

83399-6

12-18-2007

1/14

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



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 18 2007

Mr. Joseph A. Conti
Senior Director, Regulatory Affairs
Summit VetPharm, LLC
400 Kelby Street
Fort Lee, NJ 07024

Dear Mr. Conti:

Subject: Label amendment
SVP7
EPA Registration Number 83399-6
Electronic submission dated 12/7/2007, received 12/10/2007

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided you make label changes listed below before you release the product for shipment:

1. The referral statement must appear on the front panel, and must be revised to read as follows: See back panel and package insert for directions for use, precautionary statement and first aid.
2. Revise the Precautionary Statement as follows: "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. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco products."
3. Clearly state on the front panel that the unit packaging will contain one of the following sizes: 1.6 ml, 3.6 ml, 4.7 ml, or 8.0 ml for single application to dogs, specific to the pet's age and body weight. Outer packaging may contain up to xx units.
4. Change the DO NOT USE ON CATS statement on page 3 to read exactly as it appears on the label that was accepted on 7/13/2007.

5. Add a Note to Physician below the First Aid statement. Please refer to enclosed acute toxicity review for information that should be included in the Note to Physician.
6. On page 5, delete the statement: "Place your CLINIC, (Hospital) (Prescribing) label here". We cannot allow this statement for two reasons:
 - a) It is misleading because it falsely implies this product is a drug requiring a prescription.
 - b) If the clinic attached anything or wrote in the space they would be illegally altering the label.
7. Delete "at Least" from the efficacy statement of effectiveness for one month or 30 days across the board.
8. Delete "only" from the front panel statement: "Available from veterinarians only".
9. The following claims are not supported for dogs weighing over 95 pounds and must be either deleted from the label or revised to specify for fleas only.
 - a) *"Quick onset of activity (kill) within 2 hours"*
 - b) *"SVP7 contains dinotefuran, a (NEW first 6 months) neonicotinoid insecticide with knockdown in less than 2 hours"*
 - c) *"Repels and kills up to 100% of mosquitoes for at least one month"*
10. The following label claims are considered heightened efficacy and must be deleted from the label:
 - a) *"Pyriproxyfen arrests the development of immature flea stages"*
 - b) *"Pyriproxyfen metabolically attacks fleas"*
11. The following claim is not appropriate to be on the label, and must be deleted: *"Hospital (Clinic) pack (24 and 36 packages only)"*
12. The following label claim contains grammatical/structural errors and must be corrected, or deleted from the label:
 - a) *"Prevents development of fleas, flea eggs, pupae and larvae for one month or dinotefuran in providing efficacy against fleas, ticks and mosquitoes. Pyriproxyfen is an insect growth regulator which prevents development of all flea stages."*
13. Note that the claim "NEW" may be used on the label for six months from date of registration, i.e., 1/13/2008 for this product.
14. We have revised our policy and are not allowing specific percent kill claims on pet spot-on product labels. Please delete the following claims or rephrase them without

3/14

the percent kill claim:

- a) *Kills 96% of fleas in 6 hours*
- b) *Kills over 95% of fleas in 6 hours and up to 100% in 12 hours*
- c) *Repels and kills up to 100% of mosquitoes for at least one month*

A stamped copy of the label is enclosed for your records. Copies of the acute toxicity and efficacy reviews are also enclosed for your perusal.

Please submit two (2) copies of the final printed label before you release the product for shipment bearing the revised labeling.

If you have any questions about this letter, please do not hesitate to send an e-mail, or call me at (703) 308-8291.

