



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

**EPA Reg. Number:**

773-94

**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 Dogs and Puppies

**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:**

**Date:**

3/4/22

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

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 09/19/2008

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 Dogs and Puppies**  
**EPA Reg No: 773-94**  
**Amended Version 2.0 (2020 Pet Spot-On Registration Extension)**

**DATE: January 18, 2022**  
**Page 1 of 17**

{“Master Label for ACTIVYL® for Dogs and Puppies”: This master label includes text for different size packages and application rates specific to dog’s age and body weight.}

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

### **ACTIVYL for Dogs and Puppies**

{Note: “for Dogs and Puppies” 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 Dogs or Puppies, ACTIVYL Spot-On for Dogs and Puppies, ACTIVYL Spot-On for Dogs or Puppies, ACTIVYL for Dogs, ACTIVYL Spot-On for Dogs}

{Note to reviewer: One of the statements below will appear prominently on the front panel of market label as required.}

Once-A-Month Topical Flea [Spot-On] [Treatment] [Prevention] [Control] ONLY for [dogs] [and] [puppies] 8 weeks and older and weighing over [greater than] [>] 4 lb [pounds] [1.8 kg] and [up to] [less than or equal to] 14 lb [pounds] [6.6 kg] [TOY] over [greater than] [>] 14 lb [pounds] [6.6kg] and [up to] [less than or equal to] 22 lb [pounds] [10 kg] [S] over [greater than] [>] 22 lb [pounds] [10 kg] and [up to] [less than or equal to] 44 lb [pounds] [20 kg] [M] over [greater than] [>] 44 lb [pounds] [20 kg] and [up to] [less than or equal to] 88 lb [pounds] [40 kg] [L] over [greater than] [>] 88 lb [pounds] [40 kg] and [up to] [less than or equal to] 132 lb [pounds] [60 kg] [XL]

#### **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 PANELS FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS**

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

LOGO – Merck Animal Health

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. (0.77 mL) [Total X fl.oz (X ml)]

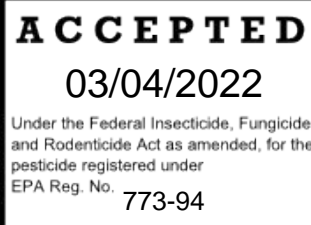
X [applicator(s)] [tube(s)], each 0.05 fl.oz. (1.54 mL) [Total X fl.oz (X ml)]

X [applicator(s)] [tube(s)], each 0.10 fl.oz. (3.08 mL) [Total X fl.oz (X ml)]

X [applicator(s)] [tube(s)], each 0.16 fl.oz. (4.62 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 dog 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.}

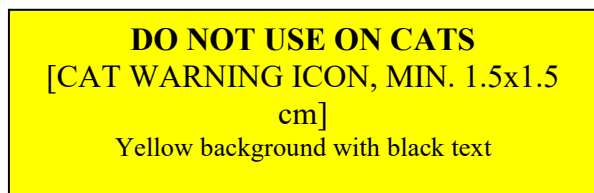
**GRAPHIC {Note to reviewer: A large clear picture of a dog in the weight range for the product as packaged will be on the front panel – see examples at end of label.}**



{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 Dogs and Puppies**  
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{A [1.5 cm x 1.5 cm] cat prohibition icon and warning text in a box will be located at the lower right hand corner of the front panel in yellow with black images and text.}

{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 Dogs and Puppies**  
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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 dog, 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 DOGS ONLY.** ▶ **DO NOT USE ON DOGS (MALE OR FEMALE) INTENDED FOR BREEDING, OR ON DOGS THAT ARE PREGNANT OR NURSING.** ▶ **DO NOT USE ON CATS OR OTHER ANIMALS.** ▶ **DO NOT APPLY MORE THAN ONCE PER MONTH.** ▶ **DO NOT ALLOW ADULTS OR CHILDREN TO TOUCH TREATED AREA (APPLICATION SITE) UNTIL IT IS COMPLETELY DRY.** ▶ **DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.** ▶ **DO NOT DOUBLE DOSE OR APPLY MORE THAN ONE TUBE/APPLICATOR PER TREATMENT FOR ONE DOG REGARDLESS OF THE DOG'S WEIGHT.** ▶ **DO NOT BATHE DOG FOR 24 HOURS 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 DOGS AND PUPPIES ONLY.**

