

773-93

01/31/2012

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



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JAN 31 2012

Patricia Sheehy  
Intervet Schering-Plough Animal Health  
556 Morris Avenue  
Summit, NJ 07091

Dear Ms. Sheehy:

Subject: PRIA Amendment to review submitted efficacy data to support the following proposed claims: "Flea efficacy demonstrated in global field studies" and "Effectively controls fleas in the home environment," "ACTIVYL for Cats and Kittens  
EPA Registration No. 773-93  
Your Submission Dated: September 8, 2011  
Decision Number 454489

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable provided you make the following changes:

- Page 2: under "Restrictions," bullet each restriction within the paragraph formatting so that they are easily distinguishable from one another.
- Pages 2 & 3: revise the sentence that reads "Do not use on cats (male or female) intended for breeding, pregnant or nursing" to read "Do not use on cats (male or female) intended for breeding, or on cats that are pregnant or nursing."
- Page 2: under "Restrictions," for each package size revise "Do not use on kittens under 8 weeks of age and weighing less than XX lbs" with "Do not use on cats or kittens under 8 weeks of age and weighing less than XX lbs."
- Page 2: revise the entire last paragraph to read: "It is recommended to reapply every 30 days or as needed, but DO NOT apply more than 1 applicator (tube) per month. When application is complete, follow the Container Handling instructions under the Storage and Disposal section below."
- Page 9: delete marketing claim #1 "Indoxacarb is (a new) (an) active ingredient from a (new) chemical class being introduced (globally) (world wide) for flea control. [These claims may only be used for 6 months from the initial date of distribution.]" because it is false and misleading.
- Page 9: revise marketing claim #17 that reads "Formulated for cats (and) (kittens) 8 weeks and older (weighing more than 2 lb (0.9 kg) and up to 9 lb (4.1kg) " to read



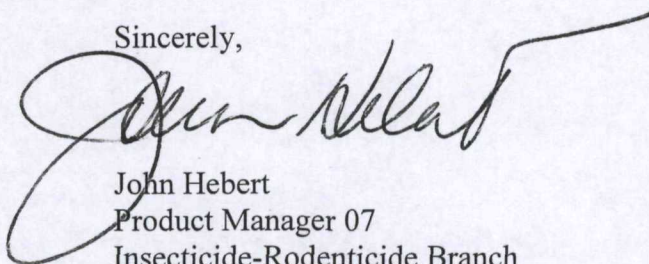
“Formulated for cats (and) (kittens) 8 weeks and older weighing more than 4.4 lb (2 kg) and up to 9 lb (4.1kg).

- On every page, for any statement that reads “for cats and kittens 8 weeks of age and older..” or any statement regarding “8 weeks” revise to read “**14 weeks**” per the Companion Animal Safety memo dated 6/2/2010.

**The efficacy studies, MRIDs 48596401-04 submitted were reviewed and the findings were summarized in the efficacy memo dated 1/25/12 (A. Metzger). Based on the review, the only claim that is supported is “Effectively controls fleas on cats in a home environment.”**

A stamped copy of the labeling is enclosed for your records. Please submit one final printed copy of the labeling before releasing the product for shipment. If you have any questions regarding this label, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Sincerely,



John Hebert  
Product Manager 07  
Insecticide-Rodenticide Branch  
Registration Division (7505P)



“Master Label”: This master label includes text for different size packages and application rates specific to pet’s age and body weight.

### FRONT PANEL

#### ACTIVYL for Cats and Kittens

**Alternate Brand Names:**

- ACTIVYL for Cats or Kittens
- ACTIVYL Spot-On for Cats and Kittens
- ACTIVYL Spot-On for Cats or Kittens
- ACTIVYL for Cats
- ACTIVYL Spot-On for Cats

For Cats and Kittens 4.4 to 9 lb (2 to 4 kg) and 8 weeks of age or older ONLY (0.51 mL size only)  
For Cats over (greater than) (>) 9 lb (4 kg) ONLY (1.03 mL size only)

**Active Ingredient:**

Indoxacarb:

(S)-methyl 7-chloro-2,5-dihydro-2-[[[(methoxycarbonyl)[4-trifluoromethoxy]phenyl]amino]  
-carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate.....19.53%

**Other Ingredients:**.....80.47%  
**Total** ..100.00%

### KEEP OUT OF REACH OF CHILDREN WARNING

SEE BACK PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED  
With COMMENTS  
In EPA Letter Dated:  
JAN 31 2012  
Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg. No:  
773-93

( ) Bracket text allows for alternative presentations of the same claim.



