



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

EPA Reg. Number:

773-93

Date of Issuance:

3/4/22

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):

Micah Reynolds  
Senior Regulatory Consultant  
Intervet, Inc. (d/b/a Merck Animal Health)  
2 Giralda Farms  
Madison, New Jersey 07940

**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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

For: Marion Johnson, Acting Product Manager 10  
Invertebrate and Vertebrate Branch 2 Registration Division (7505P)

Date:

3/4/22

2. Consistent with the guidance on [Pet Spot-On Enhanced Reporting Implementation \(updated Aug. 2019\)](#), the Agency has reviewed your request to remove the two-year registration expiration date and has found your company to be in compliance with the terms and conditions for the subject product. The accepted label dated 03/04/2022 contains appropriate mitigation measures. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 3. hereafter, and concluded that the use of the standardized templates for enhanced reporting for this product will considerably improve pharmacovigilance and thus the continued safety of this product. Therefore, the Agency is removing the two-year registration expiration date for this product. The product remains subject to all other previously required conditions of registration, including the submission of enhanced incident reports and sales information as stated in the initial registration notice dated 6/29/2010 and amended below to require continued use of the standardized templates.
3. The Agency has reviewed your request to change the terms of your registration from quarterly to annual submission of enhanced incident and sales reports using EPA's standardized templates. Based on an initial screening of sample enhanced reports, the sample submission was determined to be adequate and the templates were successfully used. Therefore, the condition of quarterly submission of enhanced incident and sales reports is hereby amended to annual submission with continued use of these standardized templates. You must submit enhanced incident and sales reports for this product to the Agency every 12 months from the date the product is first released for shipment, or from the end date in the last quarterly enhanced reporting submission. The initial released-for-shipment date must be provided to the Product Manager, once known. The enhanced reporting submission should be addressed to the Product Manager's attention and must use the standardized, electronic templates available on the EPA website through the following links: [Enhanced Incident Reporting Template](#), [Sales Reporting Template](#). Submissions must be received by the Agency no later than 60 days following the completion of the 12-month period. If the product is not marketed or sold, you must submit to the Product Manager a letter to this effect every 12 months in lieu of the enhanced incident and sales reports. Please follow appropriate procedures and flag any Confidential Business Information as such.
4. You are required to comply with the data requirements described in the DCI identified below:
  - a. Indoxacarb GDCI-067710-1382

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded

and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these terms and conditions, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04/07/2008

If you have any questions, please contact Debra Rate by phone at (202) 566-2867, or via email at [rate.debra@epa.gov](mailto:rate.debra@epa.gov).

Attachment

{Note to reviewer: text in {braces} is for information purposes and will not appear on the label. Text in [brackets] is optional or alternate wording and may or may not appear on the end-use label. Text in (parentheses) will appear on the end-use label.}

**ACTIVYL for Cats and Kittens**  
**EPA Reg No: 773-93**  
**Amended version: 1.8 (2020 Pet Spot-On Registration Extension)**

**DATED: January 18, 2022**  
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{“Master Label”: This master label includes text for different size packages and application rates specific to cat’s age and body weight.}

## {**CARTON - FRONT PANEL STATEMENTS**}

### ACTIVYL for Cats and Kittens

{Note: “for Cats and Kittens” text in primary brand name, and other iterations in the alternate brand names that follow “Activyl” to be a minimum of 75% as large as the height of the largest letter in the brand name presentation.}

{**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

{Note to reviewer: the following to be placed in box:}

{0.51 mL size only} ONLY for Cats and Kittens [2 to 9 lb] [0.9 to 4 kg] and 8 weeks of age or older (S)

{1.03 mL size only} ONLY for Cats [over] [greater than] [>] [9 lb] [4 kg] and 8 weeks of age or older (L)

#### **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%**

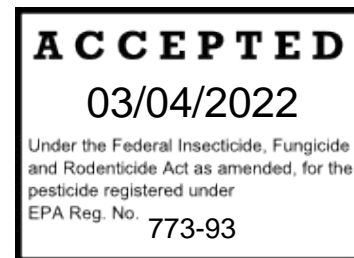
**KEEP OUT OF REACH OF CHILDREN**

## **WARNING**

SEE [BACK] [AND] [SIDE] PANEL[S] FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

