

83399-9

12/17/2013

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DEC 17 2013

Ms. Alicia Henk
Director Pharmaceutical Development and Regulatory Affairs
Ceva Animal Health
8735 Rosehill Rd., Suite 300
Lenexa, KS 66215

Dear Ms. Henk:

Subject: Label amendment – pet spot-on risk mitigation per Agency letter dated 9/30/2011
SVP8
EPA Registration Number 83399-9
Your submissions dated 8/15/2012 and 9/19/2013
OPP tracking decision number D463272.

Revised label dated Sept. 14, 2013, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is accepted subject to the comments listed below:

1. Submit the final printed label with a clear picture of a cat in each weight range for the product as packaged on the front panel of the label, plus other graphics and pictures.
2. This registration is now time-limited and expires two years from the date of this letter.
3. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning [January 1, April 1, July 1, or October 1, whichever date most closely follows the date of the letter].

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlin Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
 Product name (brand name)
 Lot #
 Where purchased: internet, store, veterinarian
 Active Ingredient(s)
 Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
 State in which the incident occurred. (standard 2 letter abbreviation)
 Registrant case #

Species: dog, cat, other (specify)
 Breed: (as reported by pet owner)
 Age: months or years
 Sex: M, F, or neutered
 Weight: pounds


Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 Body System: neurological, dermatological, GI, respiratory, ocular, other
 Major signs noted with separate column for each sign, using standard terminology
 Time to Onset: (hours, days)
 Treated by veterinarian: yes or no
 First time product used: yes or no
 Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 Any known precondition
 EPA Severity Code: death, major, moderate, minor
 Outcome: died, recovered, still treated, unknown

5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
 - A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
- Table showing number of incidents for each cat breed.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

Submit one copy of your final printed labeling as required in comment number 1 above. If you have any questions, please contact Rita Kumar at (703) 308-8291, or kumar.rita@epa.gov.

Yours Sincerely,



Reuben Baris, Acting PM 7
Insecticide-Rodenticide Branch
Registration Division (7505P)

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SVP8: EPA REG. NO. 83399-9
Revised LABELING
Date: Sept 14, 2013

"Master Label"
(This master label includes label text for different size packages and application rates specific to the pet's age and body weight)

ACCEPTED

DEC 17 2013

FRONT PANEL OF OUTER BOX

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

SVP8 for Cats

Picture of
Cat/Kitten
according to
weight range

EPA. Reg. No. 83399-9
Alternate Brand Names:

[Vectra for Cats] [Vectra Plus for Cats] [Vectra Excel for Cats] [Vectra Dual for Cats] [Vectra 2C for Cats] [Vectra Duo for Cats] [Vectra II for Cats] [Vectra 2 for Cats] [Vectra Gold for Cats] [Vectra Shield for Cats] [SimpleGuard for Cats]
[9 lbs and over (1.2ml dose)]

[Vectra for Cats and Kittens] [Vectra Plus for Cats and Kittens] [Vectra Excel for Cats & Kittens] [Vectra Dual for Cats & Kittens] [Vectra 2C for Cats & Kittens] [Vectra Duo for Cats & Kittens] [Vectra II for Cats & Kittens] [Vectra 2 for Cats & Kittens] [Vectra Gold for Cats & Kittens] [Vectra Shield for Cats and Kittens] [SimpleGuard for Cats & Kittens]
[2 to 9 lbs and over 8 weeks of age (0.8ml dose)]

[FOR CATS & KITTENS – use only on cats and kittens 2 to 9lbs and over 8 weeks of age]
[FOR CATS & KITTENS – use only on cats 9lbs and over, and over 8 weeks of age]

Effective monthly control of adult fleas, (flea) eggs, (flea) larvae and (flea) pupae
(Optional marketing claims—front or back or side panels/continued on pages 4-8)

ACTIVE INGREDIENTS:

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

KEEP OUT OF REACH OF CHILDREN

WARNING

See package insert for directions for use, precautionary statements, [and] first aid [and other information].

Net Contents: XXX fl oz
X Doses [each dose, xxx fl oz (xx ml)]

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Front, back, side and/or insert language

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

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, using tobacco products, or using the toilet. Remove and wash contaminated clothing before reuse.

HAZARDS TO DOMESTIC ANIMALS

For external use only on cats and kittens 2 to 9lbs and over 8 weeks of age (0.8 ml dose).

