

67505-4

05/30/2012

1/11



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr Edward Lawrence
Ecto Development Corporation
850 NW Pink Hill Road
Blue Springs, MO 64015

MAY 30 2012

Dear Mr Lawrence

Subject Amendment Response to Agency letter dated 9/30/2011
and Change Product Name
OLD NAME Ecto Flea & Tick Insecticide
NEW NAME Ecto Dog & Horse Flea & Tick Insecticide
EPA Reg No 67505-4
Your submission dated February 14, 2012

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(7)(a), is acceptable and a stamped copy of the label is enclosed for your records

Please be reminded that 40 CFR Part 156 140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself

If you have any questions regarding this letter, please contact Dana Pilitt, PhD of my staff at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

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

2/11

FRONT PANEL

ECTO DOG & HORSE FLEA & TICK INSECTICIDE
PLEASANT CITRUS SCENT

[Picture of Horse or Dog (in weight range)]

[Use Only For Dogs between 5 to 15 lbs]
[Use Only for Dogs between 15 & 33 lbs]
[Use Only for Dogs between 33 & 66 lbs]
[Use Only for Dogs over 66 lbs]

[For Dogs Only 1 of above descriptions per package label]

FLEA & TICK CONTROL FOR DOGS AND PUPPIES OVER 12 WEEKS OF AGE
PROTECTS HORSES FROM FLIES GNATS MOSQUITOES AND TICKS
DO NOT USE ON CATS

- KILLS & REPELS FLEAS UP TO 3 TO 4 WEEKS!
- 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 LYMEDISEASE) 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 OR 4 WEEKS!
- KILLS AND REPELS TICKS FOR UP TO [4 WEEKS] [3 TO 4 WEEKS] INCLUDING DEER TICKS (vector of LYME DISEASE) BROWN DOG TICKS AND AMERICAN DOG TICKS!
- PROTECTS HORSES FROM HOUSE FLIES STABLE FLIES, FACE FLIES HORN FLIES, EYE GNATS AND TICKS!
- KILLS AND REPELS HOUSE FLIES, STABLE FLIES FACE FLIES HORN FLIES EYE GNATS AND TICKS ON HORSES!
- AIDS IN THE CONTROL OF HORSE FLIES DEER FLIES MOSQUITOES AND BLACK FLIES ON HORSES!

ACTIVE INGREDIENTS

¹ Permethrin (CAS #52645-53 I)	45.0 %
² OTHER INGREDIENTS	<u>55.0 %</u>
TOTAL	100.0 %

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

² Contains petroleum distillate

ACCEPTED

MAY 30 2012

Under the Federal Insecticide Fungicide and Rodenticide Act as amended for the pesticide registered under EPA Reg No 67505-4

3/11

FRONT PANEL [Continued]

KEEP OUT OF THE REACH OF CHILDREN

CAUTION

DO NOT USE ON CATS

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents

1 [0.03 fl oz (1.0 mL)] [0.05 fl oz (1.5 mL)] [1 fl oz (30 mL)] Applicator or
3 [0.03 fl oz (1.0 mL)] [0.05 fl oz (1.5 mL)] [1 fl oz (30 mL)] Applicators or
3 [0.34 fl oz (10.0 mL)] Applicator or 6 [0.34 fl oz (10.0 mL)] Applicators

EPA Reg No 67505 4 EPA Est No

Manufactured For Ecto Development Corporation
Blue Springs MO 64015

(lot number statement as needed) Mfg & Printed in U S A

(label revision number) (product number)

No Cat Icon
(Cat with circle
& bar across)
Minimum Size
1.5 x 1.5 cm

**DO NOT USE ON CATS
MAY BE FATAL**
[No Cat Icon on front panel
– lower right corner]

411

SIDE / BACK PANEL

ECTO DOG & HORSE FLEA & TICK INSECTICIDE

READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS OVER 12 WEEKS OF AGE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Hazards to Humans Harmful if swallowed or absorbed through the skin Causes moderate eye irritation Avoid contact with skin eyes or clothing Wash thoroughly with soap and water after handling and before eating drinking chewing gum or using tobacco Remove and wash contaminated clothing before reuse

Hazards to Domestic Animals FOR EXTERNAL USE ON DOGS AND HORSES ONLY Do not use on puppies or foals under 12 weeks of age Consult a veterinarian before using this product on debilitated aged medicated pregnant or nursing dogs or horses Consult a veterinarian before using on dogs or horses with known organ dysfunction

DO NOT USE ON CATS May be toxic and potentially fatal if applied to or ingested by cats Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects

