09/20/2012

1/4



NVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave N W Washington D C 20460 EPA Registration No

88966-2

Date of Issuance

September 20 2012

# NOTICE OF PESTICIDE

☑ Registration

☐ Reregistration

(under the Federal Insecticide Fungicide and Rodenticide Act as amended)

Term of Issuance

Unconditional

Name of Pesticide Product **VETGUARD FOR DOGS** 

Name and Address of Registrant (include ZIP Code)

Tru Prodigy

c/o Plyxis Regulatory Consulting, Inc

4110 136th Street NW

Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant the above named pesticide is hereby registered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This action is taken under the authority of section 3(c)(5) of the Federal Insecticide Fungicide and Rodenticide Act as amended Registration under this section does not eliminate the need for continual reassessment of pesticides EPA may require submission of data at any time to maintain the registration of your product

## Terms of Registration

- EPA has registered the product listed above provided that the following changes are made to the label before you release the product for shipment
  - a Revise the EPA Registration Number to read "EPA Registration No 88966-2
  - Within 3<sup>rd</sup> sentence of the Side Effects subsection of the Precautionary Statements' section, at the bottom of page 6 of 14 you must change the word "cat to read "dog since this is a dog product
- This registration is time-limited and expires two years from the date this product is first released for shipment. You must provide the Agency with a projected "release for shipment date" in writing within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected "release for shipment date" until an actual release for shipment date is provided in writing.
- Only one basic confidential statement of formula (CSF) will be on file for this product at any time (i.e., no alternate formulations or minor formulation amendments will be submitted and/or approved for this product except to allow for alternate sources of any individual inert ingredient)

Signature of Approving Official

Date

Refer to Page 3

September 20, 2012

Richard J Gebken Product Manager (10) Registration Division Insecticide Branch

# Page 2 of 3

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- You must submit the following data within the timeframe described below
  Within sixteen (16) months of the date on this Notice of Registration provide to the Agency acceptable data packages for Guideline Studies OPPTS 830 6320 (Corrosion Characteristics) and OPPTS 830 6317 (Storage Stability)
  - You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product for the quarter that begins on August 1 2012. The quarterly reports are due two months after the end of each quarter. Please flag any Confidential Business Information CBI) 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. Kimberly Nesci)

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

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

- Along with the enhanced incident reporting you must submit an analysis of all incidents seen to include the following details
  - a All minor dermal and ocular irritation reports
  - b Summary table for dogs 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 Page 3 of 3.

reported as oral exposure and an incident with both ocular and oral exposure would be reported as ocular exposure

- c A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure
- d Summary table for dogs and table for dogs showing number of incidents that are believed due to secondary exposure (e g, multi-pet households)
- e A summary table for s 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
- f A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label
- g A summary table for dog 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 dogs in lower half of weight range number of incidents in dogs in upper half of weight range and dogs weighing more than the product weight range
- h Table showing number of incidents for each dog breed
- 1 Table showing number of incidents in dog for each clinical sign

- Table showing number of incidents in dog for each organ system
- k Report aggregate incidents but do not combine moderate and minor incidents
- 7 If EPA determines that future mitigation measures are necessary for all pet spot on products, the Agency will inform all registrants concerned. If mitigation measures are necessary EPA may take regulatory action
- Tru Prodigy must adequately address all of the mitigation actions identified in the Agency's Generic Pet Spot-On Mitigation Plan available at the following internet site <a href="http://www.epa.gov/pesticides/health/spot-on-meetings.html">http://www.epa.gov/pesticides/health/spot-on-meetings.html</a>

You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data and submit acceptable responses required for registration review of your product under FIFRA

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If you fail to comply with all of the **Terms of Registration** stated above the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) and/or automatically expire. Your release for shipment of the product constitutes your acceptance of these conditions

A copy of your label stamped 'Accepted with Comments" is enclosed for your records. If you have any questions concerning this action please contact Mr. Richard J. Gebken at (703) 305-6701 or gebken richard@epa.gov

Sincerely

Richard Gebken Product Manager 10 Insecticide Branch

Registration Division (7505C)