For external use only on cats 9 lbs and over, 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.

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. 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 or clothing:	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.	

Side Effects: Monitor your cat after application. Individual sensitivity, such as slight transitory redness, erythema, scratching, pruritus or other signs of discomfort at the site of application, may occur after using ANY pesticide product for cats. If signs of sensitivity occur, bathe your cat with mild soap or shampoo and rinse with large amounts of water. If signs of individual animal sensitivity occur and persist, contact your veterinarian. Gastrointestinal signs such as vomiting or diarrhea have also been reported, if these or other side effects occur, consult your veterinarian or call us at 1-800-999-0297. Have the product container or label with you when calling your veterinarian for advice.

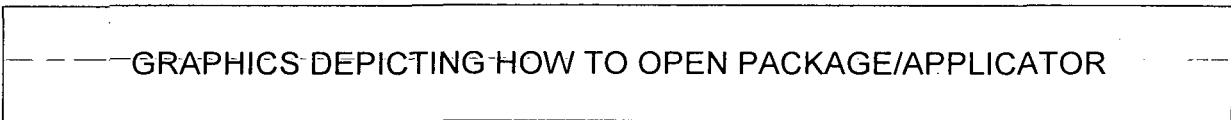
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DIRECTIONS FOR USE

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).]
Use Restriction: Use only on cats. Do not have contact or allow children to have contact with treated areas until treatment is completely dry.

HOW TO APPLY:

1. Remove applicator (tube) from package.
2. The cat should be standing or in a comfortable position for easy application.
3. 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)



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.]



[Avoid superficial application to the animal's hair.][Do not get the product in your cat's eyes or mouth.]

5. Discard empty applicator (tube) as outlined in the Storage and Disposal section.
6. Repeat every month (30 days, 4 weeks), or as recommended by your veterinarian.
7. For optimal 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.

PESTICIDE STORAGE: Store in a cool, dry place. Protect from freezing.

PESTICIDE DISPOSAL AND CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. **If empty:** Place in trash or offer for recycling, if available. **If partially filled:** call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

[NET CONTENTS: XXX fl oz (XXX ml)]

[[1] [2] [3] [4] [6] [8] [9] [12] [18] [24] [36] [dose(s)][applications][applicators]]

[each 0.027 fl oz (0.8 ml)]

[each 0.041 fl oz (1.2 ml)]

EPA Reg. No. 83399-9

EPA Est. No.

[Made in the USA (by)] [Sold by:]

Ceva Animal Health, LLC

8735 Rosehill Road

Lenexa, KS 66215

[For additional information, contact us at 1-800-999-0297 or contact.us@ceva.com]

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 (for use on front or side or back panels)

- 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)
 - Flea treatment formulated for cats 9 lbs. and over (1.2 ml dose)
 - Flea treatment formulated for cats and kittens 2 to 9 lbs. (0.8ml dose)
 - Easy, spot-on (topical) application
 - (Patented) applicator tip (Trademark) for easy application directly to the skin
 - Satisfaction guaranteed or your money back (Ceva ICON) ((Please) call our professional staff at xxx-xxx-xxxx or e-mail us at contact.us@ceva.com if you have any questions or comments about SVP8)
 - Kills fleas that may cause flea allergy dermatitis(FAD)
 - Complete flea control (for cat and kittens)
 - 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
 - Satisfaction guaranteed or Ceva Animal Health, LLC 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)

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- Formulated for cats (1.2 ml dose)
 - Formulated for cats and kittens (2 to 9lbs and over 8weeks of age) (0.8 ml dose)
 - For cats and kittens (2 to 9lbs and over 8 weeks of age) (0.8 ml dose)
 - For cats 9 lbs. and over (1.2 ml)
 - Available from (licensed) veterinarians
 - Sold by veterinarians
 - Available from licensed veterinarians
 - 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 over the cat's body to provide (full body) (all-over) protection against all stages of fleas
 - SVP8 contains dinotefuran, a 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 within 6 hours
 - Questions or comments—please call (tel. no.) or e-mail us at contact.us@ceva.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 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 fleas and 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.

