

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 7, 2014

Ms. Alicia Henk
Director, Pharmaceutical Development and Regulatory Affairs
Ceva Animal Health
8735 Rosehill Rd., Suite 300
Lenexa, KS 66215

Subject: Label Notification per PRN 98-10: Alternate brand name and a minor label revision
Product Name: SVP9 for Dogs
EPA Registration Number: 83399-10
Application Date: 6/17/2014 and 7/30/2014
Decision Number: D492620

Dear Ms. Henk:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name Vectra has been added to the product record. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Rita Kumar at 703-308-8291 or via email at kumar.rita@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Meredith F. Laws".

Meredith F. Laws, Chief
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

“Master Label”

(This master label includes label text for different size packages and application rates specific to the pet’s age and body weight)

FRONT PANEL OF OUTER BOX

NOTIFICATION SVP9 for Dogs

08/07/2014

Picture of Dog/Puppy
according to weight
range

Alternate Brand Names:

[Vectra] [Vectra D] [Vectra Plus] [Vectra 2D] [Vectra Excel] [Vectra Dual] [Vectra Duo]
[Vectra II] [Vectra +] [Vectra 2] [Vectra Gold] [Vectra Shield]
[for Dogs and Puppies 2.5 to 10 lbs, 8 weeks of age and older]
[for Dogs and Puppies 11 to 20 lbs., 8 weeks of age and older]
[for Dogs and Puppies 21 to 55 lbs., 8 weeks of age and older]
[for Dogs and Puppies 56 to 100 lbs., 8 weeks of age and older]
[for Dogs over 100 lbs]

[FOR DOGS & PUPPIES – Use only on dogs weighing 2.5 to 10 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing 11-20 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing 21-55 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing 56-100 lbs. and 8 weeks or older]
[FOR DOGS & PUPPIES – Use only on dogs weighing over 100 lbs. and 8 weeks or older]

Effective monthly control of adult fleas, (flea) eggs, (flea) larvae and (flea) pupae
(Optional marketing claims –see pages 6-9)

ACTIVE INGREDIENTS:

Dinotefuran.....22.00%
Pyriproxyfen.....3.00%
OTHER INGREDIENTS.....75.00%
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: XXX fl oz
X Doses [each dose, xxx fl oz (xx ml)]



[ICON OF CAT (1.5 cm X 1.5 cm) PLACED ON LOWER FRONT PANEL

BACK PANEL OF OUTER BOX AND INSERT LANGUAGE
(the text below appears on both the outer box and on the package insert)

(Optional marketing claims –see pages 6-9)

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed or 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, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only. Do not use on puppies less than 8 weeks old.

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 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 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 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 dog after application. Individual sensitivity, such as slight transitory redness, erythema, itching –pruritus- or other signs of discomfort at the site of application, may occur after using ANY pesticide product for dogs. If signs of sensitivity occur, bathe your dog 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 signs 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.



(alternate brand name graphic may vary)

Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

EPA Reg. No. 83399-10
EPA Est. No. TBD

[Made in the USA (by)] [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]

ADDITIONAL INSERT LANGUAGE

(the text below only appears on the package insert)

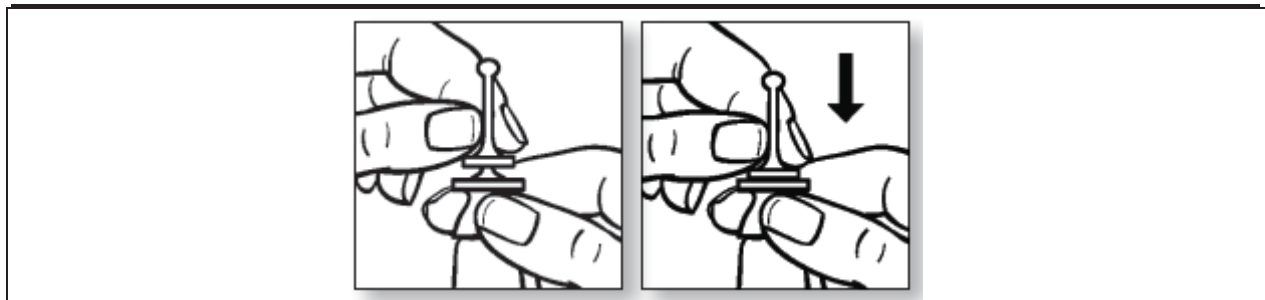
DIRECTIONS FOR USE

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).]