## BACK PANEL

### DIRECTIONS FOR USE

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

### RESTRICTIONS

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON CATS (MALE OR FEMALE) INTENDED FOR BREEDING, PREGNANT OR NURSING. DO NOT USE ON OTHER ANIMALS. DO NOT USE MORE THAN ONCE A MONTH. DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY.

### FOR EXTERNAL USE ON CATS AND KITTENS ONLY.

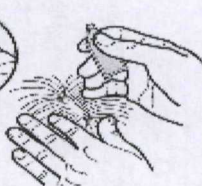
For 0.51 mL package size: Do not use on kittens under 8 weeks of age and weighing less than 4.4 lb.

For 1.03 mL package size: Do not use on kittens under 8 weeks of age and weighing less than 9 lb.

(HOW TO APPLY) Open one foil pouch and remove applicator (tube).



Step 1.



Step 2.



For cats and  
kittens 4.4 to 9 lb (2 to 4 kg)  
and 8 weeks of age or older ONLY  
(0.51 mL size only)



For cats  
over (greater than) (>) 9 lb (4 kg) ONLY  
(1.03 mL size only)

Step 1. Hold applicator (tube) in upright position away from your face and snap tip open by bending it and folding it back on itself.

Step 2. Part the hair and place applicator (tube) tip against the skin at the base of skull. Applying the product at the base of the skull will help prevent the cat from licking the product.

Step 3. Squeeze applicator firmly applying entire contents directly to skin. Do not allow product to run off. Do not have contact with treated area (application site) until completely dry

Do not use more than (1) applicator (tube) per treatment. Reapply every 30 days. When application is complete, follow the Container Disposal instructions under the Storage and Disposal section below.

( ) Bracket text allows for alternative presentations of the same claim.



## BACK PANEL (CONT'D)

FIRST AID	
<b>If in Eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a physician if irritation persists.</li></ul>
<b>If On Skin</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If Swallowed</b>	<ul style="list-style-type: none"><li>• Call poison control center or doctor immediately for treatment advice.</li><li>• Have a person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.	

**For 0.51 mL and 1.03 mL package size**  
**(note to reviewer: appropriate dose size will depending on package)**

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS

**WARNING.** Causes substantial but temporary eye injury. Harmful if absorbed through skin or swallowed. Do not get in eyes or on 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 cats and kittens only. Do not use on kittens under 8 weeks of age and weighing less than 4.4 lb/9lb (note to reviewer: weight used will be according to package size).** Do not use on cats (male or female) intended for breeding, pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated cats. Accidental ingestion by the cat may cause intermittent excess salivation. Other immediate post-treatment observations may include licking the face, shaking the head and squinting. These effects should disappear within several minutes following exposure without requiring treatment. Individual sensitivities, while rare, may occur after using any pesticide product. If signs of sensitivity continue, consult a veterinarian immediately. Certain medications can interact with pesticides.

#### PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

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**STORAGE AND DISPOSAL**

**PESTICIDE STORAGE:** Store in a cool, dry place inaccessible to children and pets.  
**CONTAINER DISPOSAL AND CONTAINER HANDLING:** **If empty**, do not reuse the container. Place in trash or offer for recycling if available. **If partly filled**, call your local solid waste agency for disposal instructions. Never place unused products down any indoor or outdoor drain.

EPA Reg. No. 773-93  
EPA Est. No. 6175-LA-1

Net Contents:    X applicator(s), each 0.02 fl.oz. (0.51 mL) {Total X fl.oz (X mL)]  
                          X applicator(s), each 0.03 fl.oz. (1.03 mL) {Total X fl.oz (X mL)]

Made in the USA.

Intervet Inc (d/b/a Merck Animal Health)    LOGO – Merck Animal Health.  
Summit, NJ 07068  
Copyright xxxx. All rights reserved.        xxxxxxxx Rev. xx/xxxx

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. total volume will correspond to number of applicators)

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## APPLICATOR LABELING

### ACTIVYL

For Cats and Kittens 4.4 to 9lb (2 to 4 kg) and 8 weeks of age or older ONLY (0.51 mL size only)  
For Cats over (greater than) (>)9 lb (4 kg) ONLY (1.03 mL size only)

Indoxacarb: .....19.53%

**KEEP OUT OF REACH OF CHILDREN**  
**WARNING**  
**READ ENTIRE LABEL BEFORE USE**

0.02 fl. oz. (0.51 mL)  
0.03 fl. oz. (1.03 mL)

EPA Reg. No. 773-93  
EPA Est. No. 6175-LA-1

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health.