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- SVP8 is useful for cats (and kittens) susceptible to Flea Allergy Dermatitis (FAD)
 - SVP8 contains the insect growth regulator pyriproxyfen that acts to 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
 - Proven treatment technology for flea infestation
 - Pyriproxyfen has an anti-feeding effect on adult fleas, thereby preventing the flea from taking a blood meal
 - Pyriproxyfen (the insect growth regulator) found in SVP8 stops the development of immature fleas
 - Pyriproxyfen controls immature fleas
 - 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 0.8ml)
 - 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
 - SVP8 contains (pyriproxyfen) a photostable insect growth regulator (IGR) (for control of all immature flea stages)
 - 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
- 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
- Available from (Ceva authorized) (Seller authorized)(approved) (endorsed) (certified) (qualified) veterinarians. (Ceva) (Seller) may take appropriate (legal) action against any person not so authorized involved in the sale of this product.
- This product has been authorized for sale by (Ceva) (Seller) exclusively through veterinarians (in the context of an established veterinarian/client/patient relationship). (Ceva) (Seller) may pursue appropriate (legal) action against any person not so authorized involved in the sale of this product.
- Sold by (Ceva authorized) (Seller authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (We)(Ceva)(Seller) (company name) may take appropriate (legal) action if the product is sold by an unauthorized person.
- Sold by (authorized) (approved) (endorsed) (certified) (qualified) veterinarians. (Seller) (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Available from (authorized) (approved) (endorsed) (certified) (qualified) veterinarians. Seller markets this product only to (authorized) (approved) (endorsed) (certified) (qualified) veterinarians, who have established (veterinary client relationship) (veterinary patient relationship) (veterinary client patient relationship). Sale or marketing of this product by (unauthorized) (not approved) (non -qualified) persons could result in appropriate action by the (manufacturer) (Ceva) (company name)
- Available from (Ceva authorized) (Seller authorized)(approved) (endorsed) (certified) (qualified) veterinarians.
- (Ceva) (Seller) may take appropriate (legal) action against any person not so authorized involved in the sale of this product.
- Available from licensed veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Sold by veterinarians. (Company name) reserves the right to take appropriate (legal) action if this product is sold by an unauthorized person.
- Sale or marketing of this product by (unauthorized) (not approved) (non -qualified) persons could result in appropriate action by the (manufacturer) (Ceva) (company name)

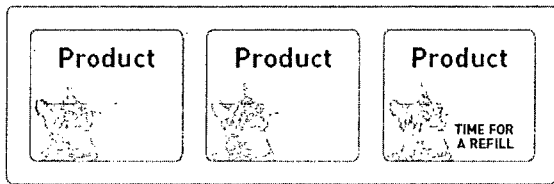
NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

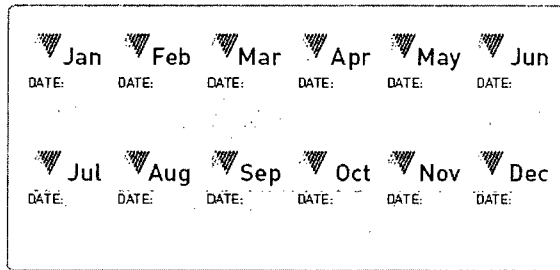
NEXT DOSE STICKERS AND REMINDER CALENDAR

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 for Cats

Alternate Brand Names:

[Vectra for Cats] [Vectra Plus for Cats] [Vectra Excel for Cats] [Vectra Dual for Cats] [Vectra 2C for Cats] [Vectra Duo for Cats] [Vectra II for Cats] [Vectra 2 for Cats] [Vectra Gold for Cats] [Vectra Shield for Cats] [SimpleGuard for Cats]
[9 lbs and over (1.2ml dose)]

[Vectra for Cats and Kittens] [Vectra Plus for Cats and Kittens] [Vectra Excel for Cats & Kittens] [Vectra Dual for Cats & Kittens] [Vectra 2C for Cats & Kittens] [Vectra Duo for Cats & Kittens] [Vectra II for Cats & Kittens] [Vectra 2 for Cats & Kittens] [Vectra Gold for Cats & Kittens] [Vectra Shield for Cats and Kittens] [SimpleGuard for Cats & Kittens]
[2 to 9 lbs and over 8 weeks of age (0.8ml dose)]

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

KEEP OUT OF REACH OF CHILDREN

WARNING

READ ENTIRE LABEL BEFORE USE

Use only on cats over 8 weeks of age, weighing [2 to 9 lbs] [9 lbs.and over]

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)*