{For 0.51 mL package size} **Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 4 lb.**

{For 0.77 mL package size} **Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 14 lb.**

{For 1.54 mL package size} **Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 22 lb.**

{For 3.08 mL package size} **Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 44 lb.**

{For 4.62 mL package size} **Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 88 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> • 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 poison control center or doctor for treatment advice.
<b>IF ON SKIN</b> • 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.
<b>IF SWALLOWED</b> • 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 by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
<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 to be located on side or back panel adjacent to cat warning box.}

**SIDE EFFECTS:** Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting, or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian. Individual sensitivities may occur after using any pesticide product. Consult a veterinarian immediately.

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**ACTIVYL for Dogs and Puppies**  
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## **{PRIMARY CARTON - BACK PANEL STATEMENTS (cont'd)}**

**For 0.51 ml/0.77 ml/1.54 ml/3.08 ml/4.62 ml**

**{Note To Reviewer: appropriate dose size will depend on package}**

### **{Presentation for multi-pack outer carton – back panel:}**

<p><b>PRECAUTIONARY STATEMENTS</b> <b>HAZARDS TO HUMANS</b> <b>WARNING.</b> 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.</p> <p><b>[HAZARDS CONTINUED ON SIDE PANEL(S)]</b></p>	<p><b>CAT WARNING ICON</b> DO NOT USE ON CATS - Keep cats away from treated dogs for 24 hours, or until product has dried. If applied to a cat or ingested by a cat, contact your veterinarian immediately.</p> <p><b>[CAT WARNING ICON, Min. 1.5x1.5 cm]</b> <b>Yellow background with black text</b></p>
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{Note to reviewer: A [1.5cm x 1.5cm] cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images and text.}

### **{Presentation for single pack outer carton – back panel:}**

<p><b>CAT WARNING ICON</b> DO NOT USE ON CATS - Keep cats away from treated dogs for 24 hours, or until product has dried. If applied to a cat or ingested by a cat, contact your veterinarian immediately.</p> <p><b>[CAT WARNING ICON, Min. 1.5x1.5 cm]</b> <b>Yellow background with black text</b></p>	<p><b>PRECAUTIONARY STATEMENTS</b> <b>HAZARDS TO HUMANS</b> <b>WARNING.</b> 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.</p> <p><b>[HAZARDS CONTINUED ON SIDE PANEL(S)]</b></p>
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{Note to reviewer: A [1.5cm x 1.5cm] cat prohibition icon and warning text in a box will be located at the lower right hand corner of the back panel in yellow with black images and text.}

{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 Dogs and Puppies**  
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## **{PRIMARY CARTON - SIDE PANEL STATEMENTS}**

### **PRECAUTIONARY STATEMENTS (cont'd)**

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

**For external use on dogs and puppies only. Only for use on dogs and puppies 8 weeks of age and older and weighing over [4 lb] [14 lb] [22 lb] [44 lb] [88 lb]. {note to reviewer: weight used will be according to package size}. Do not use on dogs (male or female) intended for breeding, or on dogs that are pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.**

#### **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.**

Made in the USA

EPA Reg. No. 773-94  
EPA Est. No. XXX

Intervet Inc (d/b/a Merck Animal Health).  
2 Giralda Farms, Madison, NJ 07940

[LOGO Merck Animal Health]

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Rev. xx/xxxx



{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 Dogs and Puppies**  
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## **{APPLICATOR LABELING STATEMENTS}**