**Enclosures** 

4/17

# [Master Label]

[Carton Label - Front Panel]

# **VETGUARD FOR DOGS**

For use ONLY on DOGS & PUPPIES 8 weeks and older

ACTIVE INGREDIENT Fipronil INERT INGREDIENTS TOTAL

9 7% <u>90 3%</u> 100 0%

For use ONLY on DOGS 5 to 22 lbs For use ONLY on DOGS 23 to 44 lbs For use ONLY on DOGS 45 to 88 lbs For use ONLY on DOGS 88 to 132 lbs

[Optional marketing claims see lists at the end of the label]

# KEEP OUT OF REACH OF CHILDREN CAUTION

See label insert for First Aid and Precautionary Statements

ACCEPTED
With COMMENTS
In EPA Letter Dated

Septents ar 20, 20/2
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg No











Net Contents 0 069 fl oz (2 01 mL) (3 applicators that contain 0 023 fl oz (0 67 mL each))

Net Contents 0 135 fl oz (4 02 mL) (3 applicators that contain 0 045 fl oz (1 34 mL each))

Net Contents 0 273 fl oz (8 04 mL) (3 applicators that contain 0 091 fl oz (2 68 mL each))

Net Contents 0 408 fl oz (12 06 mL) (3 applicators that contain 0 136 fl oz (4 02 mL each))

Manufactured for

Tru Prodigy

500 E Shore Drive Suite 130 Eagle ID 83616

[VetGuard for Dogs is a registered trade name of Tru Prodigy]

EPA Reg No 88966-E EPA Est No [Made in Germany]



[Carton Text - Front, Back, or Side Panel]

EPA Reg No 88966-E EPA Est No Batch/Lot No

#### [Carton Label - Back Panel]

Side Effects See package insert for side effects

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product

TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND DIRECTIONS ON PACKAGE INSERT BEFORE EACH USE FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY USE ON DOGS ONLY DO NOT USE ON RABBITS DO NOT USE ON CATS OR OTHER ANIMALS

VetGuard for Dogs acts quickly lasts up to 30 days and does not wash off treated dogs. VetGuard for Dogs controls fleas ticks chewing lice and mosquitoes and aids in control of sarcoptic mange mites for use ONLY on puppies 8 weeks or older and small dogs from 5 to 22 lbs. medium dogs weighing 23-44 lbs. large dogs weighing 45-88 lbs. and extra-large dogs weighing 88-132 lbs. VetGuard for Dogs keeps working even after shampooing and rinsing with water. VetGuard for Dogs continues to work if dogs are outdoors and exposed to the sun or rain or even after swimming.

To kill fleas ticks chewing lice and mosquitoes apply VetGuard for Dogs as follows

## Remove and Open Package

See package insert for opening instructions

#### Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open

### Apply VetGuard for Dogs

Find a spot between the dog s shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the dog s skin. Avoid applying on top of the hair coat. Do not touch treated area until dry











Frequency of

#### Application

Monthly application of VetGuard for Dogs controls adult flea tick and chewing lice infestations. You can reapply VetGuard for Dogs once every 30 days

Adult Fleas VetGuard for Dogs kills adult fleas for up to three months unless the risk is high for reinfestation of fleas. If your dog becomes reinfested with fleas that cause flea allergy dermatitis or if your dog is in situations where reinfestation may occur you may apply VetGuard for Dogs every 30 days

**Ticks** VetGuard for Dogs kills ticks for at least one month. Apply VetGuard for Dogs every 30 days to control ticks (larva nymph and adult) that may transmit Lyme disease. Rocky Mountain Spotted Fever ehrlichiosis babesiosis anaplasmosis.

**Chewing Lice** VetGuard for Dogs kills chewing lice for at least one month. Apply VetGuard for Dogs every 30 days to aid in the control of chewing lice

**Sarcoptic mange (mites)** VetGuard for Dogs aids in the control of sarcoptic mange infestations. Apply VetGuard for Dogs every 30 days until mites are eliminated.

