

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

NOV 2 2 2010

Mr. Joseph A. Conti Senior Director, Regulatory Affairs Summit VetPharm 301, Route 17 North Rutherford, NJ 07070

Dear Mr. Conti:

Subject:

Label amendment; additional claims

SVP7

EPA File Symbol 83399-6

Submissions dated July 2, 2010, and Nov. 12, 2010

The amendment referred to above, submitted in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below:

- 1. Per comment #4 on the Agency review dated October 4, 2010; all references to "mites" must be revised to read "mites (excluding mange mites)". Specifically, the following claims must be revised. Alternatively, all mite claims may be deleted from the label.
  - a. On page 1, revise "Mites" to read "Mites (excluding mange mites)".
  - b. On page 4, revise "For treatment control and prevention of adult and immature flea stages, ticks, mosquitoes, lice, mites and biting & sand flies (all) year-round treatment is recommended." to read "For control and prevention of ticks, mosquitoes, lice, mites (excluding mange mites), biting & sand flies, and adult and immature flea stages (all) year-round treatment is recommended".
  - c. On page 4, revise "Avoid superficial application to the dog's hair." To read as "Do not make superficial application to dog's hair." This statement appears three times on this page.
  - d. On page 4, revise comment number 7 to read "Repeat every month, or as recommended by your veterinarian, but not more often than every 30 days".

- e. On page 7, revise "After application, SVP7 spreads naturally over the dog's body to provide full-body......" to read After application, SVP7 spreads over the dog's body to provide full-body......". Delete the word "naturally" from this statement.
- f. On page 10, revise "Repellency against fleas, ticks, mosquitoes, lice, mites and sand flies for 4 weeks (30 days) (one month)" to read "Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and sand flies for 4 weeks".
- g. On page 10, revise "Contains the proven effective topical repellant, permethrin (for control of fleas, ticks, mosquitoes, lice, mites and biting & sand flies)" to read "Contains the proven effective topical repellant; permethrin (for control of fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies)".
- h. On page 10, revise "Kills mites" to read "Kills mites (excluding mange mites)".
- 2. Per comment #3 on the Agency review dated October 4, 2010; all references to fire ants must be deleted from the label. On page 12 of the label, revise "Repels fleas, ticks, mosquitoes, fire ants, biting & sand flies, lice and mites (excluding mange mites)" to read "Repels fleas, ticks, mosquitoes, biting & sand flies, lice and mites (excluding mange mites)". Alternatively, the claim may be deleted altogether.
- 3. Per comment #8 on the Agency review dated October 4, 2010; change "Kills fleas in 6 hours" to read "Starts to kill fleas in 6 hours". This claim is found on page 6 of the proposed label. Alternatively, this claim may be deleted from the label altogether.
- 4. Per comment #31 on the Agency review dated October 4, 2010; change "Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease" to read "Kills the listed vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease". This claim is found on the bottom of page 12 of the proposed label. Alternatively, the claim may be deleted altogether.
- 5. On page 12 of the label, delete "SVP7 together with heartworm preventative may be helpful in providing an extra layer of protection against possible transmission from feeding mosquitoes that may be carrying heartworm larvae." It is not appropriate to reference FDA registered drugs on EPA spot-on labels. In addition, as mentioned in the Agency review dated October 4, 2010, the claim has heightened safety implications.
- 6. On pages 11 and 12 of the label, delete the following claims: "Prevents fly strike", "Control fly strike" and "Reduces biting fly strike". The claim "Kills biting flies that may transmit fly strike." is acceptable.

A stamped copy of the label is enclosed for your records. Please submit one (1) copy of the final printed label (with all the graphics and illustrations) before you release the product for shipment bearing the amended labeling. A copy of the second efficacy review is also enclosed for your perusal. The efficacy review dated Oct. 4, 2010 was sent to you electronically.

If you have any questions, please contact me at (703) 308-8291 or send en e-mail. If you have any questions, contact Rita Kumar at (703) 308-8291 or kumar.rita @epa.gov.