SEE [PACKAGE] INSERT FOR [COMPLETE] DIRECTIONS FOR USE

PROTOTYPE GRAPHIC



{note to reviewer: A large clear picture of cat in the weight range for the product as packaged will be on the front panel – see examples at end of label.}

LOGO – Merck Animal Health

EPA Reg. No. 773-93

EPA Est. No. XXXX

Net Contents: X [applicator(s)] [tube(s)], each 0.02 fl.oz. (0.51 mL) [Total X fl.oz (X mL)]

X [applicator(s)] [tube(s)], each 0.03 fl.oz. (1.03 mL) [Total X fl.oz (X mL)]

{Note to reviewer: Only the net contents corresponding to the package size will appear on the label. Volume varies with size of cat 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.}

{Note to reviewer: text in {braces} is for information purposes and will not appear on the label. Text in [brackets] is optional or alternate wording and may or may not appear on the end-use label. Text in (parentheses) will appear on the end-use label.}

**ACTIVYL for Cats and Kittens**  
**EPA Reg No: 773-93**  
**Amended version: 1.8 (2020 Pet Spot-On Registration Extension)**

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## **{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. To prevent harm to you and your cat, read entire label and directions before each use. Follow all directions and precautionary statements carefully.

### **RESTRICTIONS**

▶ DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ▶ 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 ALLOW ADULTS OR CHILDREN TO TOUCH TREATED AREA (APPLICATION SITE) UNTIL IT IS COMPLETELY DRY. ▶ DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. ▶ DO NOT APPLY MORE THAN ONE TUBE PER TREATMENT PER CAT REGARDLESS OF THE CAT'S WEIGHT. ▶ IN MULTI-CAT HOUSEHOLDS, DO NOT ALLOW CATS TO GROOM EACH OTHER UNTIL PRODUCT HAS DRIED. ▶ DO NOT BATHE CAT FOR 24 HRS AFTER APPLICATION.

{Note to reviewer: One of these statements will be included in the restrictions corresponding to the appropriate package size.}

#### **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. Do not use on cats weighing less than 2 lb.

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

{Note to reviewer: First Aid statements may be boxed and/or bulleted if label space allows or may be presented unboxed and unbulleted. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.}

<b>FIRST AID</b>	
<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 poison control center or doctor for treatment advice.</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 by the poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>HOT LINE NUMBER</b>	
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.	

{Note to Reviewer: Side Effects box will be located in lower right-hand corner of the back panel. Due to limited space on outer container, expanded Side Effects information is contained in the package insert and the user is directed as such.}

**SIDE EFFECTS:** Monitor your cat after application. 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. Please refer to the package insert for additional side effects information. If these or other side effects occur, consult a veterinarian immediately.

{Note to reviewer: text in {braces} is for information purposes and will not appear on the label. Text in [brackets] is optional or alternate wording and may or may not appear on the end-use label. Text in (parentheses) will appear on the end-use label.}

**ACTIVYL for Cats and Kittens**

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## **{PRIMARY CARTON – SIDE PANEL STATEMENTS}**

### **PRECAUTIONARY STATEMENTS [CONT'D]:**

#### **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, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

[Hazards continued on side panels] {Note: statement may be needed when Precautionary Statements begin on one panel and continue to another package panel.}

#### **HAZARDS TO DOMESTIC ANIMALS**

**For external use on cats and kittens only. Only for use on cats and kittens 8 weeks of age and older and weighing [over] [more 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. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur, 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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**ACTIVYL for Cats and Kittens**

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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: Nonrefillable container. Do not reuse or refill this container. 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.

Made in the USA.

