

83399-9

03/14/2008

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

March 14, 2008

Joseph Conti
Summit VetPharm LLC
400 Kelby Street
Fort Lee, NJ 07024

Dear Mr. Conti:

Subject: Submission of amended labeling
SVP8
EPA Registration No. 83399-9
Submission dated February 15, 2008

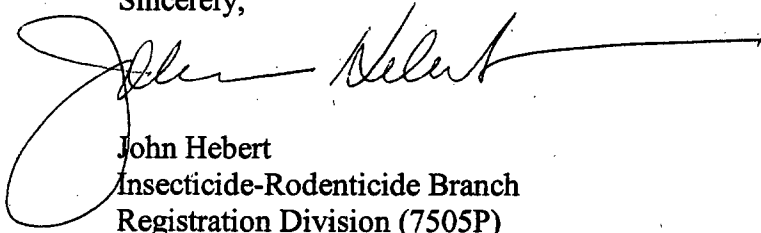
The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable with the following comments:

- On page 2, delete the phrase "(and active ingredients)" so the statement reads, "See package insert for directions for use, precautionary statements, first aid, and other information." The active ingredient information must remain on the front panel.
- On page 2, the statement "For external use on cats 9 lbs and over 8 weeks of age (1.2 ml dose)" is not clear. Therefore, revise the statement to read, "For external use on cats 9 lbs and over, and over 8 weeks of age (1.2 ml dose)."
- On page 4, revise the sixth statement so it reads, "Repeat once a month or as recommended by your veterinarian, **but do not apply more often than once a month.**"
- On page 7, delete the word "(stages)" in the 7th, bulleted marketing statement so it reads, "SVP8 kills fleas within 6 hours."
- On page 7, delete the following alternate marketing statement: "Kills." An unqualified "kills" claim is not acceptable.

- On page 8, revise the following alternate marketing statement: "Pyriproxyfen kills and controls immature fleas" so it reads, "Pyriproxyfen controls immature fleas." A kill claim for immature fleas is not acceptable.

A stamped copy is enclosed for your records. Submit two copies of your final printed labeling before you release the product for shipment. Should you have any questions, please contact me at 703-308-8735 or chao.julie@epa.gov.

Sincerely,



John Hebert
Insecticide-Rodenticide Branch
Registration Division (7505P)

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"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

SVP8

Alternate Brand Name;

Vectra for Cats (9 lbs and over)(1.2 ml dose)

Vectra for Cats and Kittens (under 9 lbs. and (over) 8 weeks of age (or older))(0.8 ml dose)

Vectra Plus for Cats (9 lbs and over)(1.2 ml dose)

Vectra Plus for Cats and Kittens (under 9 lbs and (over) 8 weeks of age (or older))(0.8 ml dose)

Vectra Excel, (Vectra Dual, Vectra 2C, Vectra Duo, Vectra II, Vectra +, Vectra 2, Vectra Gold, Vectra Shield) for Cats (9 lbs and over)(1.2 ml dose)

Vectra Excel, (Vectra Dual, Vectra 2C, Vectra Duo, Vectra II, Vectra +, Vectra 2, Vectra Gold, Vectra Shield) for Cats and Kittens (under 9 lbs and (over) 8 weeks of age (or older))(0.8 ml dose)

**Effective monthly control of; Adult fleas, (flea) eggs, (flea) larvae and (flea) pupae
Net Contents; xx Doses, each yy fl.oz. (zz ml)**

(Optional marketing claims—front or back or side panels/continued on pages 5-8)

ACTIVE INGREDIENTS:

Dinotefuran.....	22.00%
Pyriproxyfen.....	3.00%
OTHER INGREDIENTS.....	75.00%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING

xx Doses

Net Content xx doses; each xxmls

**ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR 14 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
83399-9**

Front, back, side and/or insert language

See package insert for directions for use, precautionary statements, first aid and other information (and active ingredients.)

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum and using tobacco products. Remove and wash contaminated clothing before reuse

For external use on cats and kittens under 9lbs and over 8 weeks of age (0.8 ml dose).

For external use on cats 9 lbs and over 8 weeks of age (1.2 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 your veterinarian for advice.

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 for treatment advice
If swallowed:	Call a poison control center, doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Have person sip a glass of water if able to swallow. 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 1-800-999-0297 or after 6pm EST 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 or after 6pm EST 1-888-426-4435 for emergency medical 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. Remove applicator from package.
2. The cat should be standing or 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 your face and body. Using the cap puncture the safety seal on the tube. (Screw the applicator tip onto tube.) OR

Alternate language--step 3, based on applicator:

Holding the applicator upright at the top below applicator tip, with thumb and index middle finger(of the other hand) (squeeze the tabs and) press down firmly, while pressing firmly down on applicator cap with index finger 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) 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 small disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)

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 0.8 ml dose) head until the applicator (tube) is (completely) empty, as shown in the diagram below. Do not make superficial application to the cat/kitten's hair.