Yours Sincerely,

John/Hebert

Product Manager 7

Insecticide Rodenticide Branch Registration Division (7505P)

Enclosures (2)

AMENDED LABELING Date: November 9, 2010

(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- 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])

ACCEPTED
With COMMENTS
In EPA Letter Dated:
NOV 2 2 2010

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

83399-6

Repels and Kills for one month

- Fleas
- Ticks
- Mosquitoes
- (Biting & Sucking) Lice
- Mites
- Biting & Sand Flies

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

# **ACTIVE INGREDIENTS:**

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

# KEEP OUT OF REACH OF CHILDREN

**WARNING** 

XXX Doses Net

Net Contents: xxx doses: each xxx mls

Front, back, side and/or insert language See package insert for directions for use, precautionary statements and first aid

AMENDED LABELING Date: November 9, 2010

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 substantial but temporary eye injury, harmful if swallowed or absorbed through 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.

For external use on 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 dogs or dogsknown to be sensitive to pesticide products without first consulting a veterinarian.

Individual sensitivity, such as slight transitory redness, erythema or pruritus at the site of application, may occur after using ANY pesticide product fordogs. 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. 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 eats. If applied to a eat, or ingested by a car that actively grooms a recently treated dog, this product may have serious harmful effects. If this occurs, contact your veterinarian immediately, (Caticon)

FIRST AID

AMENDED LABELING Date: November 9, 2010

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, and 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. If skin appears irritated after rinsing call a poison control center or doctor, or 1-800-999-0297 or after 6pm EST call 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 weekdays between 9am and 6pm or 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.
- 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)

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

AMENDED LABELING Date: November 9, 2010

5. [Using the tip of the applicator, part the hair down to the level of the skin (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 dog's hair.

#### OR:

- 5. [For dogs weighting 2.5 to 20 lbs] (Using the tip of the applicator, part the hair down to the level of the skin and slowly) apply the product as one spot, as shown in the diagram above, onto the skin, squeezing the applicator tube until empty.
- 5. [For dogs weighing 21 to 55 lbs or 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 dog'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 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 dog's hair.

# [GRAPHICS DEPICTING TREATMENT OF ANIMAL]

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

# OR

- 5. 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.
- 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 treatment control and prevention of adult and immature flea stages, ticks, mosquitoes, lice, mites and biting & sand flies (all) year-round treatment is recommended.

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# 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; Place in trash or offer for recycling if available. 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, 36, 72 or 144 applicators per package. Total volume will correspond to number of applicators)

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

[Made in the USA (by)] [Sold by:] Summit VetPharm, LLC

301 Route 17 North Rutherford, New Jersey 07070

AMENDED LABELING Date: November 9, 2010

# 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. 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)

- Protects for 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 one month
- Prevents development of adult and immature flea stages for one month
- Dinotefuran provides efficacy against fleas, ticks and mosquitoes.
- Pyriproxyfen is an insect growth regulator which prevents development of all flea stages.
- Picture of Dog (or Puppy)
- Prevents development of adult and immature flea stages for 30 days
- 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).
- Formula for (your) dog(s)
- Kills fleas in 6 hours
- 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 one month
- Performance (Satisfaction) guaranteed or your money back (SVP ICON) (Please call (contact) 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 works with dinotefuran and pyriproxyfen to kill and repel fleas, ticks and mosquitoes
- Starts to kill fleas within 2 hours
- Prevents re-infestation (of fleas/of ticks) for one month

