



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Katy Hernandez
Regulatory Specialist
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

Subject: Notice of Extension of Conditional Registration until June 19th, 2022
Decision: 561913

Dear Ms. Hernandez:

This letter is in reference to your request dated 03/02/2020 to extend the following conditional time-limited registration:

SVP 9 for Dogs EPA Reg. No. 83399-10

The above-referenced registration contains conditions calling for the registration to expire two years from the date the product was first released for shipment (i.e, June 19th, 2020). Additionally, your company is required to adhere to the spot-on label mitigation, submit quarterly enhanced incident reports and quarterly sales information fthe above registration.

The Agency has found Ceva in compliance with the terms and conditions for the subject product. Therefore, the following change is being made to the terms and conditions of the product listed above:

- **The 2-year time-limited registration restriction has been extended an additional two (2) years. Therefore, the new expiration date for the subject product registration is now 06/19/2022**

Please note that these spot-on products are still subject to all other previous required conditions of registration. If you have any questions, please contact Scott Campbell at Campbell.Scott@epa.gov or at (703) 347-0479.

Sincerely,

A handwritten signature in blue ink, appearing to read "Gene Benbow".

Gene Benbow, Product Manager 7
Invertebrate & Vertebrate 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 braces{} are informational to the EPA, but will not be printed. Text that appears in brackets are optional.

{FRONT PANEL OF OUTER BOX}

{Market Label-

The word Dog will be at least 75% in height of the largest letter in the primary brand name.

A large clear picture of a dog in the respective weight range will be on the front panel of the label.}

SVP9 for Dogs

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**

{The above brand names will be packaged in the weight ranges below:}

2.5 to 10 lbs., over 8 weeks of age (0.044 fl. oz.) (1.30 mL)

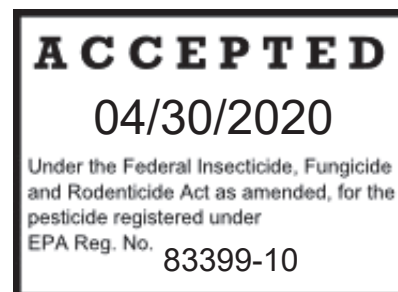
11 to 20 lbs., over 8 weeks of age (0.068 fl. oz.) (2.00 mL)

21 to 55 lbs., over 8 weeks of age (0.135 fl. oz.) (4.00 mL)

56 to 100 lbs., over 8 weeks of age (0.204 fl. oz.) (6.00 mL)

[over 100 lbs. (0.250 fl. oz.) (7.40 mL)]

{Outer box will list only one weight range based on the package dose volume}



Effective monthly control of[:] adult fleas, (flea) eggs, and (flea) larvae
[Optional marketing claims –see pages 7-10]

ACTIVE INGREDIENTS:

Dinotefuran.....22.00%

Pyriproxyfen.....3.00%

OTHER INGREDIENTS.....75.00%

TOTAL.....100.00%

Net Contents: XXX fl oz

X Doses, each dose xxx fl oz (xx ml)

**KEEP OUT OF REACH OF CHILDREN
WARNING**

See package insert for complete Directions For Use, Storage and Disposal, and other information.

FOR DOGS & PUPPIES – Use only on dogs weighing (insert product weight range) lbs. and 8 weeks or older



{Cat prohibition icon 1.5 cm X 1.5 cm} (placed on lower front panel)

{BACK PANEL OF OUTER BOX}

[Optional marketing claims –see pages 7-10]

| 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 by mouth 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 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 for emergency medical information. | |

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE WEIGHING 2.5-10 lbs. [11-20 lbs.] [21-55 lbs.] [56-100 lbs.] [over 100 lbs.]

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 dogs or dogs known to be sensitive to pesticide products without first consulting a veterinarian.

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, rinse with large amounts of water and contact your

SVP9: EPA REG. NO. 83399-10

Registration Extension

Date: Apr 09, 2020

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.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

RESTRICTIONS:

- Do not allow children to apply product.
- Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.
- Do not allow your dog to ingest this product.
- Do not treat your dog with more than one pesticide product at a time. Overdosing your dog can result in serious illness and even death.

See package insert for additional Restrictions and complete Directions For Use.