Sincerely yours,



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

Enclosures (3)

cc (stamped label and cover letter): Paula McBath Pesticide Product Registration Section
New York State Department of Environmental Conservation

4/14

"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

SVP7

Alternate Brand names;

- Vectra 3D (for Dogs and Puppies 2.5 to 20 lbs., over 7 weeks of age)[1.6 ml]
- Vectra 3D (for Dogs and Puppies 21-55 lbs., over 7 weeks of age)[3.6 ml]
- Vectra 3D (for Dogs 56-95 lbs.)(4.7 ml]
- Vectra 3D (for Dogs over 95 lbs.)(8.0ml]

- Vectra Gold (for dogs and Puppies 2.5 to 20 lbs., over 7 weeks of age)1.6 ml]
- Vectra Gold (for Dogs and Puppies 21-55 lbs., over 7 weeks of age)[3.6 ml]
- Vectra Gold (for Dogs 56-95 lbs.)(4.7 ml]
- Vectra Gold (for Dogs over 95 lbs.)(8.0 ml]

- Vectra Trio (for Dogs and Puppies 2.5 to 20 lbs., over 7 weeks of age)[1.6 ml]
- Vectra Trio (for Dogs and Puppies 21-55 lbs., over 7 weeks of age)[3.6 ml]
- Vectra Trio (for Dogs 56-95 lbs)[4.7 ml]
- Vectra Trio (for Dogs over 95 lbs)[8.0 ml]

Repels and Kills for at least one month

- Fleas
- Ticks
- Mosquitoes

(Optional marketing claims—front or back or side panels/see on pages 6-9)

ACTIVE INGREDIENTS:

Dinotefuran	4.95%
Pyriproxyfen.....	0.44%
Permethrin	36.08%
OTHER INGREDIENTS.....	58.53%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

Xx Doses

Net Contents: XX doses; each xx mls.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
DEC 18 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.
83399-6

5/14

Front, back, side and/or insert language

See package insert for directions for use, precautionary statements, first aid and ingredients.

**DO NOT USE ON CATS
[ICON OF CAT IN CIRCLE WITH SLASH THROUGH]**

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS [OR] [AND] PUPPIES OVER THE AGE OF 7 WEEKS (OVER 7 WEEKS OLD) (7 WEEKS OF AGE OR OLDER)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes moderate eye irritation. Harmful if swallowed. Harmful if absorbed through skin. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco products.

For external use dogs only

Do not use this product on cats

Use only on dogs[and/or] puppies over the age of 7 weeks (over 7 weeks)(7 weeks of age or older) (1.6 ml, 3.6 ml, 4.7 ml, 8.0 ml sizes)

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

6/14

individual animal sensitivity occur and persist, contact your veterinarian. Have the product container or label with you when calling your veterinarian for advice.

DO NOT USE ON CATS. Due to their unique physiology and inability to metabolize certain compounds – **THIS PRODUCT MUST NOT BE USED ON CATS.** Accidental application to cats, and/or grooming a recently treated dog, this product may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.
(Cat icon)

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:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center, doctor, or 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 1-888-426-4435 for emergency medical treatment 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.

7/14

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 finger(of the other hand) (squeeze the tabs and) press down firmly 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

(Remove the tube and applicator from the package. Unscrew the tube 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 smaller disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

5. [For dogs weighing 2.5lbs. to 20 lbs. and under] Using the tip of the applicator, part the hair between the shoulder blades and slowly apply the product (to one spot) (as shown below) onto the skin, squeezing the applicator (tube) until empty. Avoid superficial application to the animal's hair.

OR:

5. [For dogs weighing 21 to 55 lbs][For dogs weighing 56 to 95 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, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) is empty. Avoid superficial application to the animal's hair.

OR:

5. [For dogs weighing over 95 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

8/14

on the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) is empty. Avoid superficial application to the animal's hair.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

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

6. Unscrew applicator tip and place back in package. Replace applicator tip with original cap and place in trash. OR Discard empty applicator (tube) as outlined in the Storage and Disposal section .
7. Repeat every month, or as recommended by your veterinarian. Do not repeat in less than 30 days.
8. For optimum treatment, control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks, lice and mosquitoes, (all) year-round treatment is recommended.