Lot No:



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## FOIL POUCH LABELING

**DO NOT REMOVE APPLICATOR (TUBE) UNTIL READY TO USE**

### ACTIVYL for Cats and Kittens

**Alternate Brand Names:**

ACTIVYL for Cats or Kittens  
ACTIVYL Spot-On for Cats and Kittens  
ACTIVYL Spot-On for Cats or Kittens  
ACTIVYL for Cats  
ACTIVYL Spot-On for Cats

For Cats and Kittens 4.4 to 9 lb (2 to 4 kg) and 8 weeks of age or older ONLY (0.51 mL size only)

For Cats over (greater than) (>) 9 lb (4 kg) ONLY (1.03 mL size only)

Indoxacarb: ...19.53%

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

**READ ENTIRE LABEL BEFORE USE**

0.02 fl. oz. (0.51 mL)

0.03 fl. oz. (1.03 mL)

EPA Reg. No. 773-93

EPA Est. No. 6175-LA-1

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health.

Lot No:



### FRONT PANEL AND/OR SIDE PANEL CLAIMS

1. Intended to be sold by veterinarians.
2. Intended to be dispensed (and) (or) sold through (by) licensed veterinarians and only to their clients for pets under a direct vet-client-patient relationship.
3. Product availability intended through licensed veterinarians.
4. Kills fleas (within 24 hours of application) (maximum efficacy within 24 hours)
5. Prevents larval development
6. Larval flea stages in (the pet's) (your cat's) (the) surroundings are killed following contact with (a)(an) (alternate or brand name) treated pet.
7. Kills fleas that may cause disease, including bartonellosis and transmit tapeworm.
8. If there is a high risk of re-infestation or if the pet has fleas, once monthly application is recommended
9. Kills fleas that may cause (flea allergy dermatitis)(FAD).
10. If there is a high risk of re-infestation or if the pet has fleas which may cause (flea allergy dermatitis)(FAD) , once monthly application is recommended.
11. (Alternate or brand name) kills fleas that may cause anemia.
12. (Alternate or brand name) kills fleas that may transmit tapeworms
13. The successive feeding activity of fleas on cats may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of cats with ((alternate or brand name) kills fleas that may cause disease.
14. For the (prevention)(and)(treatment) of flea infestations on cats (and/or) (kittens 8 weeks of age or older) for (four)(4)(weeks)
15. For the (prevention)(and)(treatment) of flea infestations on cats (and/or) (kittens 8 weeks of age or older)for (one)(1)(month)
16. (Prevents) (and) (protects) against (re-)infestation (of fleas) for (four)(4)(weeks)
17. (Prevents) (and) (protects) against (re-)infestation (of fleas) for (one)(1)(month)
18. One treatment prevents flea infestations (on cats) (and/or) (kitten 8 weeks of age or older) for (four)(4)(weeks)
19. One treatment prevents flea infestations (on cats) (and/or) (kittens 8 weeks of age or older) for (one)(1)(month)
20. Protects (your cat) (and/or) (kittens 8 weeks of age or older) from fleas for (four)(4)(weeks)
21. Protects (your cat) (and/or) (kittens 8 weeks of age or older) from fleas for (one)(1)(month)
22. Monthly treatment (required)(recommended) for optimal (control)(and)(prevention)(of fleas)(on your)(cat)(and/or)(kitten)
23. Effective monthly (control) (prevention)(and)(treatment) of fleas (on cats) (and/or) (kittens 8 weeks of age or older)
24. Flea (control) (prevention)(and)(treatment) formulated for (cats)(and)(kittens 8 weeks of age or older)

( ) Bracket text allows for alternative presentations of the same claim.



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**FRONT PANEL AND/OR SIDE PANEL CLAIMS – (cont'd)**

25. (Controls)(Treatment against)(Protects against) (blood-feeding) (by) fleas
26. Monthly treatments are required for optimal (control) (and) (prevention) of flea(s) (infestations)
27. Water-resistant
28. Waterproof
29. (Alternate or brand name) (This product) Remains effective even after (bathing) (water immersion), (or) (exposure to rain) (or) (sunlight)
30. (Alternate or brand name)(This product) Remains effective after (bathing) (and) (or) (swimming)
31. (Alternate or brand name)(This product) remains efficacious following (a) (shampoo treatment) (swimming) (and) (or) (exposure to rain) (or) (sunlight).



