

83399-1

08/29/2007

1/10



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 29 2007

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

Dear Mr. Conti:

Subject: Revised labeling, in response to Agency's letter dated 5/9/2007
SVP4
EPA Registration Number 83399-1
Your submission dated 5/21/2007

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 the label changes listed below:

1. The optional marketing claim "For dogs and puppies over 7 weeks of age weighing over 55 lbs" must be made a mandatory statement, right below the product name. The relationship between package size and age and weight of the dog must be clear on the outer label.
2. On page 7, explain integrated flea management system, or delete this statement from alternative marketing text.

A stamped copy of the label is enclosed for your records. Please submit one (1) copy of final printed label before you release the product for shipment. 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

Enclosure

2/10

~~AUG 29 2007~~ ~~ACCEPTED~~
with COMMENTS
in EPA Letter Dated:

FRONT PANEL OF OUTER BOX

~~AUG 29 2007~~
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.
83399-1

SVP4

(Optional marketing claims—front and side panels/continued on pages 5-7)

- For dogs and puppies over 7 weeks of age weighing over 55lbs.
- 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%) fleas in 6 hours
- For dogs that enjoy the outdoors
- Remains effective after bathing and swimming
- Easy, spot- on (topical) application
- (Manufacturer)Guaranteed effective for at least one month or receive replacement product (or your money back)

SIDE A

ACTIVE INGREDIENTS:

Dinotefuran	14.85%
Pyriproxyfen.....	1.51%
OTHER INGREDIENTS	83.64%
TOTAL	100.00%

SIDE B

ACTIVE INGREDIENT:

Permethrin	45.00%
OTHER INGREDIENTS	55.00%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: 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)

DO NOT USE THIS PRODUCT ON CATS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: 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.

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. Sensitivities may occur after using ANY pesticide product for pets, such as slight transitory redness of the skin at the site of application. 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 (company) (or) 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.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

4/10

FIRST AID	
If in eyes:	Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice
If swallowed:	Call a poison control center, doctor, or 1-800-222-1222 immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth 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.	

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. Hold applicator with applicator point facing upward and tear off (cut off) (bend) (break off) (push down on) tip along perforation (score) (mark) (line)(to pierce seal) (as shown below). OR Hold applicator with applicator facing upward. Screw cap clockwise to pierce seal.

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

4. The dog should be standing or in a comfortable position for easy application.
5. Part the hair between the shoulder blades and slowly apply the product (to one

5/10

spot) (as shown below) onto the skin until the applicator is completely 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. Discard empty applicator as outlined in Storage and Disposal.
7. Repeat every month, for optimum treatment, control and prevention of fleas, flea eggs, flea pupae, flea larve, 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 0.16 fl. oz. (4.7 mL) [Total X fl. oz., X mL]

EPA Reg. No. 83399-1
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 guaranteed or (Summit VetPharm will supply new product)(your money back)
- Quick onset of activity (kill) within 2 hours
- Prevents re-infestation (of fleas and ticks) for up to one month
- 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 (topical) application
- Convenient, easy to apply
- Fragrance (odor) free
- Convenient to use
- Water-resistant
- Convenient (easy to apply) topical treatment
- Remains effective even after bathing, water immersion or exposure to rain or sunlight
- Still works after bathing, swimming or exposure to sunlight
- Convenient topical treatment formulated for dogs who enjoy the outdoors
- Convenient topical treatment for dogs that enjoy the outdoors
- Formulated for dogs that love the outdoors

7/10

- Rapid kill of fleas, ticks and mosquitoes is important in the prevention of disease transmission by these insects and the parasites (vectors) they may carry
- (Only) available from licensed veterinarians
- Specially formulated for dogs [and puppies 7 weeks or older] [and] [2.5-10 lbs.]
- Great for puppies from 7 weeks of age
- After application, spreads naturally over the dog's body to provide (full body) (all-over) protection against fleas, ticks and mosquitoes
- SVP4 contains dinotefuran, a neonicotinoid insecticide, which is specific to the nervous system of insects,
- Dinotefuran kills fleas within 6 hours
- SVP4 contains permethrin, an effective insecticide/acaricide that provides efficacy against fleas, ticks and mosquitoes .
- SVP4 contains the insect growth regulator pyriproxyfen that acts to prevent the development of all flea stages for at least one month.
- Approximately 95% of the flea population in a household infestation is immature flea stages that live in the dog's environment.
- SVP4 provides ongoing protection against fleas ticks and mosquitoes for at least one month
- Questions or comments—please call (tel. no.)
- For more information call (tel. no.)

- Kills vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, and heartworm
- Kills fleas, ticks and mosquitoes before they lay eggs
- Repels and kills fleas, ticks and mosquitoes
- Effective monthly treatment of fleas, ticks and mosquitoes
- Easy, effective control of fleas, ticks and mosquitoes that lasts at least 1 month
- Repels and protects against ticks, mosquitoes, and fleas

- Kills over 95% of fleas in 6 hours and up to 100% in 12 hours
- Kills fleas that may transmit disease, including bartonellosis
- Kills fleas before they lay eggs
- Kills and repels fleas before they lay eggs
- Regular use breaks the flea life cycle
- Regular use protects against all stages of the flea life cycle

- Prevents development of all flea stages for at least 1 month
- Kills up to 99% of fleas within 6 hours

- Kills and repels ticks within 24 hours
- Repels and kills ticks that (cause) (transmit) Lyme disease
- Repels and kills ticks including those that may transmit Lyme disease
- Kills ticks that may cause disease, including Lyme disease
- Repels and kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis

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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 can carry and transmit the organism which may causes Lyme disease
 - Kills ticks that may carry and transmit babesiosis
 - Kills ticks that may carry and transmit Ehrlichia
 - Kills ticks [in 24-48 hours] before they may transmit Lyme disease
 - Kills ticks[in 24-48 hours] before they may transmit Ehrlichia
 - Repels ticks before they can attach to dogs and take a blood meal
 - Repels and kills ticks, which may transmit disease
 - Kills ticks before they can lay eggs
 - Kills ticks which carry 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 heartworm (*Dirofilaria immitis*)
 - Repels and kills up to 100% of mosquitoes for at least one month
 - Proven treatment technology for flea infestations
 - Recommended for use in an integrated flea management system

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

9/10

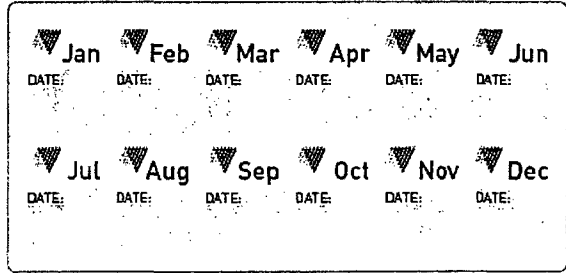
NEXT DOSE STICKERS AND REMINDER CALENDAR

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.



10/10

APPLICATOR LABELING

KEEP OUT OF REACH OF CHILDREN

CAUTION
READ ENTIRE LABEL BEFORE USE

SIDE A

Dinotefuran14.85%
Pyriproxyfen.....1.51%

SIDE B

Permethrin.....45.00%

0.16 fl. oz. (4.7 mL)

DO NOT USE ON CATS [ICON]

EPA Reg. No. 83399-1
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)