Place your
CLINIC, (Hospital) (Prescribing) label here

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), each (0.06, 0.12, 0.16, 0.3 fl. oz. (1.6, 3.6, 4.7, 8.0 mL) *Example: 3 single dose (applicators)(package) 1.6 ml (0.6 fl.oz. total 0.18 fl.oz) [Total 0.18 0.36, 0.48, 0.9 fl. oz., 4.8, 10.8, 14.1, 24.0 mL]*

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 2, 3, 4, 6, 8, 9,12, 24 or 36 applicators per package. Total volume will correspond to number of applicators)

EPA Reg. No. 83399-6
EPA Est. No.

[Made in the USA (by)] [Distributed by:] Summit VetPharm LLC, Fort Lee, NJ 07024

9/14

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 when such use and handling are contrary to the label instructions. 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 or side or back panels or insert)

- Protects for at least one month
- Performance (satisfaction) guaranteed or Summit VetPharm will supply replacement product
- Effective monthly treatment of fleas, ticks, and mosquitoes
- Repels and kills fleas, ticks and mosquitoes for at least one month.
- Prevents development of fleas, flea eggs, pupae and larvae for one month or dinotefuran in providing efficacy against fleas, ticks and mosquitoes. Pyriproxyfen is an insect growth regulator which prevents development of all flea stages.
- Picture of Dog
- Prevents development of fleas, flea eggs, pupae and larvae

- Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread naturally over the dog's body providing effective control of fleas, ticks, , and mosquitoes for thirty days (four weeks, one month).

- New (first 6 months)

- New tick, mosquito and all stages of flea control (first 6 months)

- New formula for (your) dog(s) (first 6 months)
- Kills 96% of fleas in 6 hours
- For dogs that enjoy the outdoors
- Remains effective after bathing and swimming
- Easy, spot-on (topical) application
- (Patented) applicator tip (Trademark) for easy application directly to the skin
- Guaranteed effective for at least one month

10/14

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- New (first six months)
 - New formula for your dog (first six months)
 - Performance (Satisfaction) guaranteed or your money back (SVP ICON) (Please call our professional staff at xxx-xxx-xxxx if you have any questions or comments about SVP7)
 - SVP7 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect. Permethrin is an effective insecticide/acaricide that complements
 -
 - Quick onset of activity (kill) within **2** hours
 - Persistent efficacy through 30 days
 - Prevents re-infestation (of fleas/of ticks) for up to one month Kills newly emerged fleas before they lay eggs
 - Monthly treatment is recommended for optimal control and prevention of fleas, ticks and mosquitoes
 - Once monthly application
 - X applicators
 - X monthly doses (applications) (treatments)
 - Quick-drying, non-greasy and water-resistant
 - Easy to apply spot-on application
 - Convenient, easy to apply
 - Fragrance (odor) free
 - Convenient to use
 - Water-resistant
 - Quick drying
 - Non-greasy
 - Convenient (easy to apply) topical treatment
 - Convenient (easy to apply) topical treatment [with (patented) applicator tip] that allows application down to the skin
 - Remains effective even after bathing, water immersion or exposure to rain or sunlight
 - Remains effective even after bathing
 - Remains effective after exposure to rain and sunlight
 - Still works after bathing, swimming or exposure to sunlight
 - Convenient topical treatment for dogs who enjoy the outdoors
 - Formulated for dogs that love the outdoors
 - For dogs that enjoy the outdoors
 - The killing of fleas, ticks and mosquitoes is important in the prevention of disease transmission by these parasites
 - (Only) available from (licensed) veterinarians
 - Sold by veterinarians
 - Tested on puppies from 7 weeks of age
 - Tested on puppies from 7 weeks of age
 - After application, SVP7 spreads naturally over the dog's body to provide (full body) (all-over) protection against fleas, ticks and mosquitoes

