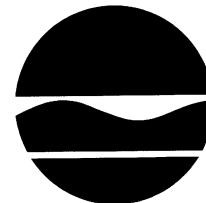


New York State Department of Environmental Conservation
Division of Solid & Hazardous Materials
Bureau of Pesticides Management
625 Broadway, Albany, New York 12233-7254
Phone: 518-402-8788 **FAX:** 518-402-9024
Website: www.dec.ny.gov
E-Mail: ppr@gw.dec.state.ny.us



Alexander B. Grannis
Commissioner

December 18, 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph A. Conti
Director of Regulatory Development
Summit VetPharm, LLC
400 Kelby Street
Fort Lee, New Jersey 07024

Dear Mr. Conti:

Re: Registration of Vectra 3D (EPA Reg. No. 83399-6) Containing the Active Ingredient Dinotefuran. Chemical Code: 044312.

The New York State Department of Environmental Conservation (Department) has completed its technical review of the major change in labeling (MCL) application received on June 4, 2007 which included two products SVP4 and SVP5 for spot on applications for once-a-month flea, tick, and mosquito control for dogs and puppies over seven weeks of age and flea treatment for cats 12 weeks of age and older. A second application was received July 20, 2007 for Vectra 3D which will be marketed in place of the SVP4 product for use on dogs.

Dinotefuran is currently registered in New York State as a technical product for formulation of insecticides; indoor commercial use to control cockroaches; and homeowner use to control cockroaches. Also, there is a bait station product registered for indoor/outdoor control of ants. The current applications were submitted as MCLs due to the addition of spot-on treatment on domestic animals at a higher application rate of the active ingredient than previously registered uses.

Vectra 3D (EPA Reg. No. 83399-6) contains the active ingredients dinotefuran at 4.95%; pyriproxyfen at 0.44% and permethrin at 36.08%. The product is sold in units sized for four weight ranges of dogs (2.5 to 20 lbs.; 21 to 55 lbs.; 56 to 95 lbs.; and over 95 lbs.). The product is a monthly spot-on treatment for dogs that protects against ticks, mosquitoes, and all stages of fleas. SVP5 contains only dinotefuran at 14.85% and is used as a monthly spot-on flea treatment for cats over 9 pounds and 6 months of age and kittens weighing 3 to 9 pounds and at least 12 weeks of age.

The application package and additional information were determined to be complete for purposes of technical review on July 23, 2007. Pursuant to the review time frame specified in ECL §33-0704.2, a registration decision date of December 20, 2007 was established. The Department has conducted the following technical review for impacts to human health as a result of potential increased exposure to homeowners from application/use of the pet spot-on products. The following review summary is provided.

Human Health Risk Assessment:

The New York State Department of Health (NYSDOH) reviewed the application and supporting data submitted by Summit VetPharm, LLC to register the pesticide products Vectra 3D (EPA Reg. No. 83399-6) and SVP5 (EPA Reg. No. 83399-4) in New York State. Both products contain the active ingredient dinotefuran (N-methyl-N'-nitro-N''-(tetrahydro-3-furanyl) methyl) guanidine) and are labeled for use as once-a-month spot-on treatments for domestic animals.

On an acute basis, neither Vectra 3D nor the SVP5 formulated product was very toxic to laboratory animals by the oral or dermal routes of exposure. The United States Environmental Protection Agency (USEPA) waived the requirement for an acute inhalation toxicity study, based in part on these products being applied in liquid form in relatively small amounts, and their method of application (as a spot to the animal's back). The formulated products were neither very irritating to the skin (tested on rabbits), nor were they skin sensitizers (tested on guinea pigs). These products, however, were moderately irritating to the eyes (tested on rabbits).