### **ACTIVYL for Dogs and Puppies**

{Note to reviewer: One of the following statements with the appropriate age/weight range will appear on the package.}  
**ONLY for dogs and puppies 8 weeks and older [and weighing]**

over [greater than] [>] 4 lb [pounds] [1.8 kg] and [up to] [less than or equal to] 14 lb [pounds] [6.6 kg]  
over [greater than] [>] 14 lb [pounds] [6.6kg] and [up to] [less than or equal to] 22 lb [pounds] [10 kg]  
over [greater than] [>] 22 lb [pounds] [10 kg] and [up to] [less than or equal to] 44 lb [pounds] [20 kg]  
over [greater than] [>] 44 lb [pounds] [20 kg] and [up to] [less than or equal to] 88 lb [pounds] [40 kg]  
over [greater than] [>] 88 lb [pounds] [40 kg] and [up to] [less than or equal to] 132 lb [pounds] [60 kg]

Indoxacarb: .....19.53%

{Note to reviewer – due to limited size of applicator label and other required labeling, the cat warning icon appears like the following below.}



**CAT Warning Icon**

**{or}**

**DO NOT USE ON CATS**

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

**READ ENTIRE LABEL BEFORE USE**

{Note to reviewer: One statement will appear on the label corresponding to the appropriate package.}

0.02 fl.oz. (0.51 mL)

0.03 fl.oz. (0.77 mL)

0.05 fl.oz. (1.54 mL)

0.10 fl.oz. (3.08 mL)

0.16 fl.oz. (4.62 mL)

EPA Reg. No. 773-94

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.}

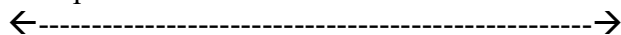
**ACTIVYL for Dogs and Puppies**  
**EPA Reg No: 773-94**  
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## **{FOIL POUCH LABELING STATEMENTS}**

To Open: Tear or cut across line with scissors



**DO NOT REMOVE APPLICATOR [TUBE] UNTIL READY TO USE**

**ONLY FOR EXTERNAL USE ON DOGS AND PUPPIES**

ACTIVYL for Dogs and Puppies

**{Alternate Brand Names: ACTIVYL for Dogs or Puppies, ACTIVYL Spot-On for Dogs and Puppies, ACTIVYL Spot-On for Dogs or Puppies, ACTIVYL for Dogs, ACTIVYL Spot-On for Dogs}**

{Note to reviewer: One of the following statements with the appropriate age/weight range will appear on the package.}

**ONLY For Dogs and Puppies 8 weeks and older and weighing**

over [greater than] [>] 4 lb [pounds] [1.8 kg] and [up to] [less than or equal to] 14 lb [pounds] [6.6 kg]

over [greater than] [>] 14 lb [pounds] [6.6kg] and [up to] [less than or equal to] 22 lb [pounds] [10 kg]

over [greater than] [>] 22 lb [pounds] [10 kg] and [up to] [less than or equal to] 44 lb [pounds] [20 kg]

over [greater than] [>] 44 lb [pounds] [20 kg] and [up to] [less than or equal to] 88 lb [pounds] [40 kg]

over [greater than] [>] 88 lb [pounds] [40 kg] and [up to] [less than or equal to] 132 lb [pounds] [60 kg]

Indoxacarb: .....19.53%

{Note to reviewer – due to limited size of applicator pouch label and other required labeling, the cat warning icon appears like the following below.}



**CAT Warning Icon {or}**

**DO NOT USE ON CATS**

**KEEP OUT OF REACH OF CHILDREN**

**WARNING**

**READ ENTIRE LABEL BEFORE USE**

{Note to reviewer: One statement will appear on the label corresponding to the appropriate package.}

0.02 fl.oz. (0.51 mL)

0.03 fl.oz. (0.77 mL)

0.05 fl.oz. (1.54 mL)

0.10 fl.oz. (3.08 mL)

0.16 fl.oz. (4.62 mL)