HOW TO APPLY:

1. **Use Restrictions: USE ONLY ON DOGS. Do not use on cats or other animals. Do not have contact or allow children to have contact with treated areas until treatment is completely dry.**
2. Remove applicator (tube) from package.
3. The dog should be standing or in a comfortable position for easy application.
4. Holding the (applicator) tube upright, pointing away from face, place thumb and index finger around the applicator tip under the large disk. With other hand, grasp the stem of applicator tip above smaller disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)



5. [For dogs weighing under 10 lbs.] [For dogs weighing 11 to 20 lbs] Using the tip of the applicator, [part the hair between the shoulder blades and] slowly apply the product (to one spot) (as shown below) directly onto the skin until the applicator (tube) is (completely) empty. [Avoid superficial application to the animal's hair.]

OR:

[For dogs weighing 21 to 55 lbs] Using the tip of the applicator, [part the hair down to the level of the skin and] slowly apply the product evenly to three spots along the dog's back (directly onto the animal's skin), beginning between the shoulder blades and continuing in the order shown in the diagram below, until the (tube) applicator is (completely) empty. [Avoid superficial application to the animal's hair.]

OR:

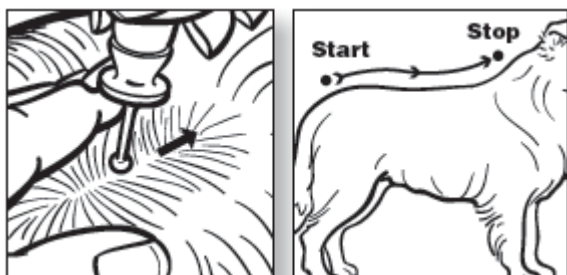
[For dogs weighing 56 to 100 lbs] [For dogs weighing over 100 lbs] Using the tip of the applicator, [part the hair down to the level of the skin and] slowly apply the product evenly to four spots on the dog's back (directly onto the animal's skin), beginning between the shoulder blades and continuing in the order shown in the diagram below, until the applicator (tube) is (completely) empty. [Avoid superficial application to the animal's hair.]

OR:

(For dogs 100 lbs or greater combine SVP9 56-100 lbs with the appropriate SVP9 size to approximate the total weight of the dog. Using the tip of the applicator, part the hair down to the level of the skin and slowly apply the product evenly to four spots on the dog's back, beginning between the shoulder blades and continuing in the order shown on the SVP9 56-100 lbs package diagram, until both applicators (tubes) are empty.) [Avoid superficial application to the animal's hair.]

OR:

(For all dog weights) Using the applicator tip, part the hair at the base of the tail and begin applying the product onto the skin in a continuous line from the base of the tail along the center of the back all the way up to the shoulder blades, as shown in the diagram, squeezing the applicator tube until it is empty. [Avoid superficial application to the animal's hair.]



Do not get the product in the dog's eyes or mouth.

6. Discard empty applicator (tube) as outlined in the storage and disposal section.
7. Repeat every month, or as recommended by your veterinarian
8. For optimal treatment, control and prevention of fleas, flea eggs, flea pupae and flea larvae (all) year-round treatment is recommended.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in a cool, dry place. Protect from freezing. **KEEP OUT OF REACH OF CHILDREN.**

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: XXX fl oz (XXX ml)

[[1] [2] [3] [4] [6] [8] [9] [12] [18] [24] [36] [applications]][applicators]]

[each 0.044 fl oz, (1.3 ml)]

[each 0.068 fl oz (2.0 ml)]

[each 0.135 fl oz (4.0 ml)]

[each 0.204 fl oz (6.0 ml)]]

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 the front, side, or back panels of the outer box or package insert)