**Mosquitoes** Apply VetGuard for Dogs every 30 days to kill adult mosquitoes. Adult mosquitoes are killed within 24 hours for up to 7 days, and within 48 hours for up to 28 days from once-a month applications.

# [Optional marketing claims]

[3 Doses]

[Quick-acting]

[Long-lasting]

[Does not wash off]

[For monthly control of fleas ticks chewing lice mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills fleas which may cause flea allergy dermatitis]

[Kills all life stages of Brown dog ticks (*Rhipicephalus sanguineus*) American dog ticks (*Dermacentor vanabilis*) Lone Star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapularis*)]

[Kills ticks that may transmit Lyme disease Rocky Mountain Spotted Fever ehrlichiosis babesiosis anaplasmosis]

[Kills Brown dog ticks American dog ticks Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Aids in control of sarcoptic mange mite infestations]

[Kills adult mosquitoes]

#### [Package Insert, Text]

# **VETGUARD FOR Dogs**

For use ONLY on DOGS & PUPPIES 8 weeks and older

ACTIVE INGREDIENT Fipronil INERT INGREDIENTS TOTAL

9 7% 90 3%

# KEEP OUT OF REACH OF CHILDREN CAUTION

[Optional marketing claims see lists at the end of the label]

#### FIRST AID

#### 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 by mouth to an unconscious person

#### 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 eye
 Call a poison control center or doctor for treatment advice

#### 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 or doctor 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 also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week)

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### **HAZARD TO HUMANS**

**CAUTION** Harmful if swallowed Avoid contact with skin eyes or clothing. Causes moderate eye irritation. Wash hands thoroughly with soap and water after handling and before eating drinking chewing gum using tobacco or using the toilet.

#### HAZARD TO DOMESTIC ANIMALS

**CAUTION** FOR USE ON DOGS AND PUPPIES ONLY DO NOT USE ON CATS OR OTHER ANIMALS Keep cats away from treated dogs for 24 hours If applied to a cat or ingested by a cat contact your veterinarian Individual sensitivities while rare may occur after using **ANY** pesticide product Pets may experience some temporary irritation at the site of product application. If signs persist or become more severe within a few days of application consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated debilitated or aged animals.

**Side Effects** After applying VetGuard for Dogs check your dog for side-effects such as redness from skin irritation scratching or other signs of discomfort. In some cases, vomiting or diarrhea have been reported. If you observe these signs or symptoms in your treated cat, contact your veterinarian. You may

also contact SAFETYCALL INTERNATIONAL at 1-855-844-4375 (independent veterinarians and pharmacists on staff 24 hours/7 days per week) For Customer Service call 1-888-314-8588

#### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product

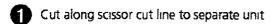
TO PREVENT HARM TO YOU AND YOUR DOG, READ THE ENTIRE LABEL AND DIRECTIONS ON PACKAGE INSERT BEFORE EACH USE FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY USE ON DOGS ONLY DO NOT USE ON RABBITS DO NOT USE ON CATS OR OTHER ANIMALS

VetGuard for Dogs acts quickly lasts up to 30 days and does not wash off treated dogs VetGuard for Dogs controls fleas ticks chewing lice and mosquitoes and aids in control of sarcoptic mange mites for use ONLY on puppies 8 weeks or older and small dogs medium dogs weighing 23-44 lbs large dogs weighing 45-88 lbs and extra-large dogs weighing 88-132 lbs. VetGuard for Dogs keeps working even after shampooing and rinsing with water. VetGuard for Dogs continues to work if dogs are outdoors and exposed to the sun or rain or even after swimming

Use VetGuard for Dogs on all dogs and puppies 8 weeks or older (small dogs from 5 to 22 lbs medium dogs weighing 23-44 lbs large dogs weighing 45-89 lbs extra-large dogs weighing 89-132 lbs ) and on breeding pregnant and lactating bitches

