

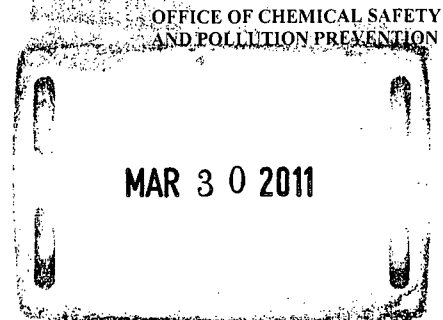
87952-1

3/30/2011

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



Mr. David H. Dawe, Ph. D.
D.H. Dawe & Associates, LLC.
Consultant for US Animal Health
16841 Four Seasons Drive
Dumfries, VA 22025

Dear Dr. Dawe:

Subject: Amendment-spot on analysis and mitigation policy
Averta-ArmorGuard Topical One Drop Flea & Tick Control
for dogs with IGR
K9 Advantix Plus 10
EPA Registration Number 87952-1
Your submission dated January 27, 2011

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

A stamped label is enclosed for your records.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely yours,

Linda A. DeLuise

Richard Gebken
Product Manager (10)
Insecticide Branch
Registration Division (7505P)

Enclosure

[Front Panel]

AVERTA-ARMORGUARD Topical One Drop Flea & Tick Control for DOGS with IGR*

*Insect Growth Regulator

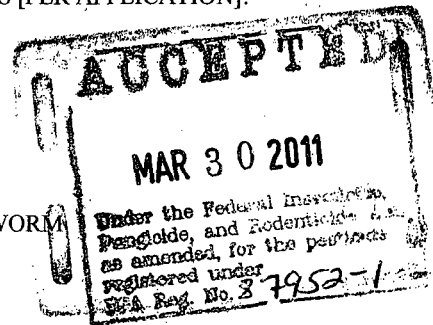


DO NOT USE ON CATS

FOR DOGS [33 lbs and Under] [Between 33 & 66 lbs] [66 lbs & Over]

Optional Marketing Statements

- FLEA AND TICK CONTROL FOR DOGS AND PUPPIES 3 MONTHS [12 WEEKS] OF AGE & OLDER
- KILLS AND REPELS [ADULT] FLEAS [FOR] UP TO 5 WEEKS!
- KILLS, REPELS AND PREVENTS REINFESTATION OF FLEAS FOR UP TO 5 WEEKS!
- KILLS AND REPELS BROWN DOG TICKS (*Rhipicephalus sanguineus*) FOR UP TO 6 WEEKS [PER APPLICATION]!
- MONTHLY FLEA, TICK, LICE & SARCOPTIC MANGE MITE APPLICATION!
- KILLS AND REPELS MOSQUITOES [ON DOGS]
- KILLS AND REPELS FLEAS AND TICKS FOR UP TO 5 WEEKS [PER APPLICATION]!
- 3 [4] [5] [6] [9] [12] MONTH SUPPLY [APPLICATIONS]
- CONTAINS BITREX
- TRIPLE PEST PROTECTION AGAINST
FLEAS
TICKS
MOSQUITOES
- FLEA, TICK & MOSQUITO APPLICATION
- KILLS MOSQUITOES THAT MAY TRANSMIT DOG HEARTWORM
- FIVE [5]-IN-ONE [1] PEST PROTECTION
FLEAS
TICKS
MOSQUITOES
LICE
SARCOPTIC MANGE MITES
- KILLS FLEAS, TICKS, MOSQUITOES, LICE & SARCOPTIC MANGE MITES ON DOGS
- REPELS & KILLS TICKS ON DOGS
- KILLS AND REPELS THE DEER TICK (THAT MAY TRANSMIT LYME DISEASE) FOR UP TO 6 WEEKS!
- BREAKS FLEA LIFE CYCLE!
- KILLS AND REPELS ADULT FLEAS FOR UP TO 5 WEEKS [PER APPLICATION]!
- STOPS FLEA EGGS FROM HATCHING!
- CONTROLS REINFESTATION!
- KILLS, REPELS AND PREVENTS REINFESTATION OF TICKS, INCLUDING BROWN DOG TICKS AND *Ixodes* spp. WHICH MAY TRANSMIT LYME DISEASE, FOR UP TO 6 WEEKS
- PROTECTS AGAINST BLOOD FEEDING MOSQUITOES THAT MAY TRANSMIT DOG HEARTWORM
- KILLS FLEA EGGS & LARVAE
- PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS
- KILLS TICKS INCLUDING THOSE THAT MAY TRANSMIT LYME DISEASE
- KILLS FLEAS, FLEAS EGGS, TICKS, MOSQUITOES, LICE, & SARCOPTIC MANGE MITES
- CONVENIENT TO USE
- KILLS, REPELS, CONTROLS & PREVENTS REINFESTATIONS
- TOPICAL PREVENTION OF TICKS, FLEAS, MOSQUITOS, LICE, & SARCOPTIC MANGE MITES FOR MONTHLY USE ON DOGS & PUPPIES 12 WEEKS OF AGE AND OLDER
- REPELS AND KILLS ADULT FLEAS BEFORE THEY LAY EGSS