- Monthly treatment is recommended for control and prevention of fleas, ticks and mosquitoes
- Once monthly application
- X applicators
- X monthly dose(s) (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
- (Only) available from licensed veterinarians (only)
- Sold (only) by veterinarians
- Tested on puppies from 7 weeks of age
- After application, SVP7 spreads naturally over the dog's body to provide (full body) (allover) protection against fleas, ticks and mosquitoes
- SVP7 provides ongoing protection killing fleas, ticks and mosquitoes for one month (30 days)
- SVP7 (contains dinotefuran, a neonicotinoid insecticide) with onset of flea knockdown in less than 2 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 one month (30 days).
- Immature flea stages are a major component of flea infestation, SVP7 contains pyriproxyfen which controls immature flea stages..
- Questions or comments—please call (tel. no.)
- For more information call (tel. no.)
- For emergencies call (tel. no)
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis and heartworm disease

- Repels and kills fleas, ticks and mosquitoes
- Easy, fast, effective control of fleas, ticks and mosquitoes that lasts 1 month
- Kills [4 types (species) of] ticks(Rhipicephalus spp, Dermacentor variabilis, Ixodes spp,Amblyomma maculatum), [3 types (species) of] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp), and all stages of fleas
- Kills fleas including those that may transmit bartonellosis and tapeworm disease
- Monthly use kills (controls) all stages of the flea life cycle
- Kills fleas that may cause flea allergy dermatitis (FAD)
- 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 that may cause FAD.
- SVP7 kills fleas that may cause Flea Allergy Dermatitis (FAD)
- Monthly use (of SVP7) breaks the flea life cycle
- Kills (controls) all stages of the flea life cycle
- Prevents development of all flea stages for 1 month (30 days)
- Repels and kills ticks that may 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 and anaplasmosis
- 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 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 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*) which may vector heartworm (*Dirofilaria immitis*) for 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 which includes treatment of both the dog and the environment
- Pyriproxyfen control and attacks (all stages of) immature fleas
- Pyriproxyfen the insect growth regulator found in SVP7 stops the development of immature fleas
- Puppy pack (24,36, 72 and 144 packages only) [1.6 and 3.6ml packages only]
- Dog (canine) pack (24,36, 72 and 144 packages only)
- Veterinary pack, Summit pack (24, 36, 72 and 144 packages only)
- Effective monthly treatment of fleas, ticks and mosquitoes

- Effective monthly treatment of fleas (ticks)( mosquitoes)
- Repels and kills fleas (ticks)(mosquitoes)
- Monthly treatment is recommended for control (and prevention) of fleas, ticks and mosquitoes,
- SVP7 provides ongoing protection against fleas, ticks and mosquitoes for one month
- SVP7 contains permethrin an effective insecticide/acaricide that combines with dinotefuran to provide efficacy against fleas, ticks and mosquitoes
- Protects against all types of Ixodes species attacking dogs
- Kills Ixodes scapularis, Ixodes pacificus and Ixodes ricinus
- Effective control of fleas, ticks and mosquitoes
- Kills [4 types (species) of ticks (Rhipicephalus spp, Ixodes spp, Dermacentor variables, Amblyomna maculatum, Amblyoma americanum), [3 types (species of)] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp),
- Repels and kills fleas that may cause anemia
- Kills fleas that may cause anemia
- Repels fleas that may cause anemia
- Prevents flea infestation which may lead to anemia
- Kills the listed pests that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, anaplasmosis and heartworm disease
- Repels and kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis and anaplasmosis
- Repels and kills mosquitoes that may transmit heartworm disease
- Repels and kills Brown dog ticks (Rhipicephalus spp), Deer ticks (Ixodes spp), American dog ticks (Dermacentor variablis) Lone Star ticks (Amblyomma americanum) and Gulf Coast ticks (Amblyomma maculatum)
- Repels and kills Deer ticks (Ixodes scapularis, Ixodes ricinus, Ixodes pacificus)
- Long lasting one month flea, tick and mosquito control for your dog
- SVP7 kills more than adult fleas you see, it controls immature flea stages
- Kills all life stages of ticks
- SVP7 repels and kills fleas, ticks, mosquitoes
- Prevents all flea stages from developing
- SVP7 kills not only adult fleas, but also breaks the flea life cycle by preventing development of immature fleas (may include diagram of flea life cycle) for 30 days (one month) (4 weeks)
- Illustration of flea life cycle
- Kills [4 types (species) of ticks (Rhipicephalus spp, Dermacentor variabilis, Ixodes spp, Amblyomma spp), [3 types (species) of mosquitoes (Culex spp. Ochlerotatus spp, Aedes spp) all stages of fleas for 30 days (one month) (4 weeks).
- Controls [4 types (species) of ticks (Rhipicephalus spp, Dermacentor variables, Ixodes spp, Amblyomma americanum, Amblyomma maculatum and Amblyomma americanum), [3 types (species) of mosquitoes (Culex spp. Ochlerotatus spp, Aedes spp) all stages of fleas for one month (30 days) (4 weeks).