A one-spot application is convenient and easy for effective treatment of adult fleas ticks chewing lice and adult mosquitoes VetGuard for Dogs aids in control of sarcoptic mange mites. Apply VetGuard for Dogs when your dog is dry VetGuard for Dogs is applied at a single point on the surface of the skin between the dog s shoulders and rapidly covers the entire dog by localizing on the surface of the skin and in the sebaceous glands. Soon after coming into contact with a treated dog adult fleas, ticksadult mosquitoes and chewing lice are rapidly killed. To kill adult fleas ticks chewing lice and adult mosquitoes apply VetGuard for Dogs as follows

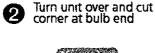
#### Remove and Open Package

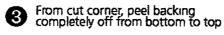


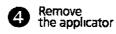




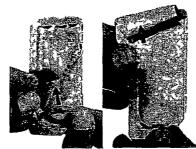














#### Open Applicator

Hold upright with foil side away from you and snap applicator tip back to open

# Apply VetGuard for Dogs

Find a spot between the dogs shoulder blades and part hair. Place the open end of the applicator just above the skin and squeeze. Apply the entire contents of the applicator in a single spot directly onto the dogs skin. Avoid applying on top of the hair coat. Do not touch treated area until dry











Frequency of

#### **Application**

Monthly application of VetGuard for Dogs controls adult flea tick and chewing lice infestations. You can reapply VetGuard for Dogs once every 30 days

**Adult Fleas** VetGuard for Dogs kills adult fleas for up to three months unless the risk is high for reinfestation of fleas. If your dog becomes reinfested with fleas that cause flea allergy dermatitis or if your dog is in situations where reinfestation may occur you may apply VetGuard for Dogs every 30 days

**Ticks** VetGuard for Dogs kills ticks for at least one month. Apply VetGuard for Dogs every 30 days to control ticks (larva nymph and adult) that may transmit Lyme disease. Rocky Mountain Spotted Fever ehrlichiosis babesiosis anaplasmosis and other tick-borne diseases.

Chewing Lice VetGuard for Dogs kills chewing lice for at least one month. Apply VetGuard for Dogs every 30 days to control chewing lice

**Sarcoptic mange mites** VetGuard for Dogs aids in the control of sarcoptic mange mite infestations Apply VetGuard for Dogs every 30 days until mites are eliminated

**Adult Mosquitoes** Apply VetGuard for Dogs every 30 days to kill mosquitoes Mosquitoes are killed within 24 hours for up to 7 days and within 48 hours for up to 28 days from once-a month applications

## **How Supplied**

VetGuard for Dogs is available in several convenient sizes for use ONLY on puppies 8 weeks or older and small dogs from 5 to 22 lbs (0 023 fi oz /0 67 mL) medium dogs 23-44 lbs (0 045 fl oz /1 34 mL) large dogs 45-88 lbs (0 091 fl oz /2 68 mL) and extra-large dogs 89-132 lbs (0 136 fl oz /4 02 mL)

VetGuard for Dogs can be used on small medium large and extra-large dogs even if breeding pregnant and lactating and on puppies that are older than 8 weeks

VetGuard for Dogs keeps working even after shampooing and rinsing with water. VetGuard for Dogs continues to work if dogs are outdoors and exposed to the sun or rain or even after swimming



DO NOT USE ON CATS Keep cats away from treated dogs for 24 hours If applied to a cat or ingested by a cat contact your veterinarian

#### PHYSICAL OR CHEMICAL HAZARDS

COMBUSTIBLE Do not use or store near heat or open flame

#### STORAGE AND DISPOSAL

Do not contaminate water food or feed by storage and disposal

#### **PESTICIDE STORAGE**

Store unused product in original container only out of reach of children and animals

#### PESTICIDE DISPOSAL

If partly filled Call your local solid waste agency or 1-800-CLEANUP for disposal instructions Never place unused product down any indoor or outdoor drain or on the ground

#### **CONTAINER DISPOSAL**

Nonrefilable container Do not reuse or refill this container **If empty** Place in trash or offer for recycling if available **If partly filled** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain

#### LIMITATION OF WARRANTY AND LIABILITY

IMPORTANT READ BEFORE USE Read the entire Directions for Use Conditions of Warranties and Limitations of Liability before using this product. If these terms and conditions are not acceptable return the unopened product container at once. By using this product user or buyer accepts the following Disclaimer of Warranties and Limitations of Liability.