EPA Reg. No. 773-94

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.}

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{Note to reviewer: Due to carton size this additional information is referred to appear 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, 0.77 mL, 1.54 mL, 3.08 mL, 4.62 mL, package sizes}  
{Note To Reviewer: appropriate dose size will depend on package}

## {PACKAGE INSERT STATEMENTS}

**DO NOT USE ON CATS**  
[CAT WARNING ICON, Min 1.5x1.5cm]  
Yellow background with black text  
DO NOT USE DOG PRODUCT ON CATS – Keep cats away from treated dogs for 24 hours, or until product has dried. If applied to a cat or ingested by a cat, contact your veterinarian.

### ACTIVYL for Dogs and Puppies

{Alternate Brand Names: ACTIVYL for Dogs or Puppies, ACTIVYL Spot-On for Dogs and Puppies, ACTIVYL Spot-On for Dogs or Puppies, ACTIVYL for Dogs, ACTIVYL Spot-On for Dogs}

{Note to reviewer: One of the statements below will appear prominently on the front panel of market label as required.}

Once-A-Month Topical Flea [Spot-On] [Treatment] [Prevention] [Control] ONLY for [dogs] [and] [puppies] 8 weeks and older and weighing over [greater than] [>] 4 lb [pounds] [1.8 kg] and [up to] [less than or equal to] 14 lb [pounds] [6.6 kg] [TOY] over [greater than] [>] 14 lb [pounds] [6.6kg] and [up to] [less than or equal to] 22 lb [pounds] [10 kg] [S] over [greater than] [>] 22 lb [pounds] [10 kg] and [up to] [less than or equal to] 44 lb [pounds] [20 kg] [M] over [greater than] [>] 44 lb [pounds] [20 kg] and [up to] [less than or equal to] 88 lb [pounds] [40 kg] [L] over [greater than] [>] 88 lb [pounds] [40 kg] and [up to] [less than or equal to] 132 lb [pounds] [60 kg] [XL]

**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**

{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.}

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## {PACKAGE INSERT STATEMENTS (cont'd)}

### 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 for complete Directions For Use. To prevent harm to you and your dog, 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 DOGS ONLY. ▶ DO NOT USE ON DOGS (MALE OR FEMALE) INTENDED FOR BREEDING, OR ON DOGS THAT ARE PREGNANT OR NURSING. ▶ DO NOT USE ON CATS OR OTHER ANIMALS. ▶ DO NOT APPLY MORE THAN ONCE PER MONTH. ▶ DO NOT ALLOW ADULTS OR CHILDREN TO TOUCH TREATED AREA (APPLICATION SITE) UNTIL IT IS COMPLETELY DRY. ▶ DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT. ▶ DO NOT DOUBLE DOSE OR APPLY MORE THAN ONE TUBE/APPLICATOR PER TREATMENT FOR ONE DOG REGARDLESS OF THE DOG'S WEIGHT. ▶ DO NOT BATHE DOG FOR 24 HOURS AFTER APPLICATION.

### FOR EXTERNAL USE ON DOGS AND PUPPIES ONLY.

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

{For 0.51 mL package size} Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 4 lb.

{For 0.77 mL package size} Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 14 lb.

{For 1.54 mL package size} Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 22 lb.

{For 3.08 mL package size} Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 44 lb.

{For 4.62 mL package size} Do not use on dogs and puppies under 8 weeks of age. Do not apply to dogs weighing less than 88 lb.

[HOW TO APPLY] Open one foil pouch and remove applicator [tube].