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- Repels and kills ticks including Deer ticks (vector of Lyme disease) American dog ticks (vector of Rocky Mountain spotted fever), Brown dog tick(vector of ehrlichiosis) and Gulf Coast ticks and Lone Star ticks (vector of hepatozoonosis) for one month (4 weeks) (30 days)
- Repels and kills Brown dog ticks (Rhipicephalus spp), American dog ticks (Dermacentor variabilis), Deer ticks (ixodes spp) and Gulf Coast ticks (Amblyomma maculatum) and Lone Star ticks (Amblyoma americanum) for one month (4weeks) (30 days)
- Kills Amblyomma americanum (Lone Star ticks) and Amblyomma maculatum (Gulf Coast ticks) for 4 week (for one month) (for 30 days)

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Waterproof

- Maintains residual efficacy after bathing and swimming
- Single application lasts 4 weeks (one month) (30 days)
- Controls the flea life cycle at all (immature) life stages for 4 weeks (30 days) (one month)
- Repellency and protection against fleas, ticks and mosquitoes for 4 weeks (30 days) (one month)
- Repellency against fleas, ticks, mosquitoes, lice, mites and sand flies for 4 weeks (30 days) (one month)
- Contains the proven effective topical, dinotefuran, for effective flea control
- Contain the proven effective topical, pyriproxyfen, for control of immature fleas
- Pyriproxyfen the insect growth regulator (found in SVP7) controls (stops) the development of immature fleas
- Contains the proven effective topical repellant, permethrin (for control of fleas, ticks, mosquitoes, lice, mites and biting & sand flies)
- Repels fleas, ticks, mosquitoes, sand flies, lice and mites (excluding mange mites)
- Repels ticks
- Repels fleas
- Repels mosquitoes
- Kills sand flies
- Repels sand flies
- Kills (biting & sucking) lice
- Repels lice
- Kills mites
- Repels mites (excluding mange mites)
- Repels (and kills) lice which may cause pruritus, erythema, (crusting and scaling)
- Repels (and kills) mites (excluding mange mites) that may cause dandruff, alopecia and pruritus
- Repels (and kills) biting & sand flies which may inflict irritating bites
- Repels (and kills) fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies
- Repels (and kills) (annoying) (bothersome) (nuisance) biting & sand flies
- SVP7 is indicated for the prevention and treatment of fleas, ticks, mosquitoes, biting & sand flies, lice and mites (excluding mange mites) on dogs over 7 weeks of age