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

2 Giralda Farms, Madison, NJ 07940

Copyright xxxx. All rights reserved.      xxxxxxxx Rev. xx/xxxx

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## **{APPLICATOR LABELING STATEMENTS}**

### **ACTIVYL**

{0.51 mL size only} ONLY for Cats and Kittens [2 to 9 lb] [0.9 to 4 kg] and 8 weeks of age or older (S)

{1.03 mL size only} ONLY for Cats [over] [greater than] [>] [9 lb] [4 kg] and 8 weeks of age or older (L)

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. XXXX

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

Lot No:



{Note to reviewer: text in {braces} is for information purposes and will not appear on the label. Text in [brackets] is optional or alternate wording and may or may not appear on the end-use label. Text in (parentheses) will appear on the end-use label.}

**ACTIVYL for Cats and Kittens**

**EPA Reg No: 773-93**

**Amended version: 1.8 (2020 Pet Spot-On Registration Extension)**

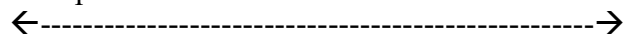
**DATED: January 18, 2022**

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## **{FOIL POUCH LABELING STATEMENTS}**

To Open: Tear or cut across line with scissors



**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}

{0.51 mL size only} ONLY for [Cats] [and] [Kittens] [2 to 9 lb] [0.9 to 4 kg] and 8 weeks of age or older (S)

{1.03 mL size only} ONLY for Cats [over] [greater than] [>] [9 lb] [4 kg] and 8 weeks of age or older (L)

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. XXX

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

Lot No:

{Note to reviewer: text in {braces} is for information purposes and will not appear on the label. Text in [brackets] is optional or alternate wording and may or may not appear on the end-use label. Text in (parentheses) will appear on the end-use label.}

**ACTIVYL for Cats and Kittens**  
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{Note to reviewer: 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 depend on package}

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## **{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, ACTIVYL Spot-On for Cats}

Once-A-Month Topical Flea Treatment

{0.51 mL size only} ONLY for Cats and Kittens [2 to 9 lb] [0.9 to 4 kg] and 8 weeks of age or older (S)

{1.03 mL size only} ONLY for Cats [over] [greater than] [>] [9 lb] [4 kg] and 8 weeks of age or older (L)

#### **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. To prevent harm to you and your cat, read entire label and directions before each use. Follow all directions and precautionary statements carefully.

#### **RESTRICTIONS**

▶ DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ▶ 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 ALLOW ADULTS OR CHILDREN TO TOUCH TREATED AREA (APPLICATION SITE) UNTIL IT IS COMPLETELY DRY. ▶ DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ▶ DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. ▶ DO NOT APPLY MORE THAN ONE TUBE PER TREATMENT PER CAT REGARDLESS OF THE CAT'S WEIGHT. ▶ IN MULTI-CAT HOUSEHOLDS, DO NOT ALLOW CATS TO GROOM EACH OTHER UNTIL PRODUCT HAS DRIED. ▶ DO NOT BATHE CAT FOR 24 HRS AFTER APPLICATION.

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

{Note to reviewer: One of these statements will be included in the restrictions corresponding to the appropriate package size.}

{For 0.51 mL package size} **Do not use on cats or kittens under 8 weeks of age. Do not use on cats weighing less than 2 lb.**

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

{Note to reviewer: text in {braces} is for information purposes and will not appear on the label. Text in [brackets] is optional or alternate wording and may or may not appear on the end-use label. Text in (parentheses) will appear on the end-use label.}

**ACTIVYL for Cats and Kittens**  
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## {PACKAGE INSERT STATEMENTS – cont’d}

[HOW TO APPLY] Open one foil pouch as directed and remove applicator (tube).



{0.51 mL size only}  
 [For cats and kittens  
 2 to 9 lb (0.9 to 4 kg) ONLY]

{1.03 size only}  
 [For cats [greater than] [>]  
 9 lb (4 kg) 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.

Cat must be dry at the time of application and remain dry for 24 hours. It is recommended to reapply every 30 days, 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.

{Note to reviewer: First Aid statements may be boxed and/or bulleted if label space allows or may be presented unboxed and unbulleted. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.}

<b>FIRST AID</b>	
<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 poison control center or doctor for treatment advice.</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 by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>HOT LINE NUMBER</b>	
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.	