{Note to reviewer: Graphics for specific dog sizes represented below – only 1 graphic per package size to be used.}



{0.51 mL size only}  
ONLY for dogs over 4 lb and up to 14 lb  
(ONLY for dogs over 1.8 kg and up to 6.6 kg)



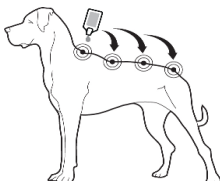
{0.77 mL size only}  
ONLY for dogs over 14 lb up to 22 lb  
(ONLY for dogs over 6.6 kg up to 10 kg)



{1.54 mL only}  
ONLY for dogs over 22 lb up to 44 lb  
(ONLY for dogs over 10 kg up to 20 kg)



{3.08 mL size only}  
ONLY for dogs over 44 lb up to 88 lb  
(ONLY for dogs over 20 kg up to 40 kg)



{4.62 mL size only}  
ONLY for dogs over 88 lb up to 132 lb  
(ONLY for dogs over 40 kg up to 60 kg)

{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.}

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## {PACKAGE INSERT STATEMENTS (cont'd)}

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. The dog should be standing for easy application. Part the hair and place applicator [tube] tip against the skin between shoulder blades.

{Note to reviewer: the following "Step 3" pertains to small dogs – packaging sizes 0.51 mL and 0.77 mL}  
Step 3. Squeeze applicator firmly applying entire contents directly to skin. Do not allow product to run off. Do not allow adults or children to touch treated area [application site] until it is completely dry.

{Note to reviewer: the following "Step 3" pertains to medium dogs – packaging size 1.54 mL}  
Step 3. Apply entire contents of tube evenly to a minimum of two spots on the back starting from between the shoulder blades and ending at the base of the tail.

{Note to reviewer: the following "Step 3" pertains to larger dogs – packaging size 3.08 mL}  
Step 3. Apply entire contents of tube evenly to a minimum of three spots on the back starting from between the shoulder blades and ending at the base of the tail.

{Note to reviewer: the following "Step 3" pertains to x-large dogs – packaging size 4.62 mL}  
Step 3. Apply entire contents of tube evenly to a minimum of four spots on the back starting from between the shoulder blades and ending at the base of the tail.

{Note to reviewer: the following use directions apply to packaging sizes 1.54 mL, 3.08 mL, and 4.62 mL}  
At each spot, part the hair until skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze a portion of the contents at each spot ensuring applicator is emptied at the last spot. Do not apply an excessive amount of solution at any one spot. Do not allow the product to run off. Do not allow adults or children to touch treated area [application site] until it is completely dry.

{Note to reviewer: the following use directions apply to all packaging sizes}  
Dog must be dry at the time of application and remain dry for 24 hours. 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.

{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 a 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 dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian. Individual sensitivities may occur after using any pesticide product. Consult a veterinarian immediately.

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## **{PACKAGE INSERT STATEMENTS (cont'd)}**

**For [0.51 ml] [0.77 ml] [1.54 ml] [3.08 ml] [4.62 ml]**  
**{note to reviewer: appropriate dose size will depend 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, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

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

**For external use on dogs and puppies only. Only for use on dogs and puppies under 8 weeks of age and older and weighing over [4 lb] [14 lb] [22 lb] [44 lb] [88 lb] {note to reviewer: weight used will be according to package size}.** Do not use on dogs (male or female) intended for breeding, pregnant or nursing. Consult a veterinarian before using this product on debilitated, aged, or medicated dogs. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals.

#### **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.

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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. (0.77 mL) [Total X fl.oz (X mL)]  
X [applicator(s)] [tube(s)], each 0.05 fl.oz. (1.54 mL) [Total X fl.oz (X mL)]  
X [applicator(s)] [tube(s)], each 0.10 fl.oz. (3.08 mL) [Total X fl.oz (X mL)]  
X [applicator(s)] [tube(s)], each 0.16 fl.oz. (4.62 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 dog 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).  
2 Giralda Farms, Madison, NJ 07940

LOGO Merck Animal Health

Copyright xxxx All rights reserved. xxxxxxxx

Rev. xx/xxxx

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### **{FRONT PANEL AND/OR SIDE PANEL CLAIMS}**