[Use of the following marketing claims as applicable to the specific size packaging]

- For Dogs Between 15 [33] and 33 [66] lbs (for 1.5 ml tubes or 3.0 ml tubes as appropriate)
- For Dogs Weighing 15 lbs and under [or less]; For Dogs Weighing Less than 15 lbs (for 1.5 ml tubes)
- For use ONLY on Dogs Weighing 66 lbs and over [or more]; For Dogs Weighing More Than 66 lbs (for 6.0 ml tubes)

**Keep out of Reach of Children
Caution**

See back/side/other panel(s) for additional Precautionary Statements and First Aid

NET CONTENTS: xx [1.5 ml (0.05 fl. oz.)] [3.0 ml (0.1 fl. oz.)] [6.0 ml (0.2 fl. oz.)] Applicator
[Contents: xx x.x ml Applicators (Total x.xx fl. oz.)]

EPA Est. No. _____

[Back/side/other panel(s)]

Active Ingredients:

Permethrin* (CAS No. 52645-53-1)	45.0%
S-Methoprene (CAS No. 65733-16-6)	1.2%
Other Ingredients:	53.8%
TOTAL	100.0%

* Cis/Trans ratio: Max 55% (±) cis and min. 45% (±) trans

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS 3 MONTHS [12 WEEKS] OF AGE & OLDER.
DO NOT USE ON CATS.

PRECAUTIONARY STATEMENTS

Hazards to Domestic Animals

CAUTION

FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 3 months of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. DO NOT USE ON CATS or animals other than dogs. Cats that actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects. Sensitivities may occur after use with ANY pesticide product for pets. If signs of sensitivity occur, bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Signs of sensitivity to this product include skin sensitivity, increased itchiness, redness, rash, hair discoloration, or hair loss at the application site. Dogs may also show "lethargy." If your pet is experiencing an adverse event, contact your veterinarian immediately, and report incident to US Animal Health at 800-XXX-XXXX

<p>DO NOT USE ON CATS – MAY BE FATAL. May be toxic or potentially fatal if applied to or ingested by cats. Keep cats away from treated dogs for 24 hours. Accidental application to cats and/or grooming a recently treated dog by cats may result in tremors and/or uncoordinated muscle movements. If applied or ingested, immediate veterinary care should be provided.</p>

Environmental Hazards: This product is extremely toxic to fish and aquatic organisms. Do not apply directly to any body of water. Dogs should not be allowed to go swimming for 12 hours following application.

PHYSICAL OR CHEMICAL HAZARDS: Combustible! Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

DO NOT USE ON CATS or animals other than dogs. **May be toxic and potentially fatal if applied to or ingested by cats.**

Do not get this product in your dog's eyes or mouth. Repeat applications may be made if necessary, but do not apply more often than once every 4 weeks.

[For Dogs Weighing 33 lbs and Under: (1.5 ml applicator tubes) Apply one tube (1.5 ml) of this product as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 33 lbs and 66 lbs: (1.5 ml applicator tubes) Apply one tube (1.5 ml) of this product as a spot or stripe to the dog's back between the shoulder blades and apply a second tube (1.5 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.]

OR

[For use ONLY on Dogs Weighing Between 33 lbs and 66 lbs: (3.0 ml applicator tubes) Apply approximately half of the tube (1.5 ml) of this product as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (1.5 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.]

OR

[For use ONLY on Dogs Weighing Between 33 lbs and 66 lbs: Apply the entire tube (3.0 ml) as a continuous stripe on the dog's back starting between the shoulder blades and ending in front of the base of the tail.]

