuous treatment (protection provided) for up to 5 days
- Effective treatment for immediate control of fleas
- Easy (convenient) spray-on application
- Performance guaranteed or your money back (Ceva icon) (Please call our professional staff at xxx-xxx-xxxx if you have any questions or comments about CAH12)
- Kills fleas that may cause flea allergy dermatitis (FAD) and anemia
- Kills fleas that may transmit bartonellosis and tapeworm
- Kills *Siphonapterae* insects on your dogs and cats
- Kills *Ctenocephalides felis* and *Ctenocephalides canis* on your dogs and cats
- Performance guaranteed or Ceva will supply replacement product or your money back
- Begins killing by (within) (2) hours
- Quick drying, non-greasy
- Quick drying
- Non-greasy
- Rapid kill of (onset of activity on) fleas is important in the prevention of disease transmission by (these) parasites
- Available from licensed veterinarians
- Easy (and convenient) to apply, effective control for fleas that applies in seconds (and works for days)
- Proven treatment technology for flea infestation
- Easy to use spray makes treatment simple (trouble free, smooth) and comfortable for your dog and cat
- A homogenous application for the whole body
- CAH12 controls infestation in flea infested dogs and cats
- 21st century flea control
- Fleas do not have to bite to die
- Kills fleas (through)(by) contact
- Sprays on in seconds, works in (2) hours (lasts for up to 5 days)
- Convenient (easy) to apply
- CAH12 (contains dinotefuran, a neonicotinoid insecticide) with flea knockdown in minutes

CAH12
EPA Registration 83399-RE
Labeling
January 22, 2014

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- Questions or comments please call (tel. no.xxx-xxx-xxxx) (or e-mail us at contact.us@ceva.com)
- For more information call (tel. no.xxx-xxx-xxxx) (or e-mail us at contact.us@ceva.com)
- For emergencies call (tel. no. xxx-xxx-xxxx)
- Kills fleas including those that may transmit bartonellosis, tapeworm and cause flea allergy dermatitis (FAD)
- Kills newly emerged adult fleas before they lay eggs
- Kills fleas that may cause anemia
- "Picture of a flea"
- For the treatment and prevention of fleas
- Single application provides up to 5 days protection
- Single application lasts for up to 5 days
- Contains the proven effective topical, dinotefuran, for fast effective flea control
- Protects traveling dogs and cats
- Ideal for use on dogs or cats in (hospitals) (and kennels) (and boarding facilities) (and groomers) (and homes)
- Treatment for boarding (boarded) dogs or cats
- Treat dogs and cats before fleas infest your (hospitals) (and kennels) (and boarding facilities) (and groomers) (and homes)
- Protect your (hospitals) (and kennels) (and boarding facilities) (and groomers) (and homes) from flea infested dogs and cats
- Short term flea treatment for dogs and cats (in hospitals) (and kennels) (and boarding facilities) (and groomers) (and homes)
- CAH12 is the only spray flea control product containing Dinotefuran
- CAH12 provides effective (short term) flea control for dogs and cats 8 weeks of age and older
- Fragrance (odor) free
- No noticeable (lingering) odors
- Noiseless (quiet) spray application
- Available from (licensed) veterinarians
- Sold by veterinarians

- CAH12 protects dogs and cats from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
 - CAH12 protects cats from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
 - CAH12 protects dogs from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
- CAH12 protects cats and dogs from fleas that may carry and transmit *Francisella tularensis*
 - CAH12 protects cats from fleas that may carry and transmit *Francisella tularensis*
 - CAH12 protects dogs from fleas that may carry and transmit *Francisella tularensis*
- CAH12 kills fleas that may carry and transmit (*Rickettsia felis*), (*Rickettsia typhi*) and (*Francisella tularensis*), (*Bartonella henselae*) (*Dipylidium canium*)
- CAH 12 protects cats and dogs in flea contaminated environments
 - CAH 12 protects cats in flea contaminated environments
 - CAH 12 protects dogs in flea contaminated environments
- Kills existing flea infestations on your dogs and cats
 - Kills existing flea infestations on your dog(s)
 - Kills existing flea infestations on your cat(s)
- Available from (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (Ceva) (Seller) may take appropriate (legal) action against any person not so authorized involved in the sale of this product.
- This product has been authorized for sale by (Ceva) (Seller) exclusively 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 only 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 legal action by the (manufacturer) (Ceva) (company name).
- Available from (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians.
- (Ceva) (Seller) may take appropriate (legal) action against any person not so authorized involved in the sale of this product.
- Available from licensed veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.

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- (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)
- Keeps dogs and cats happy and healthy by protecting them from fleas
- Protects your dogs and cats from flea bites, (pruritus), (flea bite hypersensitivity), (flea allergy dermatitis), (flea infestation)
- Untreated fleas can lead to disease transmission and home infestation, protect your dogs and cats with CAH12
- CAH12 is a spray which provides fast relief from fleas
- Provides fast relief (from fleas) (for dogs and cats)
- Protects your dogs and cats against (noxious) (painful) flea bites by (within) (2) hours
- Applies in seconds fleas begin falling (dead) off your dogs and cats by (within) (2) hours
- CAH12 provides flea control for treating boarding (boarded) dogs and cats
 - CAH12 provides flea control for treating boarding (boarded) dogs
 - CAH12 provides flea control for treating boarding (boarded) cats
- CAH12 proactive flea control for dogs and cats in your clinic
- CAH12 proactive flea control for dogs and cats in your hospital
- Kills fleas for up to 5 days
- For optimal flea control, we recommend that you continue to treat your (dog) (cat) (dog and cat) monthly (and year round) with (Vectra 3D for Dogs & Puppies) (FirstShield Trio) (SimpleGuard 3) (Vectra for Cats & Kittens) (Vectra for Cats) (FirstShield for Cats & Kittens) (FirstShield for Cats) (SimpleGuard for Cats & Kittens) (SimpleGuard for Cats) (Vectra for Dogs & Puppies) (FirstShield Dogs & Puppies)

Manufactured for [Sold by:]
[Ceva Animal Health LLC, 8735 Rosehill Rd., Lenexa, Kansas 66215]