11/14

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- SVP7 provides ongoing protection against fleas, ticks and mosquitoes for at least one month (30 days)
 - SVP7 contains dinotefuran, a (NEW first 6 months) neonicotinoid insecticide with knockdown in less than **2** hours
 - Dinotefuran kills fleas within 6 hours
 - SVP7 also contains permethrin, an effective insecticide/acaricide that combines with dinotefuran to provide efficacy against fleas, ticks and mosquitoes .
 - SVP7 contains the insect growth regulator pyriproxyfen that acts to prevent the development of all flea stages for at least one month (30 days).
 - Approximately 95% of the flea population in a household infestation are immature flea stages that live in the dog's environment.
 - Questions or comments—please call (tel. no.)
 - For more information call (tel. no.)
 - For emergencies call (tel. no)
-
- Kills the vectors that may cause Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis and heartworm disease
 - Repels and kills fleas, ticks and mosquitoes
 - Effective monthly treatment of fleas, ticks and mosquitoes
 - Easy, fast, effective control of fleas, ticks and mosquitoes that lasts at least 1 month
 - Protects against [4 types (species) of] ticks(Rhipicephalus spp, Dermacentor variables, Ixodes scapularis, Amblyomma maculatum), [3 types (species) of] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp), and all stages of fleas
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- Kills over 95% of fleas in 6 hours and up to 100% in 12 hours
 - Kills fleas that may transmit disease, including bartonellosis and tapeworm disease
 - Kills fleas before they lay eggs
 - Kills and repels fleas before they lay eggs
 - Regular use protects against all stages of the flea life cycle
 - Kills fleas that may cause flea allergy dermatitis
 - The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with SVP7 rapidly kills fleas and may reduce the incidence of FAD.
 - SVP7 is useful for dogs susceptible to Flea Allergy Dermatitis (FAD)
 - Regular use (of SVP7) breaks the flea life cycle
 - Protects against all stages of the flea life cycle
 - Prevents development of all flea stages for at least 1 month (30 days)
 - Repels and kills ticks that may (cause) (transmit) Lyme disease
 - Repels and kills ticks including those that may transmit Lyme disease
 - Repels and kills ticks that may transmit Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, hepatozoonosis

12/14

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- Repels and kills Brown dog ticks (*Rhipicephalus spp*), American dog ticks (*Dermacentor variabilis*), Deer ticks (*Ixodes scapularis*) and Gulf Coast ticks (*Amblyomma maculatum*)
 - Repels and kills ticks including Deer ticks (vector of Lyme disease), American dog ticks (vector of Rocky Mountain Spotted fever), Brown dog ticks (vector of ehrlichiosis) and Gulf Coast ticks for at least one 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
 - Repels ticks before they can attach to dogs and take a blood meal
 - Repels and kills ticks, which may transmit disease
 - Repels many ticks before they can attach and kills those ticks which attach to the dog
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- Repels and kills mosquitoes (*Culex spp*, *Ochlerotatus spp*, *Aedes spp*) and vector for heartworm (*Dirofilaria immitis*) for at least one month
 - Repels and kills up to 100% of mosquitoes for at least one month
 - Proven treatment technology for flea infestations
 - Proven treatment technology for the control of fleas, ticks and mosquitoes
 - Recommended for use in an integrated flea management system
 - Veterinarians [and the Companion Animal Parasite Council (CAPC)] (often) recommend year round use depending on the needs of your pet
 - Veterinarians recommend year round use of an ectoparasite, such as SVP7
 - Pyriproxyfen arrests the development of immature flea stages
 - Pyriproxyfen metabolically attacks fleas
 - Hospital (Clinic) pack (24 and 36 packages only)
 - Puppy pack (24 and 36 packages only, 1.6 ml and 3.6 mls)
 - Dog pack (24 and 36 packages only)

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

13/14

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.

Product Product Product

TIME FOR
A REFILL

▼ Jan ▼ Feb ▼ Mar ▼ Apr ▼ May ▼ Jun
(DATE) (DATE) (DATE) (DATE) (DATE) (DATE)

▼ Jul ▼ Aug ▼ Sep ▼ Oct ▼ Nov ▼ Dec
(DATE) (DATE) (DATE) (DATE) (DATE) (DATE)

14/14

APPLICATOR LABELING

SVP7

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

Dinotefuran4.95%
Pyriproxyfen.....0.44%
Permethrin.....36.08%

X fl. oz. (X mL)

DO NOT USE ON CATS [ICON]

EPA Reg. No. 83399-6
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)