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1/12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR - 5 2009

Mr. Joseph A. Conti
Summit Vetpharm, LLC
Parker Plaza
400 Kelby Street
Fort Lee, NJ 07024

Dear Mr. Conti:

Subject: Label amendment; reduce age of puppies from 6 months to 7 weeks.
SVP 9
EPA File Symbol 83399-10
Your submissions dated 6/1/2008, 8/18/2008, 11/5/2008 and 11/21/2008

The amendment referred to above is acceptable in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3c(7), subject to the comments listed below:

1. Registration does not eliminate the need for continual reassessment of pesticides. If the Agency determines that, at any time, additional data are required to maintain in effect an existing registration, the Agency will require submission of such data.
2. The companion animal (puppy) safety study (MRID # 47592901) that you submitted to support this action is study is classified as minimally acceptable. Since six of the 8 puppies treated in this study were 54 to 55 days old on Study Day 0, this study does not provide adequate information for use on puppies of 7 weeks of age.
3. The additional data (MRID #s 47519901 and 476048010) that you submitted to upgrade the companion animal study reviewed earlier (MRID #s 47385501) has been classified as confirmatory data.
4. This new companion animal puppy study conjunction with the previously submitted study and additional information adequately addresses the companion animal safety study requirement for use of this product on puppies at 8 weeks of age or older. Please see enclosed review for details.
5. Make the label changes listed below:
 - a) Revise proposed label to change "7 weeks" to "8 weeks" everywhere it appears on the label. This appears on almost every page.

- b) On page 2, change "USE ONLY ON DOGS (7 weeks of age or older)" to "USE ONLY ON DOGS OR PUPPIES 8 WEEKS OF AGE OR OLDER".
- c) Delete the following statements:
- Pyriproxyfen provides ovicidal, larvacidal and pupal control.
 - Kills fleas before they lay eggs.

A stamped copy of the label is enclosed for your records. Submit two (2) copies of the final printed label before you release the product for shipment bearing the revised labeling.

A copy of the companion animal safety study review is also enclosed for your perusal. If you have any questions, please do not hesitate to contact me at (703) 308-8291, or send an e-mail.

Yours Sincerely,

Rita Kumar

Rita Kumar
Senior Regulatory Specialist
Insecticide-Rodenticide Branch
Registration Division (7505C)
e-mail: kumar.rita@epa.gov

Enclosures (2)

"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

SVP9

Alternate Brand Name;

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) 7 weeks of age and older

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 (11 to 20 lbs) over 7 weeks of age and older

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 (21 to 55 lbs) 7 weeks of age and older

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 (55 to 100 lbs) 7 weeks of age and older

Vectra (Vectra D, Vectra Plus, Vectra 2D Vectra Excel, Vectra Dual, Vectra Duo, Vectra II, Vectra +, Vectra 2, Vectra Gold, Vectra Shield) for Dogs (over 100 lbs)

Effective monthly control of; Adult fleas, (flea) eggs, (flea) larvae and (flea) pupae
Net Contents; xx Doses, each yy fl. oz. (zz ml)

ACTIVE INGREDIENTS:

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

KEEP OUT OF REACH OF CHILDREN

WARNING

ACCEPTED
With COMMENTS
In EPA Letter Dated:
MAR - 5 2009

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

83399-10

4/12

Front, back, side and/or insert language

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

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS (7 weeks of age or older)(1.3ml, 2.0ml, 4.0ml , 6.0ml and 7.4ml)

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 and using tobacco. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs only.

Do not use on puppies less than 7 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. Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap or shampoo and rinse with large amounts of water. If signs of individual animal sensitivity occur and persist, contact your veterinarian. Have the product container or label with you when calling your veterinarian for advice.

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, doctor, for treatment advice
If swallowed:	Call a poison control center, doctor, for treatment advice. Do not induce vomiting unless told to do so by a poison control center

5/12

	or doctor. Have person sip a glass of water if able to swallow. Do not give anything to an unconscious person.
If on skin:	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.	

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 ONLY ON DOGS. Do not use on cats or other animals.**
2. Remove applicator from package.
3. The dog should be standing or in a comfortable position for easy application.
4. Unscrew the tube cap. Remove the cap from the tube. The cap contains a point that can pierce the safety seal on the tube. Carefully hold the tube upright, pointed away from your face and body. Using the cap puncture the safety seal on the tube. (Screw the applicator tip onto tube.)

Alternate language--step 4 based on applicator:

Holding the applicator upright at the top below applicator tip, with thumb and index middle finger(of the other hand) (squeeze the tabs and) press down firmly, while pressing firmly down on applicator cap with index finger to puncture safety seal locking the applicator tip in the dispensing position.