We previously reviewed dinotefuran in the manufacturing use product Dinotefuran Technical (99% active ingredient) and for indoor commercial use at 0.5% and homeowner use cockroach baits containing 0.05% of the active ingredient. Dinotefuran was not very acutely toxic, irritating or a skin sensitizer in laboratory animal studies. In addition, this chemical did not demonstrate developmental toxicity, genotoxicity or carcinogenicity, and the USEPA classified it as "not likely to be a human carcinogen." Dinotefuran caused some toxicity in chronic feeding studies in laboratory animals, and data indicate that this chemical has the potential to cause some neurotoxic, immunotoxic and reproductive effects. The USEPA Office of Pesticide Programs calculated an oral reference dose (RfD) of 0.02 milligrams per kilogram body weight per day (mg/kg/day) for dinotefuran based on the lowest-observed-effect level (LOEL) of 20 mg/kg/day in a one-year dog feeding study (decreased thymus weights in males) and an uncertainty factor of 1,000 (100x to account for intraspecies and interspecies differences and an additional 10x to account for using a LOEL instead of a no-observed-effect level). A search of the toxicological literature did not find any significant new information on the toxicity of dinotefuran.

There are no chemical specific federal or New York State drinking water/groundwater standards for dinotefuran or its degradate, MNG. Based on their chemical structures, these compounds fall under the 50 microgram per liter (g/L) New York State drinking water standard for "unspecified organic contaminants" (10 NYCRR Part 5, Public Water Systems). The New York State drinking water standard for the sum of "unspecified organic contaminants" and "principal organic contaminants" is 100 g/L.

The USEPA reported the results of companion animal safety studies on both the Vectra 3D and SVP5 pesticide products. Based on these studies, the USEPA concluded that there is an "...adequate margin of safety (at least 5x) between exposure associated with an application and that at which significant systemic effects may occur." Potential toxicity to domestic animals from these pesticide products should also be mitigated by the label statement "Do not use this product on debilitated, aged, medicated, pregnant or nursing animals known to be sensitive to pesticide products without first consulting a veterinarian."

The available information on the formulated products Vectra 3D and SVP5 indicates that they were not very acutely toxic, were not very irritating or sensitizing to skin, but were moderately irritating to the eyes. The active ingredient dinotefuran did not cause developmental toxicity, genotoxicity or carcinogenicity, but did cause some chronic effects as well as neurotoxic, immunotoxic and reproductive effects. The Vectra 3D and SVP5 products could be applied indoors, but significant impacts to indoor air from dinotefuran appear unlikely since this active ingredient has a low vapor pressure (1.28×10^{-8} millimeters of mercury at 20 degrees Celsius) and is applied in liquid form in small quantities (1.2 to 8.0 milliliters of product, depending on the size of the animal). While the product can cause eye irritation, the label indicates this potential and directs the user to point the tube up and away from the face and body during opening, which should help reduce accidental eye contact. The expected exposure from using the Vectra 3D and SVP5 products should not pose significant risks to users.

Product Registration Summary:

The Department will register Vectra 3D (EPA Reg. No. 83399-6) for general use in New York State. The product demonstrates low toxicity to humans and domestic animals at the labeled use rate and offers an alternative to currently registered pet spot-on products formulated with other active ingredients.

Enclosed for your record, is a copy of the stamped accepted labeling and the Certificate of Registration for Vectra 3D (EPA Reg. No. 83399-6). The Department will register SVP5 or an alternate brand name for (EPA Reg. No. 83399-4) or similar product for application to cats, when Summit VetPharm, LLC provides final product labeling for shipment into New York State. The Department has reviewed the Company's proposed label for purposes of assessing the impact to human health from its use and will not consider any application with this use pattern and/or application rate to be a major change in labeled use (MCL).

Please note that a proposal by Summit VetPharm, LLC or any other applicant, to register a product that contains dinotefuran, and whose labeled uses are likely to increase the potential for significant impact to humans, nontarget organisms, or the environment, would constitute a MCL application. Such an application must be accompanied by a new application fee and meet the requirements listed in Appendix 1.B. of "New York State Pesticide Product Registration Procedures" (September 2005). Such information as well as forms can be accessed at our website as listed in our letterhead.

Please be aware that any unregistered product may **not** be sold, offered for sale, distributed, or used in New York State.

Mr. Joseph A. Conti

4.

