

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 11, 2014

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 – Adding additional efficacy claims

SVP7 for Dogs

EPA Registration Number 83399-6 Your submission dated 11/21/2013 OPP tracking decision number D485375

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the condition listed below:

• Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data. You must comply with DCI ID# GDCI 044312-1147 issued on 3/1/2013. If you have questions about the Generic DCI issued, you may contact Steven Snyderman from the Pesticide Re-evaluation Division.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Submit one final printed copy of the label before you release the product for shipment bearing the revised labeling. Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Please be reminded that 40 CFR

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156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear on the label or durably marked on the container itself.

If you have any questions, please contact Rita Kumar at (703) 308-8291, or kumar.rita@epa.gov.

Sincerely,

Meredith F. Laws, Chief Insecticide-Rodenticide Branch Registration Division (7505P) Office of Pesticide Programs

Enclosure

LABEL AMENDMENT Date: July 31, 2014

#### "Master Label"

(This master label includes label text for different size packages and application rates specific to the pet's age and body weight) (Text that appears in parenthesis or brackets are optional)

## FRONT PANEL OF OUTER BOX

# **SVP7 for Dogs**

Picture of dog /puppy according to weight range (see pg 15 for example graphics)

#### **Alternate Brand names:**

**Vectra 3D** for Dogs and Puppies 5-10 lbs., over 8 weeks of age [0.8 ml]

Vectra 3D for Dogs and Puppies 11-20 lbs., over 8 weeks of age [1.6 ml]

Vectra 3D for Dogs and Puppies 21-55 lbs., over 8 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]

SimpleGuard 3for Dogs and Puppies 5-10 lbs., over 8 weeks of age [0.8 ml]

SimpleGuard 3for Dogs and Puppies 11- 20 lbs., over 8 weeks of age [1.6 ml]

SimpleGuard 3for Dogs and Puppies 21-55 lbs., over 8 weeks of age [3.6 ml]

SimpleGuard 3 for Dogs 56-95 lbs. [4.7 ml]

SimpleGuard 3 for Dogs over 95 lbs. [8.0ml]

[FOR DOGS & PUPPIES – Use only on dogs weighing 5 to 10 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 11 to 20 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 21-55 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing 56-95 lbs. and 8 weeks or older]

[FOR DOGS & PUPPIES – Use only on dogs weighing over 95 lbs. and 8 weeks or older]

## Repels and Kills for one month

- Fleas
- Ticks
- Mosquitoes
- (Biting & Sucking) Lice
- Mites (excluding mange mites)
- Biting & Sand Flies

(Optional marketing claims. See pages 5-12.)

# ACCEPTED

08/11/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 C

\* 83399-6

#### **ACTIVE INGREDIENTS:**

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

Net Contents: XXX fl oz XXX Doses [each dose, xxx fl oz (xxx mL)]

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#### KEEP OUT OF REACH OF CHILDREN

#### **WARNING**

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



# [ICON OF CAT (1.5 cm X 1.5 cm) PLACED ON LOWER FRONT PANEL]

(alternate brand name graphic may vary)

#### BACK PANEL OF OUTER BOX AND INSERT LANGUAGE

(the text below appears on both the outer box and the package insert)

(Optional marketing claims. See pages 5-12.)

#### READ ENTIRE LABEL BEFORE EACH USE

# USE ONLY ON DOGS [OR] [AND] PUPPIES OVER THE AGE OF 8 WEEKS (OVER 8 WEEKS OLD) (8 WEEKS OF AGE OR OLDER)

#### PRECAUTIONARY STATEMENTS

#### **HAZARDS TO HUMANS:**

**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, using tobacco products, or using the toilet.

# **HAZARDS TO DOMESTIC ANIMALS:**

Do not use this product on debilitated, aged, medicated, pregnant or nursing dogs or dogs known to be sensitive to pesticide products without first consulting a veterinarian.