[GRAPHICS DEPICTING TREATMENT OF ANIMAL]

Do not get the product in your cat's (or kitten's 0.8 ml dose) eyes or mouth

5. Discard empty applicator (tube) as outlined in Storage and Disposal.
6. Repeat once a month (30 days, 4 weeks) or as recommended by your veterinarian.
7. For optimum treatment, control and prevention of (adult) fleas, flea eggs, flea larvae and (flea) pupae, 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.

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NET CONTENTS: X applications (applicators,doses)(1,2,3,4,6,8,9,12,18,24,36 applicators, doses), each 0.027 fl. oz. (0.8 mL)

[NET CONTENTS: X applications (applicators, doses)(1,2,3,4,6,12,18, 24,36 applicators, doses), each 0.041 fl. oz. (1.2 mL)

Example; 3 doses, each xx fl oz.(0.8 ml.)

EPA Reg. No. 83399-9

EPA Est. No. xxxx-xxx

Made in the USA (by)] [Sold by:]
[Summit VetPharm, LLC] ,(400 Kelby Street) 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 directions. 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 cats and kittens (under 9lbs and 8 weeks of age or older) (0.8 ml dose) from fleas, flea eggs, flea larvae and flea pupae (for one month)
- Protects cats (9 lbs and over and 8 weeks of age or older) (1.2ml dose) from fleas, flea eggs, flea larvae and flea pupae (for one month)
- For cats and kittens under 9 lbs and(over) 8 weeks of age (or older) (0.8 ml size only)
- For cats 9 lbs and over(1.2 ml size only)
- X (single) dose(s) (applicators)
- Effective monthly treatment of (against) fleas, flea eggs, larvae and pupae
- Protects (your cat and kitten) from all stages of fleas for one month
- Prevents development of fleas, flea eggs, flea larvae and (flea)pupae
- Protects from fleas for one month
- Protects cats (1.2 ml) and kittens (0.8 ml) from the development of anemia associated with (severe) flea infestation
- Kills newly emerged fleas before they lay eggs
- Kills fleas within 6 hours
- Formulated for Cats 9 lbs. and over (1.2 ml)

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- Flea treatment formulated for cats 9 lbs. and over (1.2 ml dose)
 - Flea treatment formulated for cats and kittens under 9 lbs. (0.8ml dose)
 - Easy, spot- on (topical) application
 - (Patented) applicator tip (Trademark) for easy application directly to the skin
 - Performance guaranteed or your money back (SVP ICON) ((Please) call our professional staff at xxx-xxx-xxxx or e-mail us at info@summitvetpharm.com if you have any questions or comments about SVP8)
 - Kills fleas that may cause flea allergy dermatitis(FAD)
 - (New) complete flea control (for cat and kittens) (New-first 6 months)
 - SVP8 contains the insecticide dinotefuran, a neonicotinoid with knockdown effect. Pyriproxyfen is an insect growth regulator which controls development of immature fleas.
 - Picture of cat
 - Picture of kitten
 - Performance guaranteed or Summit VetPharm will supply replacement product
 - Persistent efficacy through 30 days
 -
 - Prevents (re-)infestation (of fleas) for one month
 - Monthly treatment (all year) is recommended for optimal control and prevention of fleas
 - Once monthly application
 - X applicators (doses)
 - X monthly doses (applications) (treatments)
 - Quick drying, non-greasy
 - Easy to apply spot-on (patented) applicator
 - Easy to apply spot-on (patented) applicator (allows the product to be applied directly to the skin)
 - Convenient, easy to apply
 - Fragrance (odor) free
 - No noticeable (lingering) odors
 - Convenient to use
 - Convenient (easy to apply) topical treatment
 - Still works after exposure to sunlight
 - Convenient (easy to apply) topical treatment [with (patented) applicator tip] (that allows application down to the skin)
 - Formulated for cats (1.2 ml dose)
 - Formulated for cats and kittens (under 9 lbs and over 8 weeks of age) (0.8 ml dose)
 - For cats and kittens (and kittens under 9 lbs and over 8 weeks of age) (0.8 ml dose)
 - For cats 9 lbs. and over (1.2 ml)
 - (Only)Available from (licensed) veterinarians
 - Sold (only) by veterinarians
 - Available from licensed veterinarians only

