

73510-4

12-8-2003

1/8



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DEC 8 2003

MarketQuest, Inc.  
c/o Ms. Rebecca M. Horton  
Registrations by Design Inc.  
118 ½ E. Main Street, Suite 1  
Salem, VA 24153

**Subject: Label Amendment in Conjunction with Submission of new Companion Animal Safety and Acute Toxicity Data  
MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator  
EPA Reg. No. 73510-4  
Your Submission Dated June 4, 2003**

Dear Ms. Horton:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments below. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. The ingredient statement is generally required on the front panel. If the size or form of the package makes it impractical to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere [40 CFR 156.10(g)(2)]. Your label indicates that the ingredient statement may appear on either the front, back or side panel. Before EPA will approve placement of the ingredient statement on the side or back panel, you must submit an explanation as to why it is not practical to place the ingredient statement on the front panel. Generally, EPA will not approve alternate placements of the ingredient statement to accommodate pictures, graphics or other marketing claims not required by FIFRA. Until alternate placement is approved, the ingredient statement must appear on the front panel.

2. You must revise the minimum retreatment interval from 3 weeks to 4 weeks. In the companion animal safety study you submitted to support treatment of dogs as young as 3 months (MRID # 459127-01), test animals received a single dose of the test substance. In accordance with EPA test guidelines, retreatment is required unless the minimum retreatment interval for the product is 30 days or more. Since test animals in the submitted study received only a single dose,

2/8

you must increase the retreatment interval on the label to 4 weeks (roughly a month). A copy of the Agency's review of the companion animal safety study is enclosed for your records.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

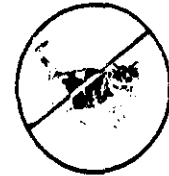


George T. LaRocca  
Product Manager (13)  
Insecticide Branch  
Registration Division (7505C)

Enclosures

[FRONT PANEL]

# MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator



FOR DOGS [15 lbs and Under][Between 15 & 33 lbs][Between 33 & 66 lbs][66 lbs & Over]

**DO NOT USE ON CATS**

Optional Marketing Statements

- CITRUS SCENT
- FLEA AND TICK CONTROL FOR DOGS AND PUPPIES 6 3 MONTHS [12 WEEKS] OF AGE & OLDER
- BREAKS FLEA LIFE CYCLE!
- KILLS AND REPELS FLEAS UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- KILLS FLEA EGGS AND LARVAE FOR UP TO 123 DAYS [PER APPLICATION]!
- PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS FOR UP TO 123 DAYS [PER APPLICATION]!
- KILLS AND REPELS MOSQUITOES!
- PROTECTS AGAINST BLOOD FEEDING BY MOSQUITOES (vector of HEARTWORM) UP TO 4 WEEKS [PER APPLICATION]!
- KILLS AND REPELS TICKS FOR UP TO 4 WEEKS [PER APPLICATION]!
- KILLS AND REPELS DEER TICKS (vector of LYME DISEASE) FOR UP TO 4 WEEKS [PER APPLICATION]!
- KILLS AND REPELS BROWN DOG TICKS (*Rhipicephalus sanguineus*) FOR UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- KILLS AND REPELS AMERICAN DOG TICKS (*Dermacentor variabilis*) FOR UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- MONTHLY APPLICATION
- MONTHLY FLEA, TICK AND MOSQUITO TREATMENT!
- KILLS AND REPELS FLEAS AND TICKS FOR UP TO A MONTH [PER APPLICATION]!
- KILLS AND REPELS ADULT FLEAS FOR UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- KILLS FLEA EGGS AND LARVAE [FOR UP TO 4 MONTHS][FOR 123 DAYS][PER APPLICATION]!
- KILLS AND REPELS TICKS FOR UP TO [4 WEEKS][3 TO 4 WEEKS] [PER APPLICATION] INCLUDING DEER TICKS (vector of LYME DISEASE), BROWN DOG TICKS & AMERICAN DOG TICKS!
- KILLS AND REPELS [ADULT FLEAS] FOR UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- 3 [4] [5] [6] [9] [12] MONTH SUPPLY [APPLICATIONS]
- Do Not Use On Cats (repeated on front panel)

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

- For Dogs Between 15 [33] and 33 [66] LBS.
- For Dogs Weighing 15 LBS. and under [or less]; For Dogs Weighing Less Than 15 LBS.
- For Dogs Weighing 66 LBS. and over [or more]; For Dogs Weighing More Than 66 LBS.

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated:**

DEC 8 2003

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

73510-4

## Keep Out of Reach of Children **CAUTION**

See back/side/other panel(s) for additional Precautionary Statements.

NET CONTENTS: xx [1 ml (.03 fl. oz.)][1.5 ml (.05 fl. oz.)][3.0 ml (.1 fl. oz.)] [4.5 ml (0.152 fl. oz.)] Applicator  
[CONTENTS: xx x.x mL Applicators (Total x.xx fl. oz.)]