# For external use on dogs only Do not use this product on cats

#### SIDE EFFECTS:

Monitor your dog after application. Individual sensitivity, such as slight transitory redness, erythema, itching -pruritus- or other signs of discomfort at the site of application, may occur after using ANY pesticide product for dogs. If signs of sensitivity occur, bathe your dog 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 signs 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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# DO NOT USE ON CATS - MAY BE FATAL

Due to their unique physiology and inability to metabolize certain compounds this product must not be used on cats. Keep cat away from treated dogs for 24 hours. If applied to a cat, or ingested by a cat that actively grooms a recently treated dog, contact your veterinarian immediately.

(alternate brand name graphic may vary)

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, and 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 or clothing:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15–20 minutes. If skin appears irritated after rinsing call a poison control center or doctor, or 1-800-999-0297 or after 6pm EST call 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 weekdays between 9am and 6pm EST or 1-888-426-4435 for emergency medical treatment information.

EPA Reg. No. 83399-6 EPA Est. No. TBD

[Made (in the USA) (by)] [Sold by:] Ceva Animal Health, LLC 8735 Rosehill Road Lenexa, KS 66215

## ADDITIONAL INSERT LANGUAGE

(the text below only appears on the package insert)

## **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.)]

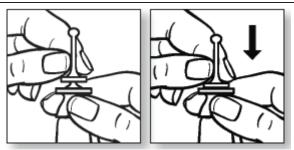
#### **HOW TO APPLY:**

1. Use Restrictions: USE ONLY ON DOGS. Do not use on cats or other animals. Do not have contact or allow children to have contact with treated areas until treatment is completely dry.

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2. Remove applicator tube from package.

- 3. The dog should be standing or in a comfortable position for easy application.
- 4. Holding the (applicator) tube 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 smaller disk. Press down firmly on small disk until both disks meet, piercing the seal. (See illustration)



5. (For all dog weights) Using the applicator tip, part the hair at the base of the tail, and begin applying the product onto the skin in a continuous line from the base of the tail along the center of the back all the way up to the shoulder blades, as shown in the diagram, squeezing the applicator tube until it's empty. (Avoid superficial application to the dog's hair.)



Do not get the product in the dog's eyes or mouth.

- 6. Discard empty applicator (tube) as outlined in the Storage and Disposal section.
- 7. Repeat every month or as recommended by your veterinarian.
- 8. For optimal treatment control and prevention of adult and immature flea stages, ticks, mosquitoes, lice, mites (excluding mange mites), biting flies, and sand flies (all) year-round treatment is recommended.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a cool, dry place. Protect from freezing. KEEP OUT OF REACH OF CHILDREN.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** 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 products down any indoor or outdoor drain.

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[each 0.27 fl oz, (8.0 mL)]

[NET CONTENTS: XXX fl oz (XXX mL)]
[[1][2][3][4][6][8][9][12][18][24][36][applications][applicators]]
[each 0.027 fl oz, (0.8 mL)]
[each 0.06 fl oz, (1.6 mL)]
[each 0.12 fl oz, (3.6 mL)]
[each 0.16 fl oz, (4.7 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, 36, 72 or 144 applicators per package. Total volume will correspond to number of applicators.]

#### 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. To the extent consistent with applicable law, any damages arising from use of this product or a breach of this warranty shall be limited to direct damages and shall not include consequential or incidental damages such as loss of profit or values.

#### ALTERNATE MARKETING TEXT

(for use on the front, side, or back panels of the outer box or on the package insert)

- Protects for one month
- Performance (satisfaction) guaranteed or (Ceva Animal Health) will supply replacement product
- Effective monthly prevention and treatment of fleas, ticks, and mosquitoes
- Repels and kills fleas, ticks and mosquitoes for one month
- Prevents development of adult and immature flea life stages 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 appropriate to weight class)
- Prevents development of adult and immature flea life stages for 30 days
- Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread over the dog's body providing effective control of fleas, ticks, and mosquitoes for thirty days (four weeks, one month).
- Formula for (your) dog(s)
- Kills fleas in 6 hours
- 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
- Satisfaction guaranteed or your money back (Ceva ICON) (Please call (contact) our professional staff at xxx-xxx-xxxx if you have any questions or comments about SVP7)
- 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
- Prevents re-infestation (of fleas/f ticks) for one month
- Monthly treatment is recommended for control and prevention of fleas, ticks and mosquitoes
- Once monthly application