EPA Reg. No. 83399-10

Lot # [label code] [UPC code]

EPA Est. No. TBD

[Ceva logo]

[Sold by:] [Manufactured for:] [Distributed by:] [Product of]

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]

[Recyclable Packaging] [Recycling Symbol]

[Vectra and Vectra logo are registered trademarks of Ceva Animal Health, LLC]

{PACKAGE INSERT}

SVP9 for Dogs

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

2.5 to 10 lbs., over 8 weeks of age (0.044 fl. oz.) (1.30 mL)

11 to 20 lbs., over 8 weeks of age (0.068 fl. oz.) (2.00 mL)

21 to 55 lbs., over 8 weeks of age (0.135 fl. oz.) (4.00 mL)

56 to 100 lbs., over 8 weeks of age (0.204 fl. oz.) (6.00 mL)

over 100 lbs. (0.250 fl. oz.) (7.40 mL)

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

Effective monthly control of[:] adult fleas, (flea) eggs, and (flea) larvae
[Optional marketing claims –see pages 7-10]

ACTIVE INGREDIENTS:

| | |
|-------------------------------|----------------|
| Dinotefuran..... | 22.00% |
| Pyriproxyfen..... | 3.00% |
| OTHER INGREDIENTS..... | 75.00% |
| TOTAL..... | 100.00% |

**KEEP OUT OF REACH OF CHILDREN
WARNING**

[Optional marketing claims –see pages 7-10]

| 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 by mouth 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 for emergency medical information. | |

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS AND PUPPIES OVER 8 WEEKS OF AGE WEIGHING 2.5-10 lbs. [11-20 lbs.] [21-55 lbs.] [56-100 lbs.] [over 100 lbs.]

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 dogs or dogs known to be sensitive to pesticide products without first consulting a veterinarian.

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, rinse with large amounts of water and 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.



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

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).]

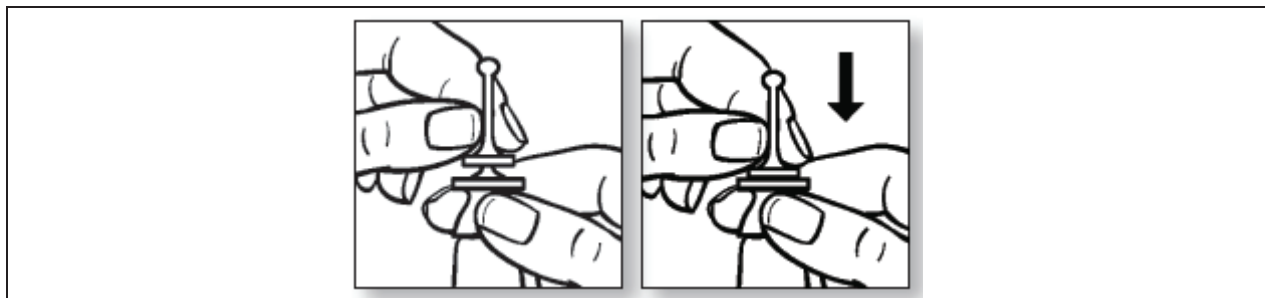
RESTRICTIONS:

- USE ONLY ON DOGS
- Do not use on cats or other animals.
- Do not allow children to apply product.
- Do not have contact or allow children to have contact with treated areas until treatment is completely dry.
- Do not allow your dog to ingest this product. Do not get the product in your dog's eyes or mouth.
- For use only on dogs and puppies 8 weeks and older and according to the dog's weight:
 - 2.5-10 lbs., 0.044 fl. oz.
 - 11-20 lbs., 0.068 fl. oz.
 - 21-55 lbs., 0.135 fl. oz.
 - 56-100 lbs., 0.204 fl. oz.
 - [over 100 lbs., 0.250 fl. oz.]
- Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.
- Do not treat your dog with more than one pesticide product at a time. Overdosing your dog can result in serious illness and even death.