OR

[For Dogs Weighing 66 lbs and Over: (1.5 ml applicator tubes) Apply one tube (1.5 ml) of this product as a stripe to the dog's back between the shoulder blades and apply a second and third tube (two 1.5 ml tubes) continuing the stripe down the center of the dog's back and apply a fourth tube (1.5 ml) to the dog's back directly in front of the base of the tail.]

OR

[For use ONLY on Dogs Weighing 66 lbs and Over: (6.0 ml applicator tubes) Apply approximately half of the tube (3.0 ml) of this product as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (3.0 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.]

OR

[For use ONLY on Dogs Weighing 66 lbs and Over: Apply the entire tube (6.0 ml) as a continuous stripe on the dog's back starting between the shoulder blades and ending directly in front of the base of the tail.]

HOW TO APPLY:

[FOR DARAN TUBES IN BLISTER CARD: Remove product tube from package. Holding tube with notched end pointing up and away from face and body, snap or cut off narrow end at notches. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap tube and put in trash.]

OR

[FOR FLAT CARD (doubled) UNIT-DOSE PACKAGING: Separate cards along the perforated line. Holding separated card by its wide end with narrow end pointing up and away from face and body, cut along dotted line. Invert card over dog and use narrow end of the card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap card and put in trash.]

OR

[FOR FLAT CARD UNIT-DOSE PACKAGING: For push pin type applicator. Remove one product tube from card. With cap end pointed up and away from face and body, depress cap to pierce tube end. Carefully remove cap, invert tube over dog, and with tube close dog's skin, squeeze tube to apply product. Wrap empty tube and put in trash.]

OR

[FOR FOLDING CARD OR TABBED CARD UNIT-DOSE PACKAGING: Remove product tab by tearing along perforation. Holding tab with tube end pointed up and away from face and body, cut along dotted line. Invert tab over dog and use narrow end of card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin.]

OR

[FOR BLISTER CARD WITH TRI-LAYER TUBES: Remove product tube(s) from package. Fold along perforation between tubes and tear off one (or more) tube(s). (Return unused tubes to package.) Holding tube with notched end pointing up and away from face and body, snap off (or cut) narrow end at notches. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin.]

[**FOR MULTI-DOSE PACKAGING: Withdraw (1.5 ml) (3.0 ml) (6.0 ml) of solution at a time. Apply entire given dose directly to the skin at the indicated locations.]

[**FOR DROPPER BOTTLE MULTI-DOSE PACKAGING: Insert dropper tube into insecticide solution, squeeze bulb, and then release to fill tube barrel to (1.5 ml) (3.0 ml) (6.0 ml) line. Position dropper tube end in dog's hair next to skin and squeeze bulb to apply all of the solution to the dog's skin as indicated for dog's size.]

[**FOR SALE TO VETERINARIANS ONLY]



DO NOT USE ON CATS

TAB LABEL (folding card and tabbed card packaging designs)

Averta-ArmorGuard Topical One Drop Flea & Tick Control for DOGS with IGR

Active Ingredients:

Permethrin (CAS No. 52645-53-1) 45.0%
S-Methoprene (CAS No.65733-16-6) 1.2%

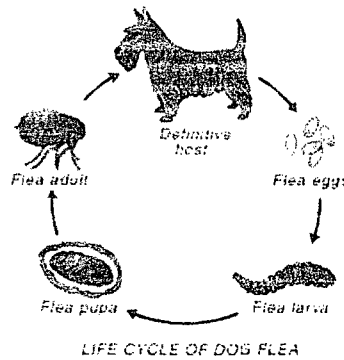
KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE MAIN LABEL FOR ADDITIONAL
PRECAUTIONS, FIRST AID, AND INSTRUCTIONS FOR USE

EPA Reg. No. 87952-1

OUTER BOX LABEL (Contains the following labeling plus full product label)

Averta-ArmorGuard Topical One Drop Flea & Tick Control for DOGS with IGR*

*Insect Growth Regulator (S-Methoprene) inhibits development of the immature stages of the fleas preventing them from reaching the biting adult stage.



4 STEPS FOR COMPLETE FLEA CONTROL

- Step 1 Shampoo or dip your dog.
- Step 2 Apply indoor and outdoor sprays, foggers, and powders labeled for flea control.
- Step 3 Apply **Averta-ArmorGuard Topical One Drop Flea & Tick Control for DOGS with IGR** for flea, tick, mosquito, lice, and Sarcoptic mange mite control.
- Step 4 Maintenance applications with on-animal sprays and powders.