Please contact our Pesticide Product Registration Section, at (518) 402-8768, if you have any questions.

Sincerely,

Maureen P Serafini

Maureen P. Serafini
Director
Bureau of Pesticides Management

Enclosure

cc: w/enc. - R. Mungari - NYS Dept. of Ag. & Markets

ecc: w/enc. - A. Grey/E. Horn - NYS Dept. of Health
W. Smith - Cornell University, PSUR

Vectra 3D is a trademark of Elanco Animal Health
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 Fort Worth, TX 76101

PURCHASE

Vectra 3D™

6 MONTHS



**FOR DOGS
WEIGHING
OVER 95 LBS**

**REPELS AND
KILLS FOR AT
LEAST ONE
MONTH**

- ▼ Fleas
- ▼ Ticks
- ▼ Mosquitoes

ACTIVE INGREDIENTS:

Desferrioxal	2.50%
Pyrethrins	0.40%
Permethrin	0.10%
OTHER INGREDIENTS	97.00%
TOTAL	100.00%

WARNING: KEEP OUT OF REACH OF CHILDREN
See package insert for directions for use and precautionary statements and first aid.

**ACCEPTED
FOR REGISTRATION**
DEC 18 2007
NYSDEC

AVAILABLE FROM LICENSED VETERINARIANS ONLY

- ▼ Convenient topical treatment with patented applicator
- ▼ Remains effective after bathing and swimming
- ▼ Kills 96% of fleas in 6 hours
- ▼ Kills fleas that may cause **flea allergy dermatitis**
- ▼ Repels and kills ticks that may cause **Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, and hepatozoonosis**
- ▼ Prevents development of fleas, flea eggs, larvae and pupae for 30 days

NET CONTENTS: 6 Doses, each 3.37 fl. oz. (9.8 mL)


Vectra 3D™ FOR DOGS WEIGHING OVER 95 LBS
 6 MONTHS



1-800-4-A-PET
©2010 by VET-1, Inc. All rights reserved. 222222
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Vectra 3D

FOR DOGS WEIGHING OVER 95 LBS

EASY, EFFECTIVE CONTROL OF FLEAS, TICKS, AND MOSQUITOES THAT LASTS AT LEAST 1 MONTH

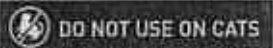
- Protects against 4 species of ticks (*Dermacentor variabilis*, *Ixodes scapularis*, *Amblyomma maculatum*), 1 species of mosquitoes (*Culex* spp., *Ochlerotatus* spp., *Aedes* spp.), and all stages of fleas
- Effective for at least 1 month

ACTIVE INGREDIENTS:

Imetechene	4.95%
Pyriproxyfen	0.44%
Permethrin	31.61%
OTHER INGREDIENTS	58.53%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

WARNING:



FOR ADDITIONAL INFORMATION, CONTACT US AT 1-800-444-4297

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS ON PUPPIES OVER 7 WEEKS OLD

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco products.
Do not use this product on dehydrated, aged, medicated, pregnant or nursing animals, or animals known to be sensitive to pesticide products without first consulting a veterinarian.

Sensitivity, such as slight temporary 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.

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

DO NOT USE ON CATS: Due to their unique physiology and inability to metabolize certain components, 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.

FIRST AID	
If in eyes:	Rinse eye open and close 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 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:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center, doctor, or 1-800-424-4255 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 1-800-424-4255 for emergency medical treatment information.	

NET CONTENTS: 6 Ounces, each 0.27 fl. oz. (8.0 mL)

EPA Reg. No. 83399-4 EPA Est. No. 68077-RL1



PLACE YOUR HOSPITAL LABEL HERE

Vectra 3D™

- ▼ Vectra 3D™ for dogs and puppies 2.5 to 20 lbs, over 7 weeks of age
- ▼ Vectra 3D™ for dogs and puppies 21 to 55 lbs, over 7 weeks of age
- ▼ Vectra 3D™ for dogs 56 to 95 lbs
- ▼ Vectra 3D™ for dogs over 95 lbs

