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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 13 2009

Mr. Joseph A. Conti
Senior Director, Regulatory Affairs
Summit VetPharm, LLC
400 Kelby Street
Fort Lee, NJ 07024

Dear Mr. Conti:

Subject: Label amendment; additional pest claims
SVP7
EPA File Symbol 83399-6
Resubmission dated February 10, 2009
Response to Agency letter dated Feb. 3, 2009

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:

On page 10 and elsewhere on the label, qualify residual efficacy claim with a time frame of 4 weeks, one month, or 30 days.

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

If you have any questions, please 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

SVP7

Alternate Brand names;

- Vectra 3D for Dogs and Puppies 2.5 to 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:
FEB 13 2009

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
- Sandflies
- (Biting & Sucking) Lice
- Mites

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

ACTIVE INGREDIENTS:

Dinotefuran	4.95%
Pyriproxyfen.....	0.44%
Permethrin	36.08%
OTHER INGREDIENTS.....	58.53%
TOTAL.....	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING
XXX Doses

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

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 animals or animals known to be sensitive to pesticide products without first consulting a veterinarian.

Individual 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.

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.
(Cat icon)

4
14

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 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. Call a poison control center, doctor, or 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 between 9am and 6pm weekdays 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. 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.)

Alternate language--step 4, based on applicator:

Holding the applicator upright at the top below applicator tip, with thumb and index finger(of the other hand) (squeeze the tabs and) press down firmly 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. Unscrew the tube cap and replace with applicator tip.) Holding the tube (applicator) upright, 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

5. [For dogs weighing 2.5lbs. to 20 lbs. and under] Using the tip of the applicator, part the hair 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 animal's hair.

OR:

5. [For dogs weighing 21 to 55 lbs][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) is empty. Avoid superficial application to the animal'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) is 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
14

6. Unscrew applicator tip and place back in package. Replace applicator tip with original cap and place in trash. OR 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 fleas, flea eggs, flea pupae, flea larvae, 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 (0.06, 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 or 36 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
400 Kelby Street
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 (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 fleas, flea eggs, larvae and pupae 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 fleas, flea eggs, larvae and pupae 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).

- Tick, mosquito and all stages of flea control
- Formula for (your) dog(s)
- Kills fleas in 6 hours
- For dogs that enjoy the outdoors
- 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)

8
14

- 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
- Quick onset of activity kills 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 doses (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) (all-over) 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
- Dinotefuran kills fleas within 6 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 flea eggs, larvae and pupae...
- 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
- Effective monthly treatment of 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* variables, *Ixodes* spp, *Amblyomma maculatum*), [3 types (species) of] mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp), and all stages of fleas

- Kills fleas in 6 hours
- Kills fleas including those that may transmit bartonellosis and tapeworm disease
- Regular use kills (controls) all stages of the flea life cycle
- Kills fleas that may cause flea allergy dermatitis
- 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)
- Regular 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

10
14

- 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
- 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 and 36 packages only, 1.6 ml and 3.6 mls)
- Dog (canine) pack (24 and 36 packages only)
- Veterinary pack, Summit pack
- Effective monthly treatment of fleas, ticks and mosquitoes
- Effective monthly treatment of fleas (ticks)(mosquitoes)
- Repels and kills fleas, ticks and 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
- Repels and kills fleas, ticks and mosquitoes
- Easy effective control of fleas, ticks and mosquitoes
- Kills [4 types (species) of ticks (Rhipicephalus spp, Ixodes spp, Dermacentor variables, Amblyomma maculatum, Amblyomma 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 variabilis) Lone Star ticks (Amblyomma americanum) and Gulf Coast ticks (Amblyomma maculatum)
- Repels and kills Deer ticks (Ixodes scapularis, Ixodes ricinus, Ixodes pacificus)
- Long lasting flea, tick and mosquito control for your pet
- SVP7 kills more than adult fleas you see, it controls flea eggs, larvae and pupae
- Kills all life stages of ticks
- SVP7 repels and kills fleas, ticks, mosquitoes before they bite
- Prevents all flea stages from developing

11
14

- SVP7 kills not only adult fleas, but also breaks the flea life cycle by preventing development of flea eggs, larvae and pupae (may include diagram of flea life cycle)
- Illustration of flea life cycle
- Kills [4 types (species) of ticks (Rhipicephalus spp, Dermacentor variables, Ixodes spp, Amblyomma spp), [3 types (species) of mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp) all stages of fleas.
- 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).
- 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 (Amblyomma 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)
- (SVP7) prevents flea and tick attachment
- SVP7 inhibits (flea) (and tick) feeding
- 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
- Repellency and protection against fleas, ticks and mosquitoes
- Repellency against fleas, ticks, mosquitoes, lice, mites and sandflies
- 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 repellent, permethrin (for control of fleas, ticks, mosquitoes, lice, mites and sandflies)
- Repels fleas, ticks, mosquitoes, sandflies, lice and mites
- Repels ticks
- Repels fleas
- Repels mosquitoes
- Kills sandflies
- Repels sandflies
- Kills (biting & sucking) lice
- Repels lice
- Kills mites
- Repels mites
- Repels (and kills) lice which may cause pruritus, erythema, (crusting and scaling)
- Repels (and kills) mites that may cause dandruff, alopecia and pruritus
- Repels (and kills) sandflies which may inflict irritating bites
- Repels (and kills) fleas, ticks, mosquitoes, lice, mites and sandflies
- Repels (and kills) (annoying) (bothersome) (nuisance) sandflies
- SVP7 is indicated for the prevention and treatment of fleas; ticks, mosquitoes, sandflies, lice and 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

12
14

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- One treatment prevents further flea infestation for 30 days (4 weeks) (one month)
 - Kills larval stages of fleas in the pet's (dog's) environment
 - Prevent all immature flea stages in the pet's (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 (*Dipylidium caninum*)
 - Stops existing flea infestations by rapidly 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) sandflies
 - 6 way protection, repels (and kills) fleas, ticks, mosquitoes, lice, sandflies and mites
 - Repels (and kills) [(biting) (chewing) lice
 - Repels mites and prevents further infestation
 - Helps to relieve your dogs discomfort by controlling flea, tick, mite 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 sandfly life cycle
 - Illustration of mite life cycle
 - Illustration of louse life cycle
 - Illustration of flea
 - Illustration of tick
 - Illustration of mosquito
 - Illustration of sandfly
 - Illustration of mite
 - Illustration of louse

NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

Prototype:

13
14

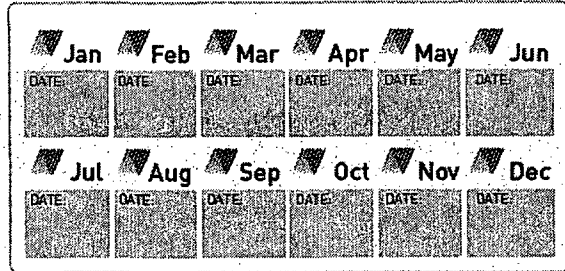
NEXT DOSE STICKERS AND REMINDER CALENDAR

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.



APPLICATOR LABELING

SVP7

KEEP OUT OF REACH OF CHILDREN

WARNING
READ ENTIRE LABEL BEFORE USE

Dinotefuran4.95%
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*)