- X applicators
- X monthly dose(s) (applications) (treatments)
- Quick-drying, non-greasy and water-resistant (waterproof)
- 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
- Available from licensed veterinarians
- Sold by veterinarians
- Tested on puppies from 8 weeks of age
- After application, SVP7 spreads 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
- 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 immature flea stages.
- Questions or comments—please call (tel. no.) (or e-mail us at contact.us@ceva.com)
- For more information call (tel. no.) (or e-mail us at contact.us@ceva.com)
- 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
- Easy, fast, effective control of fleas, ticks and mosquitoes that lasts 1 month
- Kills [4 types (species) of] ticks (Rhipicephalus spp, Dermacentor variabilis, Ixodes spp, Amblyomma maculatum), [3 types (species) of] mosquitoes (Culex spp, Ochlerotatus spp, Aedes spp), and all stages of fleas
- Kills fleas including those that may transmit bartonellosis and tapeworm disease
- Monthly use kills (controls) all stages of the flea life cycle
- Kills fleas that may cause flea allergy dermatitis (FAD)

- 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)
- Monthly 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 ticks so they fall off treated dogs and die
- Repels and kills mosquitoes (*Culex spp, Ochlerotatus spp, Aedes spp*) which may vector heartworm (*Dirofilaria immitis*) for one month
- 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 which includes treatment of both the dog and environment
- 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, 36, 72 and 144 packages only) [0,8, 1.6 and 3.6ml packages only]
- Dog (canine) pack (24, 36, 72 and 144 packages only)
- Veterinary pack, Ceva pack (24, 36, 72 and 144 packages only)
- Effective monthly treatment of fleas, ticks and mosquitoes
- Effective monthly treatment of fleas (ticks)(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
- Effective control of fleas, ticks and mosquitoes
- Kills 4 types (species) of ticks (Rhipicephalus spp, Ixodes spp, Dermacentor variables, Amblyomma maculatum, Amblyoma 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 variablis) Lone Star ticks (Amblyomma americanum) and Gulf Coast ticks (Amblyomma maculatum)
- Repels and kills Deer ticks (Ixodes scapularis, Ixodes ricinus, Ixodes pacificus)
- Long lasting one month flea, tick and mosquito control for your dog
- SVP7 kills more than adult fleas you see, it controls immature flea stages
- Kills all life stages of ticks
- SVP7 repels and kills fleas, ticks, mosquitoes
- Prevents all flea stages from developing
- SVP7 kills not only adult fleas, but also breaks the flea life cycle by preventing development of immature fleas (may include diagram of flea life cycle) for 30 days (one month) (4 weeks)
- Illustration of flea life cycle
- Kills 4 types (species) of ticks (Rhipicephalus spp, Dermacentor variabilis, Ixodes spp, Amblyomma spp), 3 types (species) of mosquitoes (Culex spp. Ochlerotatus spp, Aedes spp) all stages of fleas for 30 days (one month) (4 weeks).
- 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 (Amblyomna maculatum) and Lone Star ticks (Amblyoma americanum) for one month (4weeks) (30 days)
- Kills Amblyomma americanum (Lone Star ticks) and Amblyomma maculatum (Gulf Coast ticks) for 4 weeks (for one month) (for 30 days)
- 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 for 4 weeks (30 days) (one month)
- Repellency and protection against fleas, ticks and mosquitoes for 4 weeks (30 days) (one month)
- Repellency against fleas, ticks, mosquitoes, lice, mites and sand flies for 4 weeks (30 days) (one month)
- Contains the proven effective topical, dinotefuran, for effective flea control
- Contains 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 repellant permethrin (for control of fleas, ticks, mosquitoes, lice, mites and biting & sand flies)
- Repels fleas, ticks, mosquitoes, sand flies, lice and mites (excluding mange mites)
- Repels ticks
- Repels fleas
- Repels mosquitoes

