

1/13/2004

JAN 13 2004

Joseph E. Dyer
ECTO Development Corporation
1229 N. Jesse James Road
Excelsior Springs, MO 64024

Subject: Revised label for:
ECTO Flea & Tick Insecticide With IGR
EPA Registration No.67505-3
Application dated October 31, 2003

Dear Mr. Dyer:

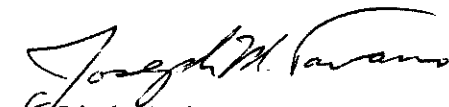
The proposed amendment to the registration of the product cited above under the Federal Insecticide, Fungicide And Rodenticide Act, as amended revising the label is acceptable subject to the comments listed below:

- 1) The statement, "Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects.", must be highlighted.
- 2) The statement, "Do not use on cats." or the cat icon, must also appear on the tube and tab labels.

A stamped copy of the draft label is enclosed for your records. Submit two copies of the finished label before the product is released for shipment under this revised label.

If you have any questions please contact Joseph Tavano at (703) 305-6411.

Sincerely,


Linda Arrington
Acting Product Manager 10
Insecticide Branch
Registration Division (7505C)



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ACCEPTED
with COMMENTS
In EPA Letter Dated

JAN 13 2004

67505-3 FLEA & TICK CONTROL FOR DOGS AND PUPPIES OVER 12 WEEKS OF AGE
as amended, for the Pesticide
registered under EPA Reg. No.

FRONT PANEL
ECTO FLEA & TICK INSECTICIDE WITH IGR

[CAT ICON IN CIRCLE
WITH SLASH THROUGH IT]

PLEASANT CITRUS SCENT

FLEA & TICK CONTROL FOR DOGS AND PUPPIES OVER 12 WEEKS OF AGE

BIO SPOT FLEA & TICK CONTROL FOR DOGS

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

DO NOT USE ON CATS

- BREAKS FLEA LIFE CYCLE!
- KILLS & REPELS FLEAS UP TO 3 TO 4 WEEKS!
- KILLS FLEA EGGS AND LARVAE FOR UP TO 123 DAYS!
- PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS FOR UP TO 123 DAYS!
- KILLS AND REPELS MOSQUITOES!
- PROTECTS AGAINST BLOOD FEEDING BY MOSQUITOES (vector of HEARTWORM) UP TO 4 WEEKS!
- KILLS & REPELS TICKS FOR UP TO 4 WEEKS!
- KILLS & REPELS DEER TICKS (vector of LYME DISEASE) FOR UP TO 4 WEEKS!
- KILLS & REPELS BROWN DOG TICKS (Rhipicephalus sanguineus) FOR UP TO 3 TO 4 WEEKS!
- KILLS & REPELS AMERICAN DOG TICKS (Dermacentor variabilis) FOR UP TO 3 TO 4 WEEKS!
- MONTHLY APPLICATION!
- MONTHLY FLEA, TICK AND MOSQUITO TREATMENT!
- KILLS AND REPELS FLEAS AND TICKS FOR UP TO A MONTH!
- KILLS AND REPELS ADULT FLEAS FOR UP TO 3 TO 4 WEEKS!
- KILLS FLEA EGGS AND LARVAE [FOR UP TO 4 MONTHS] [FOR 123 DAYS]
- KILLS AND REPELS TICKS FOR UP TO [4 WEEKS] [3 TO 4 WEEKS] 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!

ACTIVE INGREDIENTS

¹ Permethrin: (CAS #52645-53-1)..... 45.0%
 Pyriproxyfen: (CAS #95737-68-1) (Nylar®)..... 5.0%

OTHER INGREDIENTS..... 50.0%
 TOTAL 100.0%

¹ cis/trans ratio: Max 55% (+) cis and min 45% (+) trans

U.S. Patent No. 5,942,525

Nylar® is a Registered Trademark of McLaughlin Gormley King and Company

KEEP OUT OF THE REACH OF CHILDREN

DO NOT USE ON CATS

CAUTION

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: XX [0.03 fl. oz. (1 mL)][0.05 fl. oz.(1.5mL)][1 fl.oz (3.0 mL)]
[4.5 mL] Applicator

EPA Reg. No.: 67505-3

EPA Est. No.:

Manufactured For: Ecto Development Corporation
Excelsior Springs, MO 64024

67505-3

Page 1 of 8 (lot number statement as needed) Mfg. & Printed in U.S.A.
October 31, 2003 (label revision number) (product number)

E03DL01A.DOC-1

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SIDE/BACK PANEL
FLEA & TICK INSECTICIDE WITH IGR

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS OVER 12 WEEKS OF AGE
DO NOT USE ON CATS

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

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

Hazards to Domestic Animals: FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. **DO NOT USE ON CATS** or animals other than dogs. Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effect. Certain medications can interact with pesticides. It is advisable to consult a veterinarian before using this product with any other pesticide or drug.

