

83399-4



08/29/2007

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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.
SVP5
EPA Registration Number 83399-4
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. Add "(1.2 ml size only)" after the alternate brand name Vectra for Cats and Kittens 3-9 lbs. and 12 weeks of age or older, for consistency and clarification.
2. Add "(1.8 ml size only)" to the second bullet under optional marketing claims.
3. Revise the second sentence in the warranty statement on page 5 as follows: "To the extent consistent with applicable law, seller makes no warranty, express or implied,.....".
4. Add "older" (.....12 weeks of age or older) to the second from last bullet on page 5.
5. On page 2, the second statement (after OR) under the heading HAZARDS TO DOMESTIC ANIMALS is contradictory. It must be revised to read as follows: "Do not use on cats less than 9 lbs and less than 6 months of age (1.8 ml dose)."
6. On page 1, the title "ACTIVE INGREDIENTS" needs to be in singular: "ACTIVE INGREDIENT", since there is only one active ingredient in this product.

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

"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

SVP5

Alternate Brand Name;

Vectra for Cats (over 9 lbs, 6 months and older) (1.8 ml size only)

Vectra for Cats and Kittens (3-9 lbs. and 12 weeks of age or older)

(Optional marketing claims—front and side panels/continued on pages 5-6)

- For cats and kittens 3-9lbs and 12 weeks of age or older (1.2 ml size only)
- For cats over 9lbs and 6 months and older
- Effective monthly treatment of fleas
- Protects from fleas for at least one month
- Kills newly emerged fleas before they lay eggs
- Kills (96% of) fleas within 6 hours
- Flea treatment formulated for cats (and kittens 1.2 ml dose)
- Easy, spot on application
- (Manufacturer) Guaranteed effective for at least one month or receive replacement product (or your money back)

ACTIVE INGREDIENTS:

Dinotefuran.....14.85%

OTHER INGREDIENTS.....85.15%

TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION:

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 29 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
As amended, for the pesticide
Registered under EPA Reg. No.
83399-4

BACK PANEL OF OUTER BOX

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON CATS (and KITTENS 3-9lbs and OVER 12 WEEKS OF AGE . (1.2 ml dose)

USE ONLY ON CATS over 9lbs, 6 months and older (1.8 ml dose)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes. 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, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use on cats and kittens 3-9lbs and over 12 weeks of age (1.2 ml dose).

OR

Do not use on cats less than 9lbs and 6 months and older. (1.8 ml dose).

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 (company) (or) your veterinarian for advice.

PHYSICAL OR CHEMICAL HAZARDS

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

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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. Remove one applicator tube from the package and hold in an upright position.
2. The cat (and kitten 1.2 ml dose) should be in a comfortable position for easy application.
3. 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 the face and body. Puncture the safety seal of the tube.

[Instruction for alternate package replaces step 3 above:

3. *Holding the applicator upright and with the end of the applicator tube pointing away from your face and body, push firmly down on applicator cap to puncture safety seal.]*

[Instruction for alternate package replaces step 3 above:

3. *Holding the applicator upright, with thumb and middle finger squeeze the tabs, while pressing firmly down on applicator cap with index finger to*

puncture safety seal.] OR Hold the tube with the applicator pointing away from your face and body. With the other hand, turn the applicator clockwise to pierce the foil seal.

GRAPHICS DEPICTING HOW TO OPEN PACKAGE/APPLICATOR

4. Part the hair down to the level of the skin and slowly apply the product at the base of the cat's (and/or kitten's 1.2 ml dose) head until the applicator is completely empty, as shown in the diagram below. Avoid superficial application to the animal's hair.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

Do not get the product in your cat's (or kitten's 1.2 ml dose) eyes or mouth

5. Discard empty applicator as outlined in Storage and Disposal.
6. Repeat every month, or as needed. Do not reapply more frequently than every 30 days unless recommended by your veterinarian.
7. For optimum treatment, control and prevention of fleas, 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 0.061 fl. oz. (1.8 mL) [Total X fl. oz., X mL]

NET CONTENTS: X applications (applicators), each 0.041 fl. oz. (1.2 mL) [Total X fl. oz., X mL]

EPA Reg. No. 83399-4

EPA Est. No.