Certain medications can interact with pesticides It is advisable to consult a veterinarian before using this product with any other pesticide or drug

FIRST AID

If Swallowed Call a poison control center or doctor immediately for treatment advice
- Do not give any liquid to the person
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 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

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

SIDE EFFECTS
Monitor your dog after application Side effects may include signs of skin irritation such as redness scratching or other signs of discomfort Gastrointestinal signs such as vomiting or diarrhea have also been reported If these or other side effects occur consult your veterinarian or
1-800- XXX-XXX

HOT LINE NUMBER

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 XXX-XXXX for emergency medical treatment information

No Cat Icon
(Cat with circle & bar across)
Minimum Size
1 5 x 1 5 cm

NOTE TO PHYSICIAN Contains petroleum distillate - vomiting may cause aspiration pneumonia

**DO NOT USE ON CATS
MAY BE FATAL**

[No Cat Icon on back panel lower right corner]

[67505 4]
[Page 3 of 10]
[February 6 2012]

5/11

ECTO DOG & HORSE FLEA & TICK INSECTICIDE

Adverse Reactions Some animals may be sensitive to ingredients in this product. Reactions in dogs or horses may include skin sensitivity. Dogs or horses may show lethargy, increased pruritis (itchiness), erythema (redness), rash and hair discoloration or hair loss at the application site. Observe the dog or horse following treatment. Sensitivity may occur after using ANY pesticide product on pets. If signs of sensitivity occur, bathe your dog or horse with a mild, non-insecticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

PHYSICAL OR CHEMICAL HAZARDS

DO NOT USE OR STORE NEAR HEAT OR OPEN FLAMES

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. 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.

DOGS

DO NOT USE ON CATS or animals other than [dogs or horses]. May be toxic or potentially fatal if applied to or ingested by cats. Do not get this product in your dog's eyes or mouth and do not allow the dog to ingest this product. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately. 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.

[Only 1 of following descriptions per package label]

Use Only For Dogs Between 5 - 15 lbs [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. Do not use on dogs less than 5 pounds.

Use Only for Dogs Between 15 & 33 lbs [1.5 mL applicator tube] Apply one tube (1.5 mL) of product solution as a spot between the shoulder blades or as a stripe to the dog's back.

Use Only for Dogs Between 33 & 66 lbs [1.5 mL applicator tube] Apply one tube (1.5 mL) of product solution as a spot to the dog's shoulder blades or as a stripe to the dog's back and apply a second tube (1.5 mL) as a spot directly in front of the base of the tail or as a stripe to the dog's back. [Or]

[3.0 mL applicator tube] 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 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.

No Cat Icon
(Cat with circle
& bar across)

Minimum Size
1.5 x 1.5 cm

**DO NOT USE ON CATS
MAY BE FATAL**
[No Cat Icon on back panel
lower right corner]

6/11

SIDE / BACK PANEL [Continued]

ECTO DOG & HORSE FLEA & TICK INSECTICIDE

DIRECTIONS FOR USE (CONTINUED)

Use Only for Dogs Over 66 lbs (1.5 mL 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. **DO NOT USE MORE THAN 3 TUBES REGARDLESS OF DOG SIZE**] [Or]

[(4.5 mL applicator tubes) Apply approximately half of the tube (2.25 mL) of product solution as 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. **DO NOT USE MORE THAN A 4.5 mL DOSE REGARDLESS OF DOG SIZE**] [Or]

[(4.5 mL applicator tubes) 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. **DO NOT USE MORE THAN A 4.5 mL DOSE REGARDLESS OF DOG SIZE**]

HOW TO APPLY

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.

FOR FLAT CARD 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 dog's skin, squeeze tube to apply product. Wrap empty tube and put in trash.

BLISTER PACKED TUBES Remove product tube from package. Holding tube with notched end pointing up and away from face and body, 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. Wrap tube and put in trash.

PULL AND TWIST APPLICATOR TUBE Remove applicator tube from package. Hold applicator tube in an upright position. Pull cap off tube. Turn the cap around and place other end of cap back on tube. Twist cap to break seal, then remove cap from tube. The dog should be standing for easy application. Part the hair, place the tip of the tube on the skin and gently squeeze to expel the solution on the skin. Discard empty tube as described in Storage and Disposal.

