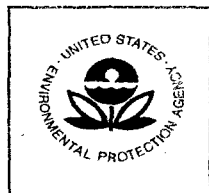


83399-6

07/13/2007

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

EPA Reg. Number:

83399-6

Date of Issuance:

JUL 13 2007

Term of Issuance: Conditional

Name of Pesticide Product:

SVP7

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Summit VetPharm LLC
400 Kelby Street
Fort Lee, NJ 07024

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) and (B) 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; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Submit the following data:

a. One year storage stability (830.6317) and corrosion characteristics (830.6320) studies. These studies can be run concurrently. It is recommended that the observation must be made at 0, 3, 6, 9, and 12 months period and the results must be submitted to the Agency on completion. These studies must be submitted within 15 months from today's date.

b. Submit a transferable residue study on dogs within 24 months from the date of this letter. Prior to initiating this study, a protocol should be submitted for Agency's review and approval.

Signature of Approving Official:

Rita Kumar

Date:

JUL 13 2007

3. Make the following label changes:
 - a. Add the phrase "EPA Registration Number 83399-6".
 - b. Submit all the graphics that you intend to use on the label.
 - c. Under the Directions for Use, page 5, comment No. 7, add the following to the existing text: "Do not reapply in less than 30 days
 - d. The following claims are not supported for dogs weighing over 95 lbs. The claims must be either deleted from the label or revised to specify for fleas only.
 - *"Quick onset of activity (kill) within 2 hours"*
 - *"SVP7 contains dinotefuran, a "NEW (first 6 months) neonicotinoid insecticide with knockdown in less than 2 hours"*
4. Submit two copies of the revised final printed label for the record. Also submit revised CSF as indicated in 3(h) above.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. A copy of the latest efficacy review is also enclosed for your perusal.

Sincerely,



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

Enclosures (2)

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SVP7: EPA FILE SYMBOL 83399-A
 PROPOSED LABELING
 Date: 7/11/2007all

"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 95lbs.) [8.0 ml]

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]

(Optional marketing claims—front and side panels/continued on pages 6-9)

- 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 more
- 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
- 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 dinotefuran in providing efficacy against fleas, ticks and mosquitoes. Pyriproxyfen is an insect growth regulator which prevents development of all flea stages.
- 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).

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 JUL 13 2007
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 As amended, for the pesticide
 Registered under EPA Reg. No.
83399-6

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- 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)

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: 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]

BACK PANEL OF OUTER BOX

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

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 old) (7 weeks of age or older) (1.6 ml and 3.6 ml sizes)

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WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco products.

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.

DO NOT USE ON CATS. Due to their unique physiology and inability to metabolize certain compounds, this product must not be used on cats. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs contact your veterinarian immediately.
 (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 immediately 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 1-800-222-1222 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 1-800-222-1212 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.
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, pointing away from face, 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, pointing away from face, place your thumb and index finger firmly around the collar. While maintaining applicator in an upright position, push down firmly 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 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)

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

5. [For dogs weighing 2.5 lbs. 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) 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) until empty. Avoid superficial application to the animal's hair.

OR

5. [For dogs weighting 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 on the dog's back, beginning between the shoulder blades and continuing in the order shown in the diagram below, squeezing the applicator (tube) until 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.
8. For optimum treatment, control and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks and mosquitoes, (all) year-round treatment is recommended.

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 oz. (1.6, 3.6, 4.7, 8.0 mL) Example: 3 applicator package [Total 0.18, 0.36, 0.48, 0.9 fl. oz., 4.8, 10.8,

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SVP7: EPA FILE SYMBOL 83399-A
PROPOSED LABELING
Date: 7/11/2007all

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-A
EPA Est. No.

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

- Protects for at least one month
- Performance (satisfaction) guaranteed or Summit VetPharm will supply replacement product
- 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

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-
- 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
 - After application, SVP7 spreads naturally over the dog's body to provide (full body) (all-over) protection against fleas, ticks and mosquitoes
 - 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 variabilis, Ixodes scapularis, Amblyomma maculatum), [3 types (species) of] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp) and all stages of fleas
 - 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

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- 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
- 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
- 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

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SVP7: EPA FILE SYMBOL 83399-A
PROPOSED LABELING
Date: 7/11/2007all

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

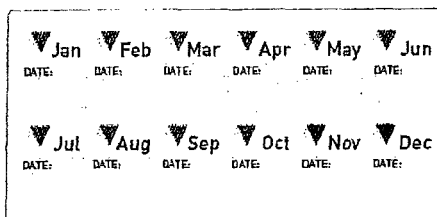
NEXT DOSE STICKERS AND REMINDER CALENDAR

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

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-
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)