

773-93

4/12/2012

1/15

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



APR 1 2 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Dear Ms. Sheehy:

Subject: PRIA Amendment to rebut Companion Animal Safety studies to lower kitten weight to 2lb and Storage Stability and Corrosion Characteristic data
ACTIVYL for Cats and Kittens
EPA Registration No. 773-93
Your Re-Submission Dated: January 13, 2012
Decision Number 452449

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended is **acceptable**.

In addition, the conditional data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is **acceptable**.

A stamped copy of the labeling and the review of the Storage Stability and Corrosion Characteristics is enclosed for your records.

Per 40 CFR 156.10(a)(6), submit one copy of your final printed labeling before you release the product for shipment. As defined in 40 CFR 152.3, "final printed labeling" means the "label or labeling of the product when distributed or sold." Clearly legible reproductions or photo reductions will be accepted for unusual labels. Note that a clean copy of the master label in most cases does not meet the definition of final printed labeling.

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)

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ACTIVYL for Cats and Kittens
EPA Reg No: 773-93
Amended version: 1.41

DATED: 4-12-2012
Page 1 of 14

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

PRIMARY CARTON - FRONT PANEL STATEMENTS

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

Once-A-Month Topical Flea Treatment

For Cats and Kittens 2 to 9 lb (0.9 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

LOGO – Merck Animal Health

ACCEPTED
APR 12 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.

PRIMARY CARTON - BACK PANEL STATEMENTS

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
Refer to the package insert for complete Directions For Use

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 cats or kittens under 8 weeks of age OR weighing less than 2 lb.

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

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • 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 physician if irritation persists.
If On Skin	<ul style="list-style-type: none"> • 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 Swallowed	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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.	

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

PRIMARY CARTON - BACK PANEL STATEMENTS (cont'd)

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 OR weighing less than 2 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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PRIMARY CARTON – SIDE PANEL STATEMENTS

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE 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. 618-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)

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

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APPLICATOR LABELING STATEMENTS

ACTIVYL

For Cats and Kittens 2 to 9 lb (0.9 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. 618-LA-1

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

Lot No:

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FOIL POUCH LABELING STATEMENTS

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 2 to 9 lb (0.9 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
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ACTIVYL for Cats and Kittens
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(Due to carton size this additional information is referred to on the carton and includes complete directions for use with all carton box mandatory required statements found on the primary carton)

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

PACKAGE INSERT STATEMENTS

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
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Once-A-Month Topical Flea Treatment

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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

DIRECTIONS FOR USE

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

RESTRICTIONS

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

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PACKAGE INSERT STATEMENTS – cont'd

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



Step 1.



Step 2.



step 3



For cats and
 kittens 2 to 9lb (0.9 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

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.

FIRST AID	
If In Eyes	<ul style="list-style-type: none"> • 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 physician if irritation persists.
If On Skin	<ul style="list-style-type: none"> • 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 Swallowed	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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PACKAGE INSERT STATEMENTS – cont'd

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PHYSICAL OR CHEMICAL HAZARDS

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STORAGE AND DISPOSAL

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PESTICIDE 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.

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Made in the USA.

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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)

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

FRONT PANEL AND/OR SIDE PANEL CLAIMS -optional

1. Intended to be sold ~~only~~ 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 ~~only~~.
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 and over 2 lbs) for (four)(4)(weeks)
15. For the (prevention)(and)(treatment) of flea infestations on cats (and/or) (kittens 8 weeks of age or older and over 2 lbs)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 and over 2 lbs) for (four)(4)(weeks)
19. One treatment prevents flea infestations (on cats) (and/or) (kittens 8 weeks of age or older and over 2 lbs) for (one)(1)(month)
20. Protects (your cat) (and/or) (kittens 8 weeks of age or older and over 2 lbs) from fleas for (four)(4)(weeks)
21. Protects (your cat) (and/or) (kittens 8 weeks of age or older and over 2 lbs) 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 and over 2 lbs)
24. Flea (control) (prevention)(and)(treatment) formulated for (cats)(and)(kittens 8 weeks of age or older and over 2 lbs)

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

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FRONT PANEL AND/OR SIDE PANEL CLAIMS - optional – (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).

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

ALTERNATE MARKETING TEXT - optional

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

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

ALTERNATE MARKETING TEXT – optional- (cont'd)

25. Proven (control) (treatment) (prevention) for flea infestations
26. Protects (your) (cat) (and) (or) (kittens 8 weeks of age or older and over 2 lbs) for up to (1 month) (one month)(a month)
27. (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 2 lb taken into a flea-contaminated environment.
28. Flea control for today's flea challenges
29. Indoxacarb is from the chemical class of oxadiazine insecticides
30. Excellent mortality
31. Pesticidal
32. (Indoxacarb is a)Voltage-dependent sodium channel blocker
33. 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.
34. Stops feeding, followed (closely) by paralysis and death.
35. (Convenient) (Single) (Spot) application that provides (control) (treatment)(protection) (of) (from) existing (flea)(infestations)
36. Protects against reinfestation(s) (of) (fleas) (on) (your) (pet) (cat) (kittens 8 weeks of age or older and over 2 lbs)
37. Effectively controls fleas on cats in a home environment

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

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OPTIONAL 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 st APPLICATION:
DATE OF 2 nd APPLICATION:
DATE OF 3 rd APPLICATION

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