

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

OFFICE OF PREVENTION PERTURBENAND TO VICE ALTERED MACES

October 13, 2004

Rebecca M. Horton MarketQuest, Inc. 746 Walker Road, Ste. 10-301 Great Falls, VA 22066

Subject:

Label Amendment - Response to Agency's March 10, 2004 letter

MarketQuest One Drop Flea & Tick Control

EPA Reg. No. 73510-2

Your Submission Dated April 22, 2004

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 listed below. Two (2) 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. Revise Precautionary Statements, Hazards to Humans section as follows:
 - "Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco."
- 2. Replace "Consult a veterinarian before using this product on debilitated, aged, or medicated animals" with "Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals" under *Hazards to Domestic Animals* section.
- 3. Replace all "4.5 ml" application rates with "6.0 ml" for Dogs weighing 66 lbs or more. As indicated in our previous letter, efficacy data does not support the lower application rate, 4.5 ml. See attached review.

If you have any questions regarding this action, please contact BeWanda Alexander of my team at (703) 305-7460.

Sincerely,

George T. LaRocca

Salctery,

JULY Market Job

George T. LaRocca

Product Manager (13)

Insecticide Branch

Registration Division (7505C)

[FRONT PANEL]

MarketQuest One Drop Flea & Tick Control

[Additional Brand Name(s): No More Fleas & TicksTM One Drop Control]

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 3 MONTHS [12 WEEKS] OF AGE & OLDER
- KILLS AND REPELS FLEAS UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- KILLS AND REPELS TICKS FOR UP TO 4 WEEKS [PER APPLICATION]!
- KILLS AND REPELS BROWN DOG TICKS (Rhipicephalus sanguineus) FOR UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- MONTHLY APPLICATION
- MONTHLY FLEA AND TICK 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 AND REPELS TICKS FOR UP TO [4 WEEKS][3 TO 4 WEEKS] [PER APPLICATION] INCLUDING BROWN DOG TICKS!
- KILLS AND REPELS [ADULT FLEAS] FOR UP TO 3 TO 4 WEEKS [PER APPLICATION]!
- 3 [4] [5] [6] [9] [12] MONTH SUPPLY
- CONTAINS BITREX
- PROTECTION AGAINST

FLEAS TICKS

ACTIVE INGREDIENT

ACITY E INGREDIENT	
Permethrin* (CAS #52645-53-1)	45%
OTHER INGREDIENTS	
TOTAL	

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

ACCEPTED
with COMMENTS
In EPA Letter Dated
001 1 3 2004
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

EPA Est. No. _____ Page 1 of 6 Pages

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

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-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.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals CAUTION

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

Hazards to Domestic Animals: For external use only. Do not apply on dogs less than 3 months of age. Repeat applications may be made as necessary, but do not apply at intervals less than 4 weeks. DO NOT USE ON CATS. Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effect. Do not use this product in households with both dogs and cats. Consult a veterinarian before using this product on debilitated, aged, or medicated animals. Consult a veterinarian before using this product on dogs with known organ dysfunction. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with a 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.

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 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.]

[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 <u>and</u> 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

[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: Do not remove tube from the pack until ready to use. Store in a cool (below 25°C) dry place out of reach of children. Do not refrigerate. Protect from direct sunlight.

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 is an effective and easy to use product. This product has demonstrated 100% control of fleas within one day of application. MarketQuest One Drop Flea & Tick Control kills and repels ticks for up to [3 to 4 weeks][4 weeks]. As with all flea and tick control products, MarketQuest One Drop Flea & Tick Control 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.

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

TUBE LABEL (folding card and flat card packaging designs)

MARKETQUEST ONE DROP FLEA & TICK CONTROL

PERMETHRIN 45% W/W



KEEP OUT OF REACH OF CHILDREN CAUTION

READ DIRECTIONS AND PRECAUTIONS BEFORE USING

EPA Reg. No. 73510-2

EPA Reg. No. 73510-2amendment April 20, 2004 EPA Est. No. Page 5 of 6 Pages

TAB LABEL (folding card and tabbed card packaging designs)

MARKETQUEST ONE DROP FLEA & TICK CONTROL

ACTIVE INGREDIENTS



Permethrin (CAS #52645-53-1)......45%

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE MAIN LABEL FOR ADDITIONAL PRECAUTIONS AND INSTRUCTIONS FOR USE

EPA Reg. No. 73510-2

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

MARKETQUEST ONE DROP FLEA & TICK CONTROL

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 for up to four weeks adult flea and tick control.
Step 4-	Maintenance treatments with on-animal sprays and powders.