- ▼ Repels and kills fleas, ticks, and mosquitoes for at least one month
- ▼ Protects against 4 types of ticks (*Rhipicephalus* spp, *Dermacentor variabilis*, *Ixodes scapularis*, *Amblyomma maculatum*), 3 types of mosquitoes (*Culex* spp, *Ochlerotatus* spp, *Aedes* spp), and all stages of fleas
- ▼ Kills 98% of fleas in 6 hours
- ▼ Kills the vectors that may cause Lyme disease, Rocky Mountain Spotted fever, babesiosis, ehrlichiosis, bartonellosis, hepatozoonosis, and heartworm disease
- ▼ Easy, spot-on topical application
- ▼ Remains effective after bathing and swimming
- ▼ Performance guaranteed or your money back
- ▼ Only available from licensed veterinarians

Using the patented applicator, Vectra 3D™ is specially designed to spread naturally over the dog's body, providing effective control of fleas, ticks, and mosquitoes for one month

ACTIVE INGREDIENTS:

Disulfenuron	4.95%
Pyriproxyfen	0.44%
Permethrin	36.08%
OTHER INGREDIENTS	58.53%
TOTAL	100.00%



KEEP OUT OF REACH OF CHILDREN

WARNING: See directions for use, precautionary statements, first aid, and ingredients.

FOR ADDITIONAL INFORMATION, CONTACT US AT 1-800-999-0297

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR PUPPIES OVER 7 WEEKS OLD

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS


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

Use only on dogs and puppies over 7 weeks old (1.6 mL and 3.6 mL sizes)

WARNING: Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco products.

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 and 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.

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 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:	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.

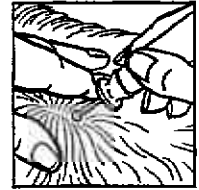
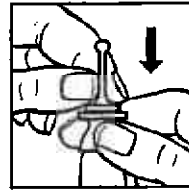
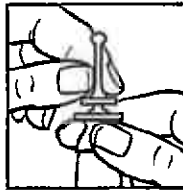
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may contact 1-888-426-4435 for emergency medical treatment information.

DIRECTIONS FOR USE

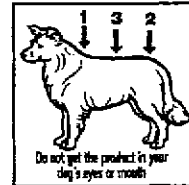
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [Precaución al consumidor: si usted no lee inglés, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.]

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. 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. Using the tip of the applicator, part the hair down to the level of the skin and slowly apply the product. Avoid superficial application to the animal's hair.



For dogs weighing 2.5 lbs to 20 lbs, apply the product to one spot, as shown in the diagram above, onto the skin, squeezing the applicator tube until empty.



For dogs weighing 21 to 55 lbs OR for dogs weighing 56 to 95 lbs, 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 above, squeezing the applicator tube until empty.



For dogs weighing over 95 lbs, 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 above, squeezing the applicator tube until empty.

6. Discard empty applicator tube as outlined in the Storage and Disposal section.
7. Repeat every month, or as recommended by your veterinarian. Do not apply in less than 30 days.
8. For optimum treatment, control, and prevention of fleas, flea eggs, flea pupae, flea larvae, ticks, and mosquitoes, 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.

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.

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. 480777L1

Made in the USA by

SUMMIT
VETPHARM, LLC

Ford Lee, NJ 07024

www.summitvetpharm.com

Satisfaction
Guaranteed

Summit VetPharm will provide
new product or your money back.



DO NOT USE ON CATS

EPA Reg. No. 83399-6 EPA Est. No. 68077IL1

WARNING
READ ENTIRE LABEL BEFORE USE
KEEP OUT OF REACH OF CHILDREN

3.0 mL	Dinotefuran.....	4.95%
	Pyriproxyfen.....	0.44%
	Permethrin.....	36.08%

Vectra 
3D™ FOR DOGS
OVER 95 LBS

1.6755" Deco Width

Pyriproxyfen..... 0.44%
Permethrin..... 36.08%

Vectra 
3D™ FOR DOGS
OVER 95 LBS