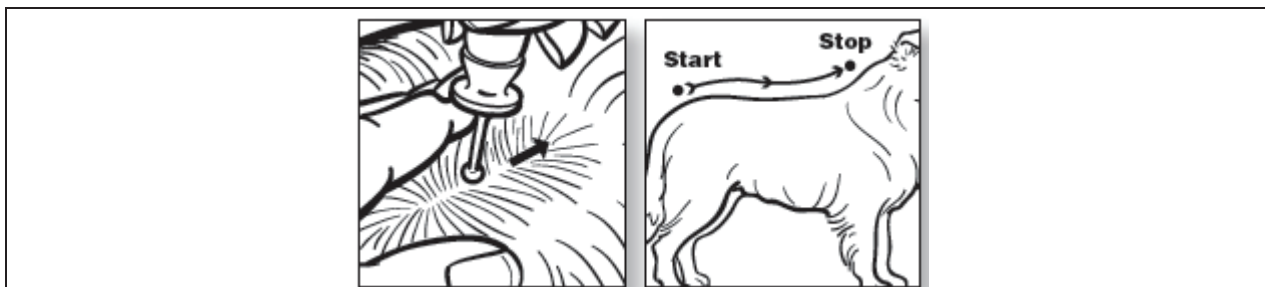
HOW TO APPLY:

1. Remove the applicator tube from the package.
2. Ensure your dog is dry before applying the product, and ensure your dog remains dry for 24 hours after application. The dog should be standing or in a comfortable position for easy application.

3. Holding the applicator tube upright, pointing away from your face, place your thumb and index finger around the applicator tip under the large disk. With your other hand, grasp the stem of the applicator tip above the smaller disk. Press down firmly on the small disk until both disks meet, piercing the seal. See illustration.



4. 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 dog's hair.



5. Discard the empty applicator tube as outlined in the Storage and Disposal section.
6. Repeat every month.
7. For optimal treatment, control and prevention of fleas, flea eggs and flea larvae, year-round monthly application 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 dose 0.044 fl oz, (1.3 ml)]
[each dose 0.068 fl oz (2.0 ml)]
[each dose 0.135 fl oz (4.0 ml)]
[each dose 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.

*Satisfaction Guarantee. We want you to be happy with any Vectra® product you purchase. If you decide this Vectra® product is not the right solution for your pet, you may return it accompanied by your proof of purchase to the original place of purchase within 60 days.

[label code] [ceva logo]
[Ceva Animal Health, LLC Lenexa, KS 66215]

{OPTIONAL MARKETING CLAIMS}

{for use on the front, side, or back panels of the outer box or on the 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 8 weeks of age or older weighing 56 to 100 lbs [6.0ml]
- For dogs over 100 lbs [7.4ml]
- Effective monthly treatment against fleas, flea eggs, and larvae on dogs [and puppies]
- Protects your dog from multiple flea stages for one month
- Protects dogs from fleas for one month
- Kills newly emerged fleas before they lay eggs
- Kills fleas within 6 hours
- Formulated for dogs [and puppies]
- Flea treatment formulated for dogs [and puppies]
- Easy, spot on [topical] application
- Satisfaction guaranteed or your money back [Ceva ICON] [Please call our professional staff at 1-800-999-0297 if you have any questions or comments about SVP9]
- Kills fleas on dogs [and puppies] that may cause flea allergy dermatitis [FAD] and anemia
- Kills fleas on dogs [and puppies] that may transmit bartonellosis and tapeworm

- Controls development of fleas, flea eggs, larvae and pupae on dogs [and puppies] for one month
- Convenient topical treatment formulated for dogs
- Controls adult fleas, [flea] eggs, and [flea] larvae on dogs [and puppies]
- Convenient topical treatment formulated for dogs [and puppies]
- [Patented] applicator tip for easy application
- Satisfaction guaranteed. Ceva Animal Health, LLC will provide new product or your money back.
- Satisfaction guaranteed. [Ceva ICON] Please call our professional staff [experts] at 1-800-999-0297 if you have any questions or comments about [insect infestations] [or] SVP9
- 60 days satisfaction guarantee
- If you are unhappy with any Vectra[®] product, you may return with receipt to place of original purchase within 60 days.
- Vectra and Vectra logo are registered trademarks of Ceva Animal Health, LLC
- Pyriproxyfen is an insect growth regulator which controls the development of multiple flea stages.
- SVP9 is 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] by controlling fleas, flea eggs, and flea larvae for one month
- One month multistage flea protection for dogs [and puppies]
- 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 on dogs [and puppies] for one month
- [Year round] Monthly treatment with SVP9 is recommended for control and prevention of fleas on dogs [and puppies]
- Once monthly application
- X applicator tubes {*1,2,3,4,6,8,9,12,18,24,36*}
- X monthly doses [applications] [treatments] {*1,2,3,4,6,8,9,12,18,24,36*}
- 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]
- Available from licensed veterinarians
- Sold by veterinarians
- After application, SVP9 spreads across the dog's body to provide [full body] [all-over] protection against fleas