OR Holding the applicator upright, place your thumb and index finger firmly around the collar. While maintaining applicator in an upright position, push firmly down on the top of the applicator tip, piercing the seal. (see illustration)

OR

4. (Remove the tube and applicator from the package. Unscrew the cap and replace with applicator tip) Holding the tube (applicator) upright, place thumb and index finger around the applicator tip under the large disk. With other hand grasp the stem of applicator tip above small disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)

OR

6/12

4. Hold the applicator upright at the top below the (applicator) tip, with the tip facing away from the face and body. (Being careful not to squeeze the tube), using the thumb and index finger (of the other hand) squeeze the tabs (neck, collar) pressing down firmly to puncture the safety seal (locking) (putting) (placing) the applicator tip in the dispensing position. OR

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

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:

5. [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:

- 5 [For dogs weighing 56 to 100 lbs] [For dogs weighing over 101 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:

- 5 (For dogs 100 lbs or greater combine SVP9 55-100 lbs with the appropriate SVP9 size to approximate the total weigh 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 55-100 lbs package diagram, until both applicators (tubes) are empty.)

- 6 Discard empty applicator (tube) as outlined in the storage and disposal section.

OR

Unscrew applicator tip and place back in package. Replace applicator tip with

original cap and place in trash.

7 For treatment, control and prevention of fleas, flea eggs, flea pupae and flea larvae (all) year-round treatment is recommended.

OR

7. Repeat every month, or as recommended by your veterinarian.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

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

STORAGE AND DISPOSAL

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

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

Disposal: If empty, do not reuse the container. Place in trash or offer for recycling if available. If partially filled, call your local solid waste agency for disposal instructions.

Never place unused products down any indoor or outdoor drain.

NET CONTENTS: X applications (applicators 1,2,3,4,6,8,9,12,18, 24, 36)), each 0.044 fl. oz. (1.3ml) [Total X fl. oz., X ml] X applications (applicators), each 0.068 fl. oz. (2.0 ml) [Total X fl. oz., X mL]

X applications (applicators), each 0.135 fl. oz. (4.0 ml) [Total x fl. oz., x ml]

X applications (applicators), each 0.204 fl. oz. (6.0 ml) [Total X fl. oz., X ml]

X applications (applicators), each 0.25 fl. oz. (7.4ml) [Total x fl. oz., x ml]

EPA Reg. No. 83399-10

EPA Est. No.

Made in the USA (by) [Distributed by:]

[Summit VetPharm, LLC], 400 Kelby Street, Fort Lee, New Jersey 07024

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. 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

(Optional marketing claims—front, back and side panels

- For dogs and puppies 7 weeks of age or older weighting 2.5 to 10 lbs (1.3ml)
- For dogs and puppies 7 weeks of age or older weighting 11 to 20 lbs (2.0ml)
- For dogs and puppies 7 weeks of age or older weighting 21 to 55 lbs (4.0ml)
- For dog and puppies over 7 weeks of age or older weighting 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 7 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 7 weeks of age 1.3, 2.0, 4.0 ,6.0 and 7.4ml)
- Flea treatment formulated for dogs (and puppies over 7 weeks of age 1.3, 2.0, 4.0 ,6.0 and 7.4ml)
- Easy, spot on (topical) application
- Performance guaranteed or your money back (SVP 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 (SVP 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 naturally 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 7 weeks)

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- Protects dogs (and puppies over 7 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 Summit VetPharm will supply replacement product
 - Quick onset of activity (kills) 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 7 weeks 1.3, 2.0, 4.0, 6.0 and 7.4ml)
 - Formulated for dogs (and puppies over 7 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 info@summitvetpharm.com
 - For more information call (tel. no.) or email us at info@summitvetpharm.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

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- 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 7 weeks of age
 - Kills fleas before they lay eggs
 - 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 7 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 7 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 7 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

11/12

SVP9: EPA REG. NO. 83399-10

PROPOSED LABELING

Date: 11/5/2008

- SVP9 protects dogs (and puppies over 7 weeks) from fleas that may carry and transmit Rickettsia felis and Rickettsia typhi
- SVP9 protects dogs (and puppies over 7 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
- Pyriproxyfen provides ovicidal, larvacidal and pupal control
- SVP9 kills by contact
- Fleas do not have to bite to die

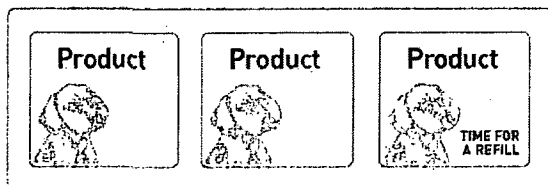
NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

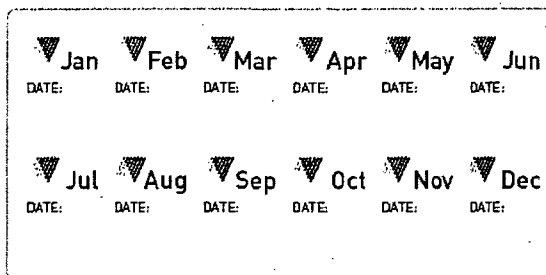
NEXT DOSE STICKERS AND REMINDER CALENDAR

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.



APPLICATOR LABELING

SVP9

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

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

- 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)*