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### ALTERNATE MARKETING TEXT

1. Indoxacarb is (a new) (an) active ingredient from a (new) chemical class being introduced (globally) (world wide) for flea control. [These claims may only be used for 6 months from the initial date of distribution.]
2. Once-A-Month Topical Flea (Treatment) (Prevention) (Control) for (cats) (and) (kittens 8 weeks of age or older)
3. (Once) monthly (a month) application (treatment) (for) (cats) (and) (kittens 8 weeks of age or older )
4. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities) (i.e., flea allergy dermatitis).
5. X applicators
6. X monthly doses (applications) (treatments)
7. Quick drying (non-greasy)
8. Long Lasting for up to 1 month (30 days)
9. (Effective) Long-lasting protection for up to 1 month (30 days)
10. Easy to apply (spot-on) (topical) (application) (treatment)
11. Convenient (to use)
12. Easy (Convenient) to apply
13. Easy (spot on) (to use) application
14. (Convenient) (Single) (Spot) application
15. No (noticeable) odor
16. Fragrance free
17. Formulated for cats (and) (kittens) 8 weeks and older (weighing more than 2 lb (0.9 kg) and up to 9 lb (4.1kg)
18. Formulated for cats weighing more than 9 lb (4.1kg)
19. Monthly use breaks the flea life cycle
20. Questions (or) (comments) call (1-800-Tel. Number) (or) (Tel. No.)
21. For more information call (1-800- Tel. Number) (or) (Tel. No.)
22. For emergencies call (1-800- Tel. Number) (or) (Tel. No.)-same as above
23. If you have any questions, call Intervet Inc. Technical Services at (1-800- Tel. Number) (or) (Tel. No.)
24. (Manufacturer) (Satisfaction) Guaranteed or your money back.
25. Recommended year round (control) (treatment) (prevention) (against fleas)

( ) Bracket text allows for alternative presentations of the same claim.



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**ALTERNATE MARKETING TEXT (cont'd)**

26. Proven (control) (treatment) (prevention) for flea infestations
27. Protects (your) (cat) (and) (or) (kittens 8 weeks of age or older ) for up to (1 month) (one month)(a month)
28. (Alternate or brand name)(This product) (It) may also be used to (control) (prevent) infestation on flea-free (cats) (and) (or) (kittens) 8 weeks (of age) or older and weighing more than 4.4 lb taken into a flea-contaminated environment.
29. Flea control for today's flea challenges
30. Indoxacarb is from the chemical class of oxadiazine insecticides
31. Excellent mortality
32. Pesticidal
33. (Indoxacarb is a) Voltage-dependent sodium channel blocker
34. Indoxacarb (the active) (in alternate or brand name) (in this product) blocks the channels that regulate the flow of sodium through the insect's nervous system.
35. Stops feeding, followed (closely) by paralysis and death.
36. (Convenient) (Single) (Spot) application that provides (control) (treatment)(protection) (of) (from) existing (flea)(infestations)
37. Protects against reinfestation(s) (of) (fleas) (on) (your) (pet) (cat) (kittens 8 weeks of age or older)
38. Effectively controls fleas on cats in a home environment



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### NEXT DOSE STICKERS/ TREATMENT REMINDER (prototype)

Use these handy stickers to help remember when your pet's next dose is due. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given, and on the same date for each of the remaining months.

#### Alternate text

It may be hard to remember when your cat('s) (and/or) (kitten's) next dose is due. The following has been developed as a tool to help you keep track of every dose. When you use the last tube in this package, consult your veterinarian and order more (product) (alternate or brand name), if needed.

Attach these (stickers) (reminders) to your (wall) (desk) calendar (daily planner) on the days the first dose is to be given. Place another (sticker) (reminder) on the same date for the remaining months.

### STICKER PROTOTYPE:

Picture of cat may vary. Up to 12 sticker count consistent with package



### CARD Prototype:

PET'S NAME
PRODUCT: (preprinted alternate brand name)
DATE OF 1 <sup>st</sup> APPLICATION:
DATE OF 2 <sup>nd</sup> APPLICATION:
DATE OF 3 <sup>rd</sup> APPLICATION

( ) Bracket text allows for alternative presentations of the same claim.