- For dogs and puppies 8 weeks of age or older weighing 2.5 to 10 lbs (1.3ml)
- For dogs and puppies 8 weeks of age or older weighing 11 to 20 lbs (2.0ml)
- For dogs and puppies 8 weeks of age or older weighing 21 to 55 lbs (4.0ml)
- For dog and puppies over 8 weeks of age or older weighing 56 to 100 lbs (6.0ml)
- For dogs over 100 lbs (7.4ml)
- Effective monthly treatment of (against) fleas, flea eggs, larvae and pupae
- Protects (your dog and puppy 8 weeks of age or older) from all stages of fleas for one month
- Protects from fleas for one month
- Kills newly emerged fleas before they lay eggs
- Kills fleas within 6 hours
- Formulated for dogs (and puppies over 8 weeks of age 1.3, 2.0, 4.0 ,6.0 and 7.4ml)
- Flea treatment formulated for dogs (and puppies over 8 weeks of age 1.3, 2.0, 4.0 ,6.0 and 7.4ml)
- Easy, spot on (topical) application
- Satisfaction guaranteed or your money back Ceva ICON) (Please call our professional staff at xxx-xxx-xxxx if you have any questions or comments about SVP9)
- Kills fleas that may cause flea allergy dermatitis (FAD) and anemia
- Kills fleas that may transmit bartonellosis and tapeworm disease
- Controls development of fleas, flea eggs, larvae and pupae for one month
- Convenient topical treatment formulated for dogs
- Controls adult fleas, (flea) eggs, larvae and pupae
- Convenient topical treatment formulated for dogs (and puppies 1.3, 2.0, 4.0 6.0 and 7.4ml)
- (Patented) applicator tip for easy application
- Satisfaction guaranteed (Ceva ICON) Please call our professional staff (experts) at xxx-xxx-xxxx if you have any questions or comments about (insect infestations) or SVP9
- SVP9 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect. Pyriproxyfen is an insect growth regulator which controls development of all flea stages.
- Using the (patented) (Trademark) applicator, SVP9 is specially designed to spread over the dog's body providing effective control of immature flea stages for thirty days (four weeks, one month).
- Picture of dog or puppy(older than 8 weeks)
- Protects dogs (and puppies over 8 weeks 1.3, 2.0, 4.0 ,6.0 and 7.4ml) by controlling fleas, flea eggs, flea larvae and flea pupae for one month
- Controls fleas, flea eggs, flea larvae and flea pupae for one month
- Performance guaranteed or Ceva Animal Health, LLC will supply replacement product
- Onset of activity within 2 hours
- Persistent efficacy through 30 days
- Prevents (re-)infestation for one month
- Monthly treatment (all year) is recommended for control and prevention of fleas
- Once monthly application

- X applicators (tubes)
- X monthly doses (applications) (treatments)
- Quick drying, non-greasy
- Easy to apply spot-on (topical) application
- Convenient, easy to apply
- Fragrance (odor) free
- No noticeable odors
- Convenient to use (easy to apply)
- Convenient (easy to apply) topical treatment (with (patented) applicator tip) [that allows application (down) to the skin]
- Convenient topical treatment formulated for dogs (and puppies over 8 weeks 1.3, 2.0, 4.0, 6.0 and 7.4ml)
- Formulated for dogs (and puppies over 8 weeks 1.3, 2.0, 4.0, 6.0 and 7.4ml)
- Rapid kill of fleas is important in the prevention of disease transmission by (these) parasites
- (Only) Available from licensed veterinarians (only)
- Sold (only) by veterinarians (only)
- After application, SVP9 spreads across the dog's (and/or puppies 1.3, 2.0, 4.0, 6.0 and 7.4ml dose) body to provide (full body) (all-over) protection against fleas
- SVP9 provides ongoing protection against fleas which may transmit disease for one month
- Effective monthly control of all stages of fleas
- SVP9 contains dinotefuran, a neonicotinoid insecticide with knockdown, which is specific to the nervous system of insects.
- SVP9 contains dinotefuran, a neonicotinoid insecticide with knockdown, specific to the acetylcholine receptors of the insect nervous system
- Dinotefuran kills fleas within 6 hours
- SVP9 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.) or email us at contact.us@ceva.com
- For emergencies call (tel. no.)
- Kills fleas that may transmit diseases, including bartonellosis, tapeworm and tularemia
- Kills fleas
- Easy to apply, effective control of fleas that lasts 1 month
- Kills fleas in 6 hours
- Acts to kill fleas that may transmit disease, such as bartonellosis, and tape worm tularemia
- Regular (monthly) use breaks the flea life cycle
- Starts working with first application and continues to control all stages of fleas for one month
- Starts with first application, killing fleas in 6 hours
- Treatment of dogs (and puppies 1.3, 2.0, 4.0, 6.0 and 7.4 ml dose) with SVP9 kills fleas that may cause flea allergy dermatitis (FAD)
- SVP9 contains the insect growth regulator pyriproxyfen that acts to prevent the development of all stages of fleas for one month