- Kills sand flies
- Repels sand flies
- Kills (biting & sucking) lice
- Repels lice
- Kills mites
- Repels mites (excluding mange mites)
- Repels (and kills) lice which may cause pruritus, erythema, (crusting and scaling)
- Repels (and kills) mites (excluding mange mites) that may cause dandruff, alopecia and pruritus
- Repels (and kills) biting & sand flies which may inflict irritating bites
- Repels (and kills) fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies
- Repels (and kills) (annoying) (bothersome) (nuisance) biting & sand flies
- SVP7 is indicated for the prevention and treatment of fleas, ticks, mosquitoes, biting & sand flies, lice and mites (excluding mange mites) on dogs over 8 weeks of age
- For the treatment and prevention of flea infestation
- For the control of all stages of flea infestation
- One treatment prevents further flea infestation for 30 days (4 weeks) (one month)
- Kills larval stages of fleas in the dog's environment
- Prevents all immature flea stages in the 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 (Dipylidum caninum)
- Stops existing flea infestations by 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)] sand flies and biting flies
- 6 way protection, repels (and kills) fleas, ticks, mosquitoes, lice, biting & sand flies and mites (excluding mange mites)
- Repels (and kills) [(biting) (chewing)] lice
- Repels mites (excluding mange mites) and prevents further infestation
- Helps to relieve your dogs discomfort by controlling flea, tick, mite (excluding mange mites) 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 sand fly life cycle
- Illustration of mite life cycle
- Illustration of louse life cycle
- Illustration of flea
- Illustration of tick
- Illustration of mosquito
- Illustration of sand fly

- Illustration of mite
- Illustration of louse
- Illustration of biting fly
- Illustration of biting fly life cycle
- Repels (and kills) biting flies which may inflict irritating bites
- Prevents fly strike
- Controls fly strike
- Repels (and kills) fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and biting & sand flies
- Repels (and kills) (annoying) (bothersome) (nuisance) biting & sand flies
- SVP7 is indicated for the prevention and treatment of fleas, ticks, mosquitoes, sand flies, lice and mites (excluding mange mites) on dogs over 8 weeks of age
- Kills biting flies
- Repels biting flies
- Repels fleas, ticks, mosquitoes, fire ants, biting & sand flies, lice and mites (excluding mange mites)
- Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) for 4 weeks (30 days) (one month)
- Helps to relieve your dog's discomfort by controlling fleas, ticks, mites (excluding mange mites), biting flies, and lice infestations
- Repels and kills mosquitoes and biting & sand flies that may transmit vector borne disease
- Repels and kills sand flies that may transmit leishmaniasis
- Kills the vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis and heartworm disease
- Repels and kills sand flies that may transmit leishmaniasis
- Monthly treatment is recommended for control (and prevention) of fleas, ticks, lice, mites (excluding mange mites), biting & sand flies and mosquitoes
- Results indicate that SVP7 repels and prevents biting flies from blood feeding on dogs
- Controls infestations of chewing lice
- Kills and repels mosquitoes which may transmit West Nile virus
- Kills and repels mosquitoes which may transmit disease
- Reduces biting fly strike
- Reduces flea feeding
- Continues to kill and repel fleas and ticks after shampooing
- Triple powered formula for control of fleas, ticks, mosquitoes, flies, mites and lice
- Prevents re-infestation of fleas, ticks and chewing lice
- Kills chewing lice
- Kills attached ticks when applied to dog with pre-existing infestation
- Using the (patented) (Trademark) applicator, SVP7 is specially designed to spread naturally over the dog's body providing effective control of fleas, ticks, lice, mites (excluding mange mites) and mosquitoes for thirty days (four weeks, one month).
- Kills fleas that may cause flea allergy dermatitis and flea bite dermatitis
- SVP7 works on multiple sites of the nervous system of fleas & ticks
- Kills the listed vectors that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, leishmaniasis, tularemia and heartworm disease
- Contains the proven effective topical repellent, permethrin (for control of fleas, ticks, mosquitoes, lice, mites (excluding mange mites), biting flies (and sand flies))