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FIRST AID
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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 eyes 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 eyes.
 ° Call a poison control center or doctor for treatment advice.
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HOT LINE NUMBER
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 for emergency medical treatment information.
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Adverse Reactions: Some animals may be sensitive to ingredients in this product. Reactions in dogs may include skin sensitivity. Dogs may show lethargy, increased pruritis (itchiness), erythema (redness), rash and hair discoloration or hair loss at the application site. Observe the dog following treatment. Sensitivity may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your dog with a mild, non-insecticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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SIDE/BACK PANEL
ECTO FLEA & TICK INSECTICIDE WITH IGR

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

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, except to reapply after shampooing the dog.

[For Dogs Weighing 15 lbs and Under: (1.0 mL applicator tubes) Apply one tube (1.0 mL) of product solution 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 (1.5 mL) of product solution as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 33 to 66 lbs: (1.5mL applicator tubes) Apply one tube (1.5 mL) of product solution 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 strip to the dog's back directly in front of the base of the tail.] OR

[(3 mL applicator tubes) Apply approximately half of the tube (1.5 mL) of product solution 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 strip to the dog's back directly in front of the base of the tail.] OR

[(3 mL applicator tube) 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: (1.5mL applicator tubes) Apply one tube (1.5 mL) of product solution 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 (2.25mL) of product solution 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 strip to the dog's back directly in front of the base of the tail.] OR

[(4.5 mL applicator tube) 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.]

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ECTO FLEA & TICK INSECTICIDE WITH IGR

DIRECTIONS FOR USE (Continued)

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.

FOR FLAT CARD (doubled) UNIT-DOSE PACKAGING: Separate cards along the perforated line. Holding separated card by its wide end with narrow end pointed 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.

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 dogs skin, squeeze tube to apply product. Wrap empty tube and put in trash.

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. Wrap tab and put in trash.

BLISTER CARD WITH TRI-LAYER TUBES: Remove product tube(s) from package. Fold along perforation between tubes and tear off one tube. {Return unused tubes to package.} Holding tube with notched end pointing up and away from face and body, snap 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.

² **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.

² **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 (1.5 mL) (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.

² **FOR SALE TO VETERINARIANS ONLY**

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SIDE/BACK PANEL
ECTO FLEA & TICK INSECTICIDE WITH IGR

ECTO FLEA & TICK INSECTICIDE WITH IGR is an effective and easy to use product. This product has demonstrated greater than 92% control of fleas within one day of application. This product 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, This product 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.

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STORAGE AND DISPOSAL

Storage: Store in a cool dry place away from heat and open flame. Protect from freezing.

Disposal: Do Not Puncture or Incinerate! If **empty:** 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:

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NOTICE OF WARRANTY ³

ECTO DEVELOPMENT CORPORATION 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.

OR

Buyer assumes all responsibility for safety and use not in accordance with directions.

³ The use of any notice of warranty statement is optional.

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TUBE LABEL (folding card and flat card packaging designs)

ECTO FLEA & TICK INSECTICIDE WITH IGR

PERMETHRIN 45% W/W
PYRIPROXYFEN 5% W/W

**KEEP OUT OF THE REACH OF CHILDREN
READ DIRECTIONS AND
PRECAUTIONS BEFORE USING**

EPA Reg. No. 67505-3

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

ECTO FLEA & TICK INSECTICIDE WITH IGR

BIOLAR (NYLAR®) inhibits development of the immature stages of the flea 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

As Part of a complete flea control program
USE Bio Flea Halt! Outdoor Yard Spray Concentrate, and Bio Flea Halt! Carpet Powder or Carpet Spray with Biolar Insect Growth Regulator, along with on-animal flea & tick products.

**4 STEPS FOR
COMPLETE FLEA CONTROL**

- Step 1 - Shampoo or dip your dog
- Step 2 - Treat indoor and outdoor premise with Bio Flea Halt! indoor and outdoor sprays, foggers and powders
- Step 3 - Apply Bio Spot-On for up to four weeks adult flea and tick control
- Step 4 - Maintenance treatments with on-animal sprays and powders