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 dogs under a direct vet-client-patient relationship.
3. Product availability intended through licensed veterinarians.
4. Kills fleas that may transmit bartonellosis and transmit tapeworms.
5. Once monthly application for control of flea infestation [and prevention of re-infestation].
6. 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.}
7. Once monthly application for control of fleas which may cause flea allergy dermatitis (FAD).
8. [Activyl® for Dogs and Puppies] kills fleas that may cause flea-bite anemia.
9. [Activyl® for Dogs and Puppies] kills fleas that may transmit tapeworms.
10. The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs with Activyl® for Dogs and Puppies kills fleas.
11. For the prevention [and] [treatment] of flea infestations on dogs [and/or] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs] for [four] [4] [weeks] [one] [1] [month].
12. Prevents [and] [protects] against [re-]infestation [of fleas] for [four] [4] [weeks].
13. Prevents [and] [protects] against [re-]infestation [of fleas] for [one] [1] [month].
14. One treatment prevents flea infestations on dogs [and/or] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs] for [four] [4] [weeks].
15. One treatment prevents flea infestations [dogs] [and/or] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs] for [one] [1] [month].
16. Protects your dog [and/or] [puppy] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs] from [fleas] for [four] [4] [weeks].
17. Protects your dog [and/or] [puppy] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs] from [fleas] for [one] [1] [month].
18. Monthly treatment for control [and] [prevention] of fleas [on your] [dog] [and/or] [puppy] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]
19. Effective monthly control [prevention] [and] [treatment] of fleas [on] [dogs] [and] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]
20. Flea control [prevention] [and] [treatment] formulated for [dogs] [and] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]

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21. Controls[Treatment against][Protects against] [by] fleas following exposure to the product.
  22. Monthly treatments are for control [and] [prevention] of flea(s) [infestations]
  23. Prevents and controls flea re-infestations
  24. For treatment, control and prevention of fleas [on your dog] treat monthly throughout the year.
  25. Activyl® for Dogs and Puppies [This product] kills all flea stages [ - egg, larvae, and adult]
  26. Waterproof
  27. [Activyl® for Dogs and Puppies] [This product] Remains effective even after [bathing] [swimming] [water immersion], [or] [exposure to rain] [or] [sunlight]
  28. [Activyl® for Dogs and Puppies] [This product] Remains effective after [bathing] [and] [or] [swimming]
  29. [Activyl® for Dogs and Puppies] [This product] Remains efficacious following [a] [shampoo treatment] [swimming] [and] [or] [exposure to rain] [or] [sunlight].
  30. Starts killing fleas within 8 hours
  31. [Activyl® for Dogs and Puppies] [This product] remains effective against cat fleas after antibacterial shampoo treatment
  32. Once-a-month Topical Flea Treatment
  33. X Monthly Doses {Note to reviewer: corresponding with net contents and with corresponding images of number of monthly applicators contained in packaging}
  34. {Note to reviewer: only one, appropriate to the package size will appear on the label.}  
{0.51 mL size only} 8 Weeks+ / >4-14 lb ONLY / TOY  
{0.77 mL size only} 8 Weeks+ / >14-22 lb ONLY / S  
{1.54 mL size only} 8 Weeks+ / >22-44 lb ONLY / M  
{3.08 mL size only} 8 Weeks+ / >44-88 lb ONLY / L  
{4.62 mL size only} 8 Weeks+ / >88-132 lb ONLY / XL
  35. {Note to reviewer: only one, appropriate to the package size will appear on the label.}  
{0.51 mL size only} TOY  
{0.77 mL size only} S  
{1.54 mL size only} M  
{3.08 mL size only} L  
{4.62 mL size only} XL



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**{ALTERNATE MARKETING TEXT}**

1. Once-A-Month Topical Flea Treatment [Prevention] [Control] for [dogs] [and] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]
2. [Once] monthly [a month] application [treatment] [for] [dogs] [and] [puppies] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]
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 [Fast Acting] 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] [monthly use] [monthly treatment]
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 dogs [and] [puppies] 8 weeks and older and weighing more than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs].
17. [Manufacturer] [Satisfaction] Guaranteed or your money back.