- Regular use (of SVP9) protects your dog (and puppy) against all stages of the flea life cycle
- May be used on puppies from 8 weeks of age
- Regular use (of SVP9) breaks the flea life cycle
- Protects against all stages of the flea life cycle
- Controls development of all fleas stages for one (1) month
- Proven treatment technology for flea infestation
- Proven treatment technology for all stages of flea infestations
- Pyriproxyfen arrests the development of immature fleas
- Pyriproxyfen metabolically attacks fleas
- Prevents re-infestation (by fleas) for one month
- Available in (5),(4) sizes for (accurate) dosing
- Easy to use, (patented) applicator makes treatment simple (trouble free, smooth) and comfortable for your pet (dog, puppy over 8 weeks of age)
- No drip applicator
- For indoor dogs
- For indoor and outdoor dogs
- No drip applicator, squeeze tube to dispense for easy application
- The (patented) applicator (tip) offers a rounded end minimizing possibility for skin abrasions
- SVP9 prevents infestation in flea free dogs (puppies over 8 weeks) and protects animal in flea contaminated environments
- A single dose effectively stops flea infestation and prevents re-infestation for one month
- SVP9 may be used to prevent re-infestation in dogs (and puppies over 8 weeks) that are flea free
- SVP9 kills fleas on your dog and the emerging fleas in your dog's (pet's) environment
- Kills adult fleas which may cause Flea Allergy Dermatitis (FAD)
- 21st century flea control
- One piece applicator allows for easy (more convenient) administration
- Provides ongoing protection against fleas and the diseases they may transmit for one month
- SVP9 protects dogs (and puppies over 8 weeks) from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
- SVP9 protects dogs (and puppies over 8 weeks) from fleas that may carry and transmit *Francisella tularensis*
- SVP9, flea control for an age old problem
- Dog (veterinary, summit, canine, pooch) (24 and 36 applicator packs)
- Kills fleas which may cause anemia
- Fleas do not have to bite to die
- Contains pyriproxyfen an insect growth regulator
- Kills fleas that may cause anemia
- Protects your dog from flea infestation that may cause anemia
- SVP9 provides ovicidal activity
- Remains effective after exposure to sunlight

- Proven treatment (technology) for flea infestation
- SVP9 kills by contact
- Fleas do not have to bite to die
- 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 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.
- (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)

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

NEXT DOSE STICKERS AND REMINDER CALENDAR

It can be hard to remember when your dog's due for its next dose of Product. So we developed these tools to help you keep track of every dose. When you use the last tube in this package, call your veterinarian to order more Product.

Attach these stickers to your wall calendar or day planner on the date you give the first dose of Product, and then place another sticker on the same date for each of the next two months.



To use the calendar, simply write in the dates you are planning to use Product. Then, peel off the backing and place it in a hard-to-miss location.

Jan	Feb	Mar	Apr	May	Jun
DATE:	DATE:	DATE:	DATE:	DATE:	DATE:
Jul	Aug	Sep	Oct	Nov	Dec
DATE:	DATE:	DATE:	DATE:	DATE:	DATE:

APPLICATOR LABELING

SVP9 for Dogs & Puppies

Alternate Brand Names:

**[Vectra D] [Vectra Plus] [Vectra 2D] [Vectra Excel] [Vectra Dual] [Vectra Duo] [Vectra II]
[Vectra +] [Vectra 2] [Vectra Gold] [Vectra Shield]
[for Dogs and Puppies 2.5 to 10 lbs, 8 weeks of age and older]
[for Dogs and Puppies 11 to 20 lbs., 8 weeks of age and older]
[for Dogs and Puppies 21 to 55 lbs., 8 weeks of age and older]
[for Dogs and Puppies 56 to 100 lbs., 8 weeks of age and older]
[for Dogs over 100 lbs]**

Dinotefuran.....22.00%
Pyriproxyfen.....3.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

READ ENTIRE LABEL BEFORE USE

Use only on dogs & puppies over 8 weeks of age weighing (insert weight range) lbs.



(0.044 fl. oz.) 1.30 ml
(0.068 fl. oz.) 2.00 ml
(0.135 fl. oz.) 4.00 ml
(0.204 fl. oz.) 6.00 ml
(0.250 fl. oz.) 7.40 ml

EPA Reg. No. 83399-10
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)