- Effective multistage flea control for dogs [and puppies]
- Dinotefuran kills fleas within 6 hours on dogs
- SVP9 kills fleas within 6 hours on dogs
- Questions or comments—please call 1-800-999-0297 or e-mail us at contact.us@ceva.com
- For more information call 1-800-999-0297 or email us at contact.us@ceva.com
- For emergencies call 1-800-999-0297
- Kills fleas on dogs [and puppies] that may transmit bartonellosis, tapeworm and tularemia
- Kills fleas on dogs [and puppies]
- Easy to apply, effective control of fleas on dogs [and puppies] that lasts 1 month
- Kills fleas in 6 hours on dogs
- Acts to kill fleas on dogs that may transmit bartonellosis, tapeworm and tularemia
- Regular [monthly] use breaks the flea life cycle
- Starts working with the first application and continues to control fleas on dogs [and puppies] for one month
- Starts with the first application, killing fleas in 6 hours on dogs
- Treatment with SVP9 kills fleas that may cause flea allergy dermatitis [FAD] on dogs
- SVP9 contains the insect growth regulator pyriproxyfen that acts to prevent the development of fleas for one month on dogs
- May be used on puppies from 8 weeks of age
- Regular use [of SVP9] breaks the flea life cycle
- Controls development of multiple flea stages [for one (1) month] [through 30 days]
- Proven treatment formulation for flea infestations on dogs [and puppies]
- Pyriproxyfen arrests the development of immature fleas
- Prevents re-infestation [by fleas] on dogs [and puppies] 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 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 [and puppies], and protects dogs in flea contaminated environments
- A single dose effectively stops flea infestation and prevents re-infestation on dogs [and puppies] for one month
- SVP9 may be used to prevent re-infestation in dogs [and puppies] that are flea free
- Kills adult fleas on dogs [and puppies] which may cause Flea Allergy Dermatitis [FAD]
- 21st century flea control
- One piece applicator allows for easy [more convenient] administration

- SVP9 protects dogs [and puppies over 8 weeks of age] from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
- SVP9 protects dogs [and puppies] from fleas that may carry and transmit *Francisella tularensis*
- SVP9, flea control for an age old problem
- Kills fleas on dogs [and puppies] which may cause anemia
- Fleas do not have to bite to die
- Contains pyriproxyfen an insect growth regulator
- Kills fleas on dogs [and puppies] 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 on dogs [and puppies]
- SVP9 kills by contact

(Next Dose Stickers and Reminder Calendar)

Prototype:

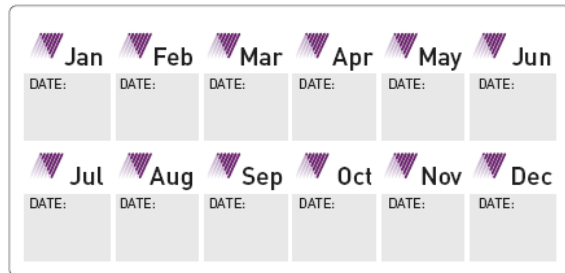
NEXT DOSE STICKERS AND REMINDER CALENDAR

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.



(APPLICATOR TUBE LABELING)

SVP9 for Dogs

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

{The above brand names will be packaged in the weight ranges below:}

- 2.5 to 10 lbs., over 8 weeks of age (0.044 fl. oz.) (1.30 mL)**
- 11 to 20 lbs., over 8 weeks of age (0.068 fl. oz.) (2.00 mL)**
- 21 to 55 lbs., over 8 weeks of age (0.135 fl. oz.) (4.00 mL)**
- 56 to 100 lbs., over 8 weeks of age (0.204 fl. oz.) (6.00 mL)**
- [over 100 lbs. (0.250 fl. oz.) (7.40 mL)]**

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)
[label code]