**SIDE EFFECTS:** Monitor your cat after application. 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. In rare cases, application site reactions (e.g. scratching, redness, hair loss) may occur. These effects usually resolve without requiring treatment. Rare cases (fewer than 1 in 1,000) of neurological signs (e.g. incoordination, tremor, impaired balance, convulsions, dilated pupils, and impaired vision) and/or vomiting and very rare cases (fewer than 1 in 10,000) of decreased appetite, lethargy, hyperactivity, or vocalization may occur. These effects will generally

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resolve with supportive treatment. *If these or other side effects occur consult a veterinarian immediately.*

## {PACKAGE INSERT STATEMENTS – cont’d}

### 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, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

#### HAZARDS TO DOMESTIC ANIMALS

**For external use on cats and kittens only. Only for use on cats and kittens 8 weeks of age and older and weighing [over] [more 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 may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides.

#### PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat and open flame.

### STORAGE AND DISPOSAL

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

**PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. 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. XXX

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

{Note to reviewer: Only the net contents corresponding to the package size will appear on the label. Volume varies with size of cat 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.}

Made in the USA.

Intervet Inc (d/b/a Merck Animal Health) LOGO – Merck Animal Health.  
2 Giralda Farms, Madison, NJ 07940  
Copyright xxxx. All rights reserved. xxxxxxxx Rev. xx/xxxx

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**ACTIVYL for Cats and Kittens**

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**{FRONT PANEL AND/OR SIDE PANEL CLAIMS -optional}**

1. Intended to be sold through 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]
5. Kills adult cat flea [(*Ctenocephalides felis*)] and reduces egg production [as early as] two [2] days after treatment
6. Kills adult cat flea [(*Ctenocephalides felis*)] and reduces egg production for one [1] month
7. Inhibits [adult] flea emergence [and [interrupts] [inhibits] [flea] reproduction] [for [one] [1] month]
8. [Activyl® for Cats and Kittens] Reduces flea egg viability [and adult flea emergence]
9. [Activyl® for Cats and Kittens] [This product] kills all flea stages [- egg, larvae, and adult]
10. Kills fleas that may transmit bartonellosis and transmit tapeworm.
11. Once monthly application for control of flea infestation [and prevention of re-infestation].
12. Kills fleas that may cause flea allergy dermatitis (FAD). {Note to reviewer: FAD acronym will only be used if the whole written phrase appears before it at least once on the label.}
13. Once monthly application for control of fleas which may cause flea allergy dermatitis (FAD).
14. [Activyl® for Cats and Kittens] kills fleas that may cause anemia.
15. [Activyl® for Cats and Kittens] kills fleas that may transmit tapeworms
16. For the prevention [and] [treatment] of flea infestations on cats [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] for [four] [4] [weeks]
17. For the prevention [and] [treatment] of flea infestations on cats [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] for [one] [1] [month]
18. Prevents [and] [protects] against [re-]infestation of fleas for [four] [4] [weeks]
19. Prevents [and] [protects] against [re-]infestation of fleas for [one] [1] [month]
20. One treatment prevents flea infestations on cats [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] for [four] [4] [weeks]
21. One treatment prevents flea infestations on cats [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] for [one] [1] [month]
22. Protects your cat [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] from fleas for [four][4] [weeks]

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23. Protects your cat [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] from fleas for [one][1][month]
  24. Monthly treatment for control [and] [prevention] of fleas [on your] [cat] [and/or] [kitten].
  25. Monthly control [prevention] [and] [treatment] of fleas [on cats] [and/or] [kittens 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs]
  26. Flea control [prevention][and][treatment] formulated for [cats][and][kittens 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs]
  27. Controls [Treatment against] [Protects against] [blood-feeding] [by] fleas following exposure to the product
  28. Monthly treatments for control [and] [prevention] of flea[s] [infestations].
  29. Waterproof
  30. [Activyl® for Cats and Kittens] [This product] Remains effective even after [bathing] [water immersion], [or] [exposure to rain] [or] [sunlight]
  31. [Activyl® for Cats and Kittens] [This product] Remains effective after [bathing] [and] [or] [swimming]
  32. [Activyl® for Cats and Kittens] [This product] remains efficacious following [a] [shampoo treatment] [swimming] [and] [or] [exposure to rain] [or] [sunlight].
  33. X Monthly Doses {Note to Reviewer: corresponding images of number of monthly applicators contained in packaging.}
  34. 8 Weeks+ / 2-9 lb ONLY / S {-or-} 8 Weeks+ / >9 lb ONLY / L {Note to Reviewer: packaging callouts dependent on each weight.}
  35. S {Note to Reviewer: corresponding to 0.51 ml package size}
  36. L {Note to Reviewer: corresponding to 1.03 ml package size.}