4/8

[BACK/SIDE/OTHER PANEL(S)]

**ACTIVE INGREDIENTS**

Permethrin\* (CAS #52645-53-1) ..... 45.0%  
Pyriproxyfen (CAS #95737-68-1) (Nylar®) ..... 1.9%

**OTHER INGREDIENTS** ..... 53.1%

**TOTAL** ..... 100.0%

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

Nylar® is a registered trademark of McLaughlin Gormley King Company U.S. Patent No. 5,942,525

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS 6 3 MONTHS [12 WEEKS] OF AGE & OLDER.**

**DO NOT USE ON CATS.**

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

**CAUTION**

~~Hazards to Humans: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.~~

~~Hazards to Domestic Animals: FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 6 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 effect. 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".~~

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

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

**FIRST AID**

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact x-xxx-xxx-xxxx for emergency medical treatment information

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.

**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 3 weeks.

[For Dogs Weighing 15 lbs and Under: (1.0 ml applicator tubes) Apply one tube (1.0 ml) of this product as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 15 and 33 lbs: (1.5 ml applicator tubes) Apply one tube (1.5ml) of this product as a spot or stripe to the dog's back between the shoulder blades.]

5/8

[For Dogs Weighing Between 33 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

[(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

[Apply the entire tube (3.0 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.]

[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 tube (1.5 ml) continuing the stripe down the center of the dog's back and apply a third tube (1.5 ml) to the dog's back directly in front of the base of the tail.]

OR

[(4.5 ml applicator tubes) Apply approximately half of the tube (2.25 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 (2.25 ml) as a spot or stripe to the dog's back directly in front of the base of the tail.]

OR

[Apply the entire tube (4.5 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 SARAN 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 in close to 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

6/8

[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 1.0 ml (1.5 ml)(3.0 ml)(4.5 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 1.0 ml (1.5ml)(3.0 ml)(4.5 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]

### STORAGE AND DISPOSAL

**Storage:** Store in a cool, dry place. Protect from freezing.

**Disposal: If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

**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.

MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator is an effective and easy to use product. This product has demonstrated greater than 92% control of fleas within one day of application. It prevents eggs from fleas on treated dogs from developing into biting adults for up to [4 months][123 days]. As with all flea and tick control products, MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard). Consult your veterinarian, entomologist, or retailer for program recommendations.

OR

MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator is an effective and easy to use product. This product has demonstrated greater than 92% control of fleas within one day of application. It prevents eggs from fleas on treated dogs from developing into biting adults for up to [4 months][123 days]. MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator kills and repels Deer Ticks (vector of Lyme Disease), Brown Dog Ticks, and American Dog Ticks for up to [3 to 4 weeks][4 weeks]. This product also kills and repels mosquitoes and protects against blood feeding by mosquitoes (vector of heartworm) for up to 4 weeks.

### NOTICE OF WARRANTY

MARKETQUEST, INC. MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED, CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORDANCE WITH THE STATEMENTS MADE ON THIS LABEL.

### MarketQuest, Inc.

746 Walker Road, Suite 10-301  
Great Falls, VA 22066

Optional informational text featured on supplemental distribution label(s):

Sergeant's is committed to providing high quality products.

If you have questions or comments about this product, please write: Sergeant's Consumer Response, P.O. Box 540399, Omaha, NE 68154-0399.

In Case of Emergency, Call: 7:30 a.m. - 4:30 p.m. CST: 1-800-224-PETS  
After Hours: 1-800-781-4738

7/8

TUBE LABEL (folding card and flat card packaging designs)

MARKETQUEST ONE DROP FLEA & TICK CONTROL WITH NYLAR® INSECT GROWTH REGULATOR

PERMETHRIN 45.0% W/W  
PYRIPROXYFEN 1.9% W/W



KEEP OUT OF REACH OF CHILDREN

**CAUTION**

READ DIRECTIONS AND  
PRECAUTIONS BEFORE USING

EPA Reg. No. 73510-4

8/8

**TAB LABEL** (folding card and tabbed card packaging designs)

**MARKETQUEST ONE DROP FLEA & TICK CONTROL WITH NYLAR® INSECT GROWTH REGULATOR**

**ACTIVE INGREDIENTS**

Permethrin (CAS #52645-53-1).....	45.0%
Pyriproxyfen (CAS #95737-68-01)(Nylar®).....	1.9%



**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**  
 SEE MAIN LABEL FOR ADDITIONAL  
 PRECAUTIONS AND INSTRUCTIONS FOR USE

EPA Reg. No. 73510-4

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

**MARKETQUEST ONE DROP FLEA & TICK CONTROL WITH NYLAR® INSECT GROWTH REGULATOR**

\*Nylar inhibits development of the immature stages of the fleas for up to 4 months preventing them from reaching the biting adult stage.

- Nylar – Registered Trademark of McLaughlin Gormley King and Company

(picture of flea life cycle here)

**4 STEPS FOR COMPLETE FLEA CONTROL**

- Step 1- Shampoo or dip your dog.
- Step 2- Treat indoor and outdoor premise with indoor and outdoor sprays, foggers and powders labeled for flea control.
- Step 3- Apply MarketQuest One Drop Flea & Tick Control with Nylar® Insect Growth Regulator for up to four weeks adult flea and tick control.
- Step 4- Maintenance treatments with on-animal sprays and powders.