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Made in the USA (by) [Distributed by:]
[Summit VetPharm, LLC] , 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 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 cat (and kittens over 3-9lbs and 12 weeks of age or older) (1.2 ml dose) from fleas for at least one month
- Performance guaranteed or (Summit VetPharm will supply new product) (or your money back)
- Quick onset of activity (kill) within 2 hours
- Prevents (re-)infestation (of fleas) for at least one month
- Monthly treatment is recommended for optimal control and prevention of fleas
- Begins working upon application
- 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
- No noticeable odors
- Convenient to use
- Convenient (easy to apply) topical treatment
- Still works after exposure to sunlight
- Convenient topical treatment specially formulated for cats (and kittens 3-9lbs. and 12 weeks of age or older) (1.2 ml dose)
- Formulated for cats (and kittens 3-9lbs and 12 weeks of age or) (1.2 ml dose)
- For cats (and kittens 3-9lbs and 12 weeks of age or older) (1.2 ml dose)

-
- Rapid kill of fleas is important in the prevention of disease transmission by (these) parasites
 - Available from (licensed) veterinarians
 - Sold by veterinarians
 - Formulated for cats (and kittens 3-9lbs and 12 weeks of age or older) (1.2 ml dose)
 - After application, SVP5 spreads across the cat's (and/or kitten's 1.2 ml dose) body to provide (full body) (all-over) protection against fleas
 - SVP5 provides ongoing protection against fleas (and the diseases they may transmit) for at least one month
 - Effective monthly control of adult fleas
 - SVP5 contains dinotefuran, a neonicotinoid insecticide, which is specific to the nervous system of insects.
 - Dinotefuran kills (99% of) fleas within 6 hours
 - SVP5 kills (99% of) fleas within 6 hours
 - Questions or comments—please call (tel. no.)
 - For more information call
 - For emergencies call (tel. no.)
 - Kills fleas that may transmit disease, including bartonellosis
 - Kills fleas
 - Easy to apply, effective control of fleas that lasts at least 1 month
 - Kills over 95% of fleas in 6 hours and up to 100% in 12 hours
 - Regular use breaks the flea life cycle
 - Begins working upon application and kills up to 99% of fleas within 6 hours

 - Proven treatment technology for flea infestations

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

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SVP5: EPA REG. NO. 83399-4

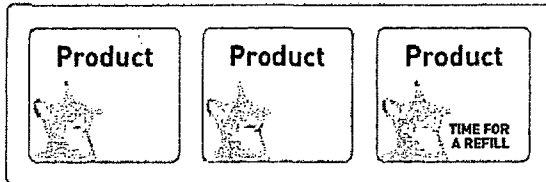
PROPOSED LABELING

Date: 5/21/2007

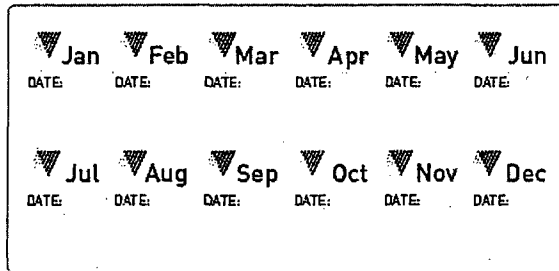
NEXT DOSE STICKERS AND REMINDER CALENDAR

It can be hard to remember when your cat'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

SVP5

KEEP OUT OF REACH OF CHILDREN

CAUTION
READ ENTIRE LABEL BEFORE USE

Dinotefuran.....14.85%

0.061 fl. oz. (1.80 mL)
0.0441 fl. oz. (1.20 mL)

EPA Reg. No. 83399-4
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)