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**{ALTERNATE MARKETING TEXT – optional}**

1. Once-A-Month Topical Flea [Treatment][Prevention] [Control] for [cats] [and] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs]
2. [Once] monthly [a month] application [treatment] [for] [cats] [and] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] to control fleas
3. [Reapplication at monthly intervals] [Monthly reapplications] may be appropriate depending upon [the level of flea challenge] [and] [individual sensitivities] [i.e., flea allergy dermatitis].
4. X applicators {Note to reviewer: corresponding with net contents.}
5. X monthly doses [applications] [treatments] {Note to reviewer: corresponding with net contents.}
6. Quick drying [non-greasy]
7. Long Lasting control of fleas for up to 1 month [30 days]
8. Long-lasting protection against fleas 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. No fragrance added
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 kg]
17. Formulated for cats weighing more than [9 lb] [4 kg]
18. Monthly use breaks the flea life cycle
19. [Manufacturer] [Satisfaction] Guaranteed or your money back.
20. Monthly treatment for year-round control [treatment] [prevention] against fleas.

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**{ALTERNATE MARKETING TEXT – optional- (cont'd)}**

21. Control [Treatment] [Prevention] for flea infestations
22. Protects your cat [and/or] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs] for up to [1 month] [one month][a month]
23. [Activyl® for Cats and Kittens] [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 lbs] [9 lbs] taken into a flea-contaminated environment.
24. Reduction in flea egg production as early as [two] [2] days [after] [following] treatment
25. [Indoxacarb] Demonstrates residual activity for [1 month] [4 weeks] against cat fleas (*Ctenocephalides felis*)
26. Indoxacarb [the active ingredient] [in this product] [in Activyl® for Cats and Kittens] blocks the channels that regulate the flow of sodium through the insect's nervous system.
27. Controls [Prevents] flea feeding, followed [closely] by paralysis and death after exposure to the product.
28. Convenient [Single] [Spot] application that provides [control] [treatment] [prevention] [of][from] existing flea [infestations]
29. Protects against reinfestation(s) [of] fleas [on] [your] [cat] [kittens] 8 weeks of age or older and [weighing] [over] [2 lbs] [9 lbs]
30. Product contained in child resistant packaging



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### **{OPTIONAL NEXT DOSE STICKERS/ TREATMENT REMINDER}**

Use these handy stickers to help remember when your cat's next dose is due. When you use the last tube in this package, consult your veterinarian and order more [product], 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.

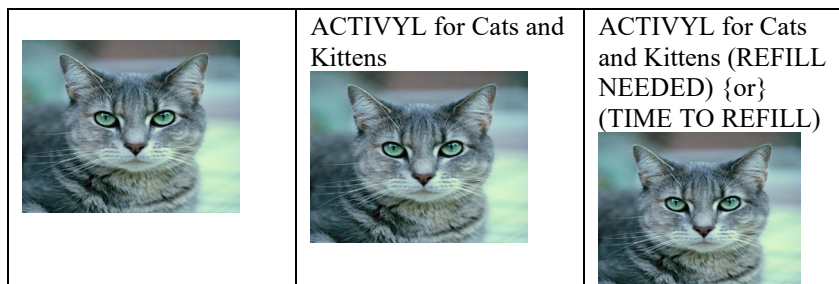
{Alternate text}

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], 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:}**

<b>CAT'S NAME</b>
<b>PRODUCT: ACTIVYL for Cats and Kittens</b>
<b>DATE OF 1<sup>st</sup> APPLICATION:</b>
<b>DATE OF 2<sup>nd</sup> APPLICATION:</b>
<b>DATE OF 3<sup>rd</sup> APPLICATION</b>

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**Representative Images for outer container or used throughout the label:**



[Representative image of small cat]



[Representative image of large cat]