- 11-way protection against fleas, flea eggs, larvae, pupae, ticks, mosquitoes, sand & biting flies, biting & sucking lice, mites (excluding mange mites)
- Reduced flea feeding means reduced likelihood of transmission of vector borne disease
- Limited feeding reduces likelihood of anemia, irritation, flea allergy dermatitis and transmission of disease
- Repellency against fleas, ticks, mosquitoes, lice, mites (excluding mange mites) and sand flies for 4 weeks (30 days) (one month)
- (Regular use) (monthly use) protects your dog against all flea stages
- SVP7 for dogs susceptible to flea allergy dermatitis (FAD)
- Begins reducing flea feeding in 5 minutes
- For year round control, apply SVP7 monthly year round for optimum control of fleas, ticks, mosquitoes, flies, lice and mites.
- Persistent (sustained) efficacy for (one month) (thirty days)
- Kills newly emerged fleas before they lay eggs
- Contains (free) calendar (reminder) stickers
- Monthly year round (use) (treatment) can help your dog stay happy and protected
- Helps (outdoor) dogs stay protected from fleas, ticks, mosquitoes, sand flies, biting flies, biting & sucking lice, mites (excluding mange mites)
- 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 results 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 approve) (non-qualified) persons could result in appropriate action by the (manufacturer) (Ceva) (company name).

- Kills fleas in 4 hours
- Kills reinfesting fleas in 4 hours
- Kills flea eggs, breaks life cycle, prevents flea eggs from hatching (into adults)
- Prevents adult flea emergence for 2 months
- Breaks the flea life cycle for 2 months
- Kills (all) immature stages of fleas for 1 month
- Inhibits fleas laying new eggs for 1 month
- Prevents eggs (on treated dogs) from developing into adults for 64 days / 2 months
- Stops development of fleas for 2 months
- Kills mosquitoes before they bite/feed
- Kills mosquitoes on dogs in 1 hour starting 1 day after treatment (for 28 days/1 month)
- Kills mosquitoes on dogs for 28 days/1 month
- Prevents flies from biting for 1 month starting ~1 day after treatment
- Prevents flies from feeding after 30 minutes starting 1 day after treatment
- Remains effective for one month after application, even after one shampoo, if shampooed after day 14 [day 7]
- Remains effective (against fleas/ticks) for one month after application, even after water immersion
- Remains effective against fleas and ticks for one month after application, even after one shampoo, if shampooed after day 14 (or 7)
- Remains effective against flea egg emergence for one month after application, even after water immersion or one shampoo 14 days (or 7 days) after treatment
- Dinotefuran + Permethrin work better than permethrin alone in a spot on against fleas

LABEL AMENDMENT Date: July 31, 2014

# NEXT DOSE STICKERS/ TREATMENT REMINDER CALENDAR

## Prototype:

#### 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.



LABEL AMENDMENT Date: July 31, 2014

#### APPLICATOR LABELING

Alternate Brand Names:

**Vectra 3D** for Dogs and Puppies 5-10 lbs., over 8 weeks of age [0.8 ml]

Vectra 3D for Dogs and Puppies 11-20 lbs., over 8 weeks of age [1.6 ml]

Vectra 3D for Dogs and Puppies 21-55 lbs., over 8 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]

SimpleGuard 3 for Dogs and Puppies 5-10 lbs., over 8 weeks of age, [0.8 ml]

SimpleGuard 3 for Dogs and Puppies 11-20 lbs., over 8 weeks of age, [1.6 ml]

SimpleGuard 3 for Dogs and Puppies 21-55 lbs., over 8 weeks of age, [3.6 ml]

SimpleGuard 3 for Dogs 56-95 lbs. [4.7 ml]

SimpleGuard 3 for Dogs over 95 lbs. [8.0ml]

#### KEEP OUT OF REACH OF CHILDREN

WARNING

#### READ ENTIRE LABEL BEFORE USE

Dinotefuran	4.95%
Pyriproxyfen	0.44%
Permethrin	36.08%

XXX fl oz (X mL)

Use only on dogs & puppies over 8 weeks of age weighing [insert wt range] lbs



(alternate brand name graphic may vary)

EPA Reg. No. 83399-6 EPA Est. No. TBD

Lot # (designation will identify producing establishment)

LABEL AMENDMENT Date: July 31, 2014

# EXAMPLE GRAPHICS OF DOGS ACCORDING TO WEIGHT RANGE

Vectra 3D brand pictures



[Alternate brand name pictures may vary.]