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

18. Monthly treatment for year round [control] [prevention] against fleas
19. Control [Treatment][Prevention] for flea infestations
20. Protects your dog [and/or] [puppy > 8 weeks] and [weighing greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs] for [1 month][one month][a month] against fleas
21. Prevents [flea] re-infestation on dogs taken into a flea-contaminated environment.
22. Indoxacarb the active ingredient] [in brand name] [in this product] [in Activyl® for Dogs and Puppies] blocks the channels that regulate the flow of sodium through the insect's nervous system.
23. Convenient [Single] [Spot application that provides [Control][Treatment][Protection] [of][from]existing flea [infestations]
24. Protects against [re]infestation(s) of fleas [on] [your] [dog] [and] [puppy] [greater than] [older than] 8 weeks and [weighing] greater than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]
25. When used monthly, [Activyl® for Dogs and Puppies] [this product] breaks the flea life cycle.
26. Activyl® for Dogs and Puppies [this product] can be used on puppies [greater than] [older than] 8 weeks of age and [weighing] more than [4 lbs] [14 lbs] [22 lbs] [44 lbs] [88 lbs]
27. Activyl® for Dogs and Puppies [this product] Remains effective [even] after [bathing] [swimming] [water immersion], [or] [exposure to rain] [or] [sunlight]
28. Activyl® for Dogs and Puppies [this product] remains efficacious following [a] [shampoo treatment][swimming] [and] [or] [exposure to rain] [or] [sunlight]
29. Product contained in child resistant packaging

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{NEXT DOSE STICKERS/ TREATMENT REMINDER}

Use these handy stickers to help remember when your dog's next dose is due. When you use the last tube in this package, consult your veterinarian and order more [Activyl® for Dogs and Puppies] [product], if needed.

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

{Alternate text}

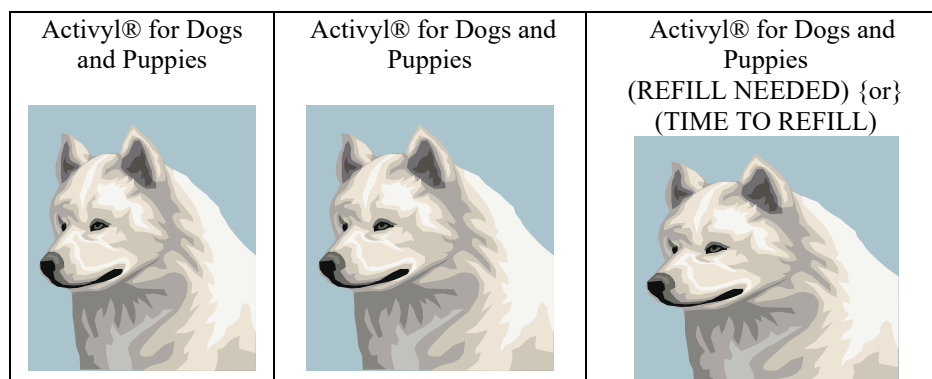
It may be hard to remember when your dog's [and/or] [puppy's] [greater than] [older than] 8 weeks next dose is due. The following has been developed as a tool to help you keep track of every dose. When you use the last tube in this package, consult your veterinarian and order more [Activyl® for Dogs and Puppies] [product], if needed.

Attach these [stickers] [reminders] to your [wall] [desk] calendar [daily planner] on the day the first dose is to be given. Place another [stickers] [reminder] on the same date for the remaining months.

{STICKER PROTOTYPE:}

{Note to reviewer: Sticker will be a clear picture of dog in the weight range for the product being packaged.}

{Picture of dog may vary. Up to 12 sticker count consistent with package}



{CARD Prototype:}

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

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**Representative Images for outer container, including cat warning icon images used throughout the label:**



[large dog]



[medium dog]



[toy dog]



[X-large dog]



[small dog]