



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Registration Division (7505C)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

773-93

Date of Issuance:

JUN 29 2010

NOTICE OF PESTICIDE:

- Registration
- Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

ACTIVYL for Cats and Kittens

Name and Address of Registrant (include ZIP Code):

Intervet Inc.
 56 Livingston Avenue
 Roseland, NJ 07068

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(a) provided that:

1. This registration is time-limited and expires two years from the date this product is first released for shipment.
 - You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

Continued on pages 2 through 4

Signature of Approving Official:

Meredith Laws

Meredith Laws, Chief
 Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

JUN 29 2010

- 2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
- 3. You must submit the following data within the timeframes described below:
 - The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning October 1, 2010.
 - Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).
 - The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
 Product name (brand name)
 Lot #
 Where purchased: internet, store, veterinarian
 Active Ingredient(s)
 Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
 State in which the incident occurred. (standard 2 letter abbreviation)
 Registrant case #

Species: dog, cat, other (specify)
 Breed: (as reported by pet owner)
 Age: months or years
 Sex: M, F, or neutered
 Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 Body System: neurological, dermatological, GI, respiratory, ocular, other
 Major signs noted with separate column for each sign, using standard terminology
 Time to Onset: (hours, days)
 Treated by veterinarian: yes or no
 First time product used: yes or no
 Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 Any known precondition
 EPA Severity Code: death, major, moderate, minor
 Outcome: died, recovered, still treated, unknown

5. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

6. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.

7. You make the following changes to your label:

- Revise the EPA Registration Number to read "773-93."

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- 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 non-refillable containers. The code may appear either on the label or durably marked on the container itself. This information can be added by non-notification per PR Notice 98-10.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted with Comments" is enclosed for your records. If you have any questions concerning this action, please contact John Hebert at 703-308-6249 or hebert.john@epa.gov.

Meredith Laws, Chief
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

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“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 (0.51 mL size only)
For Cats over (greater than) (>) 9 lb (4 kg) (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:
JUN 29 2010

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.

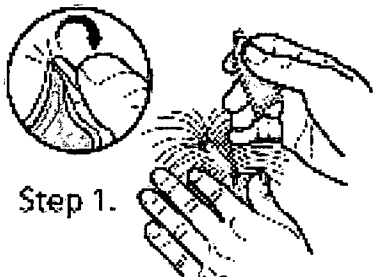
BACK PANEL

DIRECTIONS FOR USE

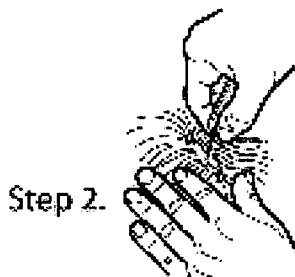
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR PET, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY. DO NOT USE ON PREGNANT OR NURSING CATS. **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.**

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



Step 1.



Step 2.



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



Image for cats over (greater than) (>) 9 lb (4 kg) (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. Avoid contact with treated area (application site) until 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.

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BACK PANEL (CONT'D)

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.	

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. Do not use on pregnant or nursing cats. 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.

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

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BACK PANEL (CONT'D)

STORAGE AND DISPOSAL

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

CONTAINER DISPOSAL: 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-OG
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.
Roseland, NJ 07068
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(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

ACTIVYL

For Cats and Kittens 4.4 to 9 lb (2 to 4 kg) and 8 weeks of age or older (0.51 mL size only)
For Cats over (greater than) (>)9 lb (4 kg) (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-OG
EPA Est. No. 6175-LA-1

Intervet Inc.

Lot No:

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 (0.51 mL size only)
For Cats over (greater than) (>) 9 lb (4 kg) (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-OG
EPA Est. No. 6175-LA-1

Intervet Inc.

Lot No:

FRONT PANEL AND/OR SIDE PANEL CLAIMS

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) for (four)(4)(weeks)
15. For the (prevention)(and)(treatment) of flea infestations on cats (and/or) (kittens)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) for (four)(4)(weeks)
19. One treatment prevents flea infestations (on cats) (and/or) (kittens) for (one)(1)(month)
20. Protects (your cat) (and/or) (kitten) from fleas for (four)(4)(weeks)
21. Protects (your cat) (and/or) (kitten) 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)
24. Flea (control) (prevention)(and)(treatment) formulated for (cats)(and)(kittens)
25. (Controls)(Treatment against)(Protects against) (blood-feeding) (by) fleas

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

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

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).

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)
3. (Once) monthly (a month) application (treatment) (for) (cats) (and) (kittens)
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 4.4 lb (2 kg) and up to 9 lb (4.1kg) (9 lb (4.1kg) and under)
18. Formulated for cats (and) (kittens) over 8 weeks old (weighing more than 4.4 lb (2 kg) and up to 9 lb (4.1kg) (9 lb (4.1kg) and under)
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.

ALTERNATE MARKETING TEXT (cont'd)

26. Proven (control) (treatment) (prevention) for flea infestations
27. New (for first 6-months only)
28. New formula for your (cat) (and) (or) (kitten) (for first 6-months only)
29. Protects (your) (cat) (and) (or) (kitten) for up to (1 month) (one month)(a month)
30. (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.
31. Flea control for today's flea challenges
32. Indoxacarb is from the chemical class of oxadiazine insecticides
33. Excellent mortality
34. Pesticidal
35. (Indoxacarb is a)Voltage-dependent sodium channel blocker
36. 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.
37. Stops feeding, followed (closely) by paralysis and death.
38. (Convenient) (Single) (Spot) application that provides (control) (treatment)(protection) (of) (from) existing (flea)(infestations)
39. Protects against reinfestation(s) (of) (fleas) (on) (your) (pet) (cat) (kitten)

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

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