**CONDITIONS** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product ineffectiveness injury and other unintended consequences may result because of such factors as manner of use or application (including misuse) the presence of other materials weather conditions and other unknown factors all of which are beyond the control of Tru Prodigy. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES** To the extent consistent with applicable law Tru Prodigy makes no other warranties express or implied of merchantability or of fitness for a particular purpose or otherwise that extend beyond statements on this label

**LIMITATIONS OF LIABILITY** To the extent consistent with applicable law neither Tru Prodigy the manufacturer nor the Seller shall be liable for any indirect special incidental or consequential damages resulting from the use handling application storage or disposal of this product. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses injuries or damages resulting from the use handling application or storage of this product whether in contract warranty tort negligence strict liability or otherwise shall not exceed the purchase price paid

EPA Reg No 88966-E EPA Est No

#### Manufactured for

Tru Prodigy 500 E Shore Drive Suite 130 Eagle ID 83616

[Made in Germany]
[VetGuard for Dogs is a registered trade name of Tru Prodigy]

[Optional Bar Code]

14/17

# [Insert with Calendar Reminder Stickers - Front]

## [Optional marketing claims]

[Long-lasting]

[Does not wash off]

[For monthly control of adult fleas ticks chewing lice adult mosquitoes]

[Kills adult fleas]

[Kills newly emerged adult fleas prior to egg-laying]

[Effective treatment that kills adult fleas which may cause flea allergy dermatitis]

[Kills all life stages of Brown dog ticks (*Rhipicephalus sanguineus*) American dog ticks (*Dermacentor variabilis*) Lone Star ticks (*Amblyomma americanum*) and deer ticks (*Ixodes scapulans*)]

[Kills ticks that may transmit Lyme disease Rocky Mountain Spotted Fever ehrlichiosis babesiosis anaplasmosis]

[Kills Brown dog ticks American dog ticks Lone Star ticks and deer ticks for up to one month]

[Eliminates chewing lice infestations]

[Aids in control of sarcoptic mange mite infestations]

[Kills adult mosquitoes]



#### **VetGuard for Dogs**

See other side for stickers to remind you it's time to reapply VetGuard for Dogs

Some Tips and Other Information for Using VetGuard for Dogs

Follow the label instructions for how to apply and be sure that VetGuard for Dogs is applied to the skin not on top of the fur and not near the collar Removing the collar before application may help to prevent the collar from absorbing the VetGuard dose

Apply VetGuard for Dogs when your dog is dry Make sure you apply all of the dose that is in the applicator

Fleas have many life stages and serious infestations can take up to 3 applications every 30 days for complete control. In fact, the flea life-cycle in the home can last as long as 21 days.

# [insert with Calendar Reminder Stickers - Back]

Reminder It's time to repurchase VetGuard for Dogs!

You can use these stickers to remind you when to apply and re-purchase VetGuard for Dogs

The first time you treat your dog peel off the sticker and place on your calendar that day. To remind you when the next application is due place the other two stickers on your calendar 1 and 2 months after the first application.

3 Months Sticker 1 Apply VetGuard for Dogs

Sticker 2 Apply VetGuard for Dogs Sticker 3 Apply VetGuard for Dogs

For Customer Service please call 1-888-314-8588

[For more information visit www xxxxx com]

Tru Prodigy

500 E Shore Drive Suite 130 Eagle ID 83616



[Optional Bar code]

# [Pictogram of Back of Blister With Opening Instructions]



# [Text for Back of Blister]

Keep Out of Reach of Children

CAUTION See full label for additional instructions and precautions before using

Only for Dogs & Puppies

**VetGuard for Dogs** 

**EPA Reg No 88966-E** 

Lot/Batch No

0 023 fl oz (0 67 mL)

0 045 fl oz (1 34 mL)

0 091 fl oz (2 68 mL)

0 136 fi oz (4 02 mL)

9 7% Fipronil