No Cat Icon
(Cat with circle & bar across)

Minimum Size
1.5 x 1.5 cm

**DO NOT USE ON CATS
MAY BE FATAL**
[No Cat Icon on back panel
lower right corner]

7/11

ECTO DOG & HORSE FLEA & TICK INSECTICIDE

DIRECTIONS FOR USE (CONTINUED)

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

³ **FOR MULTI-DOSE PACKAGING** Withdraw 1.5 mL of solution at a time Apply entire given dose directly to the skin at the indicated locations

³ **DROPPER BOTTLE MULTI-DOSE PACKAGING** Insert dropper tube into insecticide solution squeeze bulb and then release to fill tube barrel to 1.5 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

³ **FOR SALE TO VETERINARIANS ONLY**

HORSES

**DO NOT USE ON HORSES INTENDED FOR FOOD USE
DO NOT USE ON FOALS UNDER 12 WEEKS (3 MONTHS) OF AGE**

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

Apply one tube (10.0 mL) of product solution as follows

5 mL along the back line starting at the poll (top of head behind the ears) along the base of the neck down the dorsal midline to the dock (base of the tail)

- 1 mL to the top of the forehead under the forelock
- 1 mL as a stripe to the front of each foreleg from the ankle up to the knee (2 mL total)
- 1 mL as a stripe to the front of each hindleg from the ankle up to the hock (2 mL total)
- Do not allow product to contact horses' eyes or mucous membranes
- Wrap tube and put in trash
- Do not reapply for 14 days (2 weeks)

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or 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 [No Cat Icon on back panel or 1-800- XXX- XXXX for disposal instructions

No Cat Icon
(Cat with circle
& bar across)

Minimum Size
1.5 x 1.5 cm

**DO NOT USE ON CATS
MAY BE FATAL**
[No Cat Icon on back panel
lower right corner]

SIDE / BACK PANEL [Continued]

ECTO DOG & HORSE FLEA & TICK INSECTICIDE

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

NOTICE OF WARRANTY ⁴

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.

⁴ The use of any notice of warranty statement is optional.

9/11

TUBE LABEL (folding card and flat card packaging designs)

ECTO DOG & HORSE FLEA & TICK INSECTICIDE
{NO CAT ICON}
PERMETHRIN 45 % W/W

KEEP OUT OF THE REACH OF CHILDREN
{DO NOT USE ON CATS - MAY BE FATAL }

READ DIRECTIONS AND
PRECAUTIONS BEFORE USING

EPA Reg No 67505 4

{USE THIS STATEMENT AND/OR NO CAT ICON IN CIRCLE WITH SLASH}

10/11

TAB LABEL (folding card and tabbed card packaging designs)

ECTO DOG & HORSE FLEA & TICK INSECTICIDE
{NO CAT ICON}
PERMETHRIN 45 % W/W

KEEP OUT OF THE REACH OF CHILDREN
{DO NOT USE ON CATS - MAY BE FATAL }

READ DIRECTIONS AND
PRECAUTIONS BEFORE USING

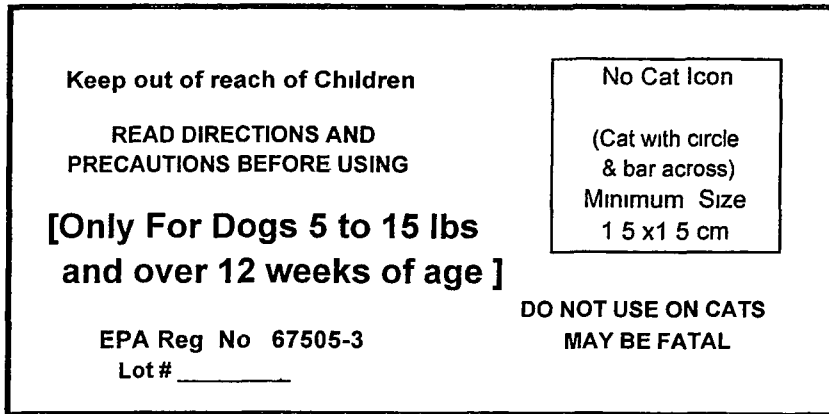
EPA Reg No 67505-4

{USE THIS STATEMENT AND/OR NO CAT ICON IN CIRCLE WITH SLASH}

[67505-4]
[Page 9 of 10]
[February 6 2012]

ATTACHMENT A

VIEW OF DOG APPLICATOR VIAL / TUBE LABELING [OR IMMEDIATE CONTAINER LABELING]



[ONE OF THE FOLLOWING TEXTS PER VIAL / TUBE OR IMMEDIATE CONTAINER LABELING]

Only For Dogs 5 to 15 lbs
and over 12 weeks of age

Only for Dogs 15 to 33 lbs
and over 12 weeks of age

Only for Dogs 33 to 66 lbs
and over 12 weeks of age

Only for Dogs Over 66 lbs
and over 12 weeks of age