- For the treatment and prevention of flea infestation
- For the control of all stages of flea infestation
- One treatment prevents further flea infestation for 30 days (4 weeks) (one month)
- Kills larval stages of fleas in the dog's environment
- Prevent all immature flea stages in the dog's environment from developing
- Controls the development of all immature flea stages in the environment
- Controls existing flea infestations by rapidly killing adult fleas and preventing development of immature flea stages
- Kills fleas that may serve as an intermediate host for tapeworms (Dipylidum caninum)
- Stops existing flea infestations by killing adult fleas
- Prevents flea eggs from hatching
- Prevents larval stages from developing
- Effectively (and efficiently) breaks the flea life cycle
- Effectively targets all (life) stages of fleas (and ticks)
- Repels and kills mosquitoes that may transmit vector borne disease
- Prevents blood feeding by mosquitoes
- Repels (and kills) [(annoying) (bothersome) (nuisance) sand flies and biting flies
- 6 way protection, repels (and kills) fleas, ticks, mosquitoes, lice, biting & sand flies and mites (excluding mange mites)
- Repels (and kills) [(biting) (chewing) lice
- Repels mites (excluding mange mites) and prevents further infestation
- Helps to relieve your dogs discomfort by controlling flea, tick, mite (excluding mange mites) and lice infestations
- SVP7 controls flea infestation that may lead to painful skin irritation and bacterial infection
- Illustration of flea life cycle
- Illustration of tick life cycle
- Illustration of mosquito life cycle
- Illustration of sand fly life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of sand fly
- Illustration of mite
- Illustration of louse
- Illustration of biting fly
- Illustration of biting fly life cycle
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- Repels (and kills) biting flies which may inflict irritating bites
- Prevents fly strike
- Controls fly strike

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- Repels (and kills) fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies
- Repels (and kills) (annoying) (bothersome) (nuisance) biting & sand flies
- SVP7 is indicated for the prevention and treatment of fleas, ticks, mosquitoes, sand flies, , lice and mites (excluding mange mites) on dogs over 7 weeks of age
- Kills biting flies
- Repels biting flies

- Repels fleas, ticks, mosquitoes, fire ants, biting & sand flies, , lice and mites (excluding mange mites)
- Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) for 4 weeks (30 days) (one month)
- Helps to relieve your dogs discomfort by controlling fleas, ticks, mites (excluding mange mites), biting flies, and lice infestations
- Repels and kills mosquitoes and biting & sand flies that may transmit vector borne disease
- Repels and kills sand flies that may transmit leishmaniasis
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease
- Repels and kills sand flies that may transmit leishmaniasis
- Monthly treatment is recommended for control (and prevention) of fleas, ticks, lice, mites (excluding mange mites), biting (& sand flies and mosquitoes,
- Results indicate that SVP7 repels and prevents biting flies from blood feeding on dogs

Controls infestations of chewing lice

- SVP7 together with heartworm preventative may be helpful in providing an extra layer of protection against possible transmission from feeding mosquitoes that may be carrying heartworm larvae.
- Kills and repels mosquitoes which may transmit West Nile virus

Reduces biting fly strike

Reduces flea feeding

Continues to kill and repel fleas and ticks after shampooing

Prevents re-infestation of fleas, ticks and chewing lice

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• Kills chewing lice

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- Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread naturally over the dog's body providing effective control of fleas, ticks, lice, mites (excluding mange mites) and mosquitoes for thirty days (four weeks, one month).
- Kills fleas that may cause flea allergy dermatitis and flea bite dermatitus

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- Kills the listed vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis, tularemia and heartworm disease
- Kills biting flies
- Repels biting flies
- Contains the proven effective topical repellent, permethrin (for control of fleas, ticks, mosquitoes, lice, mites (excluding mange mites),, biting flies (and sand flies)

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- Reduced flea feeding means reduced likelihood of transmission of vector borne disease
- Limited feeding reduces likelihood of anemia, irritation, flea allergy dermatitis and transmission of disease
- Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and sand flies for 4 weeks (30 days) (one month)

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• Begins reducing flea feeding in 5 minutes

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# NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

AMENDED LABELING Date: November 9, 2010

## **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.

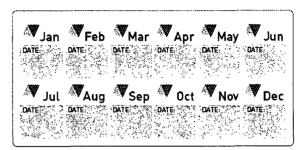
Attach these stickers to your wall calendar or day planner on the date you give the first dose of Product, and then place another sticker on the same date for each of the next two months.







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.





AMENDED LABELING Date: November 9, 2010

# APPLICATOR LABELING

SVP7

KEEP OUT OF REACH OF CHILDREN

WARNING READ ENTIRE LABEL BEFORE USE

 Dinotefuran
 4.95%

 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)