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- SVP8 provides ongoing protection against fleas (and the diseases they may transmit) for one month
- Effective monthly control of all stages of fleas (flea stages)
- After application, SVP8 spreads naturally over the cat's body to provide (full body) (all-over) protection against all stages of fleas
- SVP8 contains dinotefuran, a (NEW- first 6 months) neonicotinoid insecticide, which is specific to the nervous system of insects.
- SVP8 contains dinotefuran, a neonicotinoid insecticide, specific to the acetylcholine receptors of the insect nervous system
- Dinotefuran kills fleas within 6 hours
- SVP8 kills fleas (stages) within 6 hours
- Questions or comments—please call (tel. no.) or e-mail us at info@summitvetpharm.com
- For more information call (tel. no.)
- SVP8 protects cats (and kittens 0.8 ml) from fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*
- SVP8 protects cats (and kittens 0.8 ml) from fleas that may carry and transmit *Francisella tularensis*
- SVP8 kills fleas that may carry and transmit *Rickettsia felis*, *Rickettsia typhi* and *Francisella tularensis*
- For emergencies call (tel. no.)
 - Kills fleas that may transmit disease, including bartonellosis , tapeworm and tularemia
 - Controls (fleas) (all stages of fleas)
 - Easy to apply, effective control of fleas that lasts 1 month (30 days) (4 weeks)
- Kills
- Kills fleas within 6 hours
- Kills fleas that may transmit disease, such as bartonellosis and tapeworm disease .
- Regular use breaks the flea life cycle
- Starts working with first application and continues to kill all adult fleas and control immature fleas for up to one month
- Starts with first application, killing fleas in 6 hours
- Recommended for use in an integrated flea management system
- Treatment of cats (and kittens under 9lbs and over 8 weeks of age) with SVP8 kills fleas that may cause flea allergy dermatitis (FAD)
- Kills fleas that may cause flea allergy dermatitis (FAD) and anemia
- The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats with SVP8 kills fleas and may reduce the incidence of FAD.
- SVP8 is useful for cats (and kittens) susceptible to Flea Allergy Dermatitis (FAD)
- SVP8 contains the insect growth regulator pyriproxyfen that acts to control (prevent) the development of all immature fleas for one month (30 days) (4 weeks)
- Regular use (of SVP8) protects your cat (and kitten) against all stages of the flea life cycle
- Proven treatment technology for problem flea infestations

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- Proven treatment technology for flea infestation
 - Pyriproxyfen (the insect growth regulator) found in SVP8 stops the development of immature fleas
 - Pyriproxyfen kills and controls immature fleas
 - New (first 6 months)
 - New complete flea control (first 6 months)
 - New formula for (your) cat(s) (first 6 months)
 - May be used as part of a treatment strategy for control of Flea Allergy Dermatitis (FAD)
 - A single dose effectively stops flea infestation and prevents re-infestation for one month (30 days, 4 weeks)
 - For both indoor and outdoor cats (and kittens 0.8 ml)
 - Single spot control for all flea stages
 - SVP8 may be used to prevent infestation in flea free cats (and kittens 0.8ml)
 - SVP8 prevents infestation in flea free cats (and kittens) and protects animals in flea contaminated environments
 - Kills adult fleas which may cause flea allergy dermatitis (FAD)
 - SVP8, flea control for an age old problem
 - Patented applicator makes it easier to apply and minimizes risk of skin abrasion
 - Controls and stops flea infestations
 - Prevents (flea) re-infestation
 - Kitten pack (24 and 36 applicator packs, 0.8 ml size only)
 - Feline (cat) pack (24 and 36 applicator packs, 1.2ml size only)
 - Kills fleas and prevents infestation for one month
 - Apply monthly for long lasting flea control and year round protection
 - SVP8 kills more than the adult fleas you see, it controls immature fleas
 - Fleas do not have to bite to die
 - SVP8 kills fleas on contact
 - SVP8 kills not only adult fleas, it breaks the flea life cycle (flea life cycle diagram)
 - SVP8 kills fleas on your cat and the emerging fleas from your cat's (pet's) environment
 - Eliminates existing flea infestations on your pet (cat or kitten)
 - Kills adult fleas and controls immature fleas with two effective ingredients (dinotefuran and pyriproxyfen)
 - Proven effective topical flea control containing dinotefuran and pyriproxyfen
 - 21st century flea control

 - After application, SVP8 spreads naturally over the cat's body to provide (full body) (all-over protection against all flea stages)

 - Remains effective after exposure to sunlight

 - Kills fleas before they lay eggs

 - Proven treatment technology for flea infestation

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- Contains pyriproxyfen an insect growth regulator
- Kills fleas that may cause anemia
- Protect your cat from flea infestation that may cause anemia
- Pyriproxyfen provides ovicidal activity

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

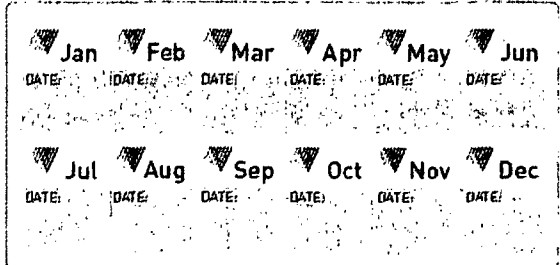
NEXT DOSE STICKERS AND REMINDER CALENDAR

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. Do not apply more than once a month.



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APPLICATOR LABELING

SVP8

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

Dinotefuran.....	22.00%
Pyriproxyfen.....	3.00%

0.027 fl. oz. (0.80 mL)
0.041 fl. oz. (1.20 mL)

EPA Reg. No. 83399-9
EPA Est. No. TBD

Lot # (*designation will identify producing establishment*)