



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

EPA Reg. Number:

773-95

Date of Issuance:

3/4/22

NOTICE OF PESTICIDE:

Registration  
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Activyl® Tick Plus 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 2Registration 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 6/20/2011 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 12/12/2014

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).

Enclosure

{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® Tick Plus for Dogs and Puppies  
EPA File Symbol: 773-95  
**Amended Version - 1.5.7 (2020 Pet Spot-On Registration Extension)**

DATED: January 18, 2022  
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{“Master Label for ACTIVYL® Tick Plus 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® Tick Plus 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® Tick Plus”, to be a minimum of 75% as large as the height of the largest letter in the brand name presentation.}

{Alternate Brand Names: Activyl® Tick Plus Spot-On for Dogs, Activyl® Tick Plus for Dogs or Puppies, Activyl® Tick Plus Spot-On for Dogs and Puppies, Activyl® Tick Plus Spot-On for Dogs or Puppies}

{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 and Tick [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] 11 lb [pounds] [5.0 kg] over [greater than] [>] 11 lb [pounds] [5.0 kg] 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]

#### Active Ingredients:

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.....13.01%  
Permethrin\*:  
3-(phenoxybenzyl)-methyl-(±) cis, trans-3-(2,2-dichloroethenyl)-2,2-Dimethylcyclopropanecarboxylate.....42.50%

Other Ingredients:.....44.49%  
**Total 100.00%**

\*cis/trans ratio Min. 35%(±) cis and Max. 65%(±)trans

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE BACK AND SIDE PANELS FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS**

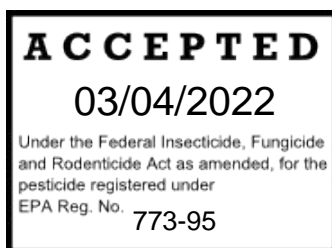
**SEE [PACKAGE] INSERT FOR [COMPLETE] DIRECTIONS FOR USE**

EPA Reg. No. 773-95  
LOGO – Merck Animal Health

EPA Est. No. XXX

Net Contents:

X [applicator(s)] [tube(s)], each 0.02 fl.oz. (0.5 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.03 fl.oz. (1.0 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.07 fl.oz. (2.0 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.14 fl.oz. (4.0 mL) [Total X fl.oz (X ml)]



{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® Tick Plus for Dogs and Puppies

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X [applicator(s)] [tube(s)], each 0.20 fl.oz. (6.0 mL) [Total X fl.oz (X ml)]

{Note to reviewer: Only the net contents above 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.}

**DO NOT USE ON CATS**  
**[CAT WARNING ICON, Min.**  
**1.5x1.5 cm]**

Yellow background with black text

**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.}

{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.}

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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 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. For indoor use only. Application of product on pets must only be done indoors.

### 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 0.5 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 4 lb.

{For 1.0 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 11 lb.

{For 2.0 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 22 lb.

{For 4.0 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 44 lb.

{For 6.0 mL package size} Do not use on dogs or 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 if label space allows or unboxed. If unboxed, First Aid statements still to be grouped near Precautionary Statements and be ordered by the most severe route of exposure.}

FIRST AID	
<b>If in Eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a 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 a poison control center or doctor immediately for treatment advice.</li><li>• Have 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>
HOT LINE NUMBER	
Have the product container or label with you when calling a 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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## {PRIMARY CARTON - BACK PANEL STATEMENTS (cont'd)}

<p><b>CAT WARNING ICON</b> DO NOT USE ON CATS - MAY BE FATAL Keep cats away from treated dogs for 24 hours. If applied to cats or ingested by cats, contact your veterinarian immediately. [CAT WARNING ICON, Min. 1.5x1.5 cm] <b>Yellow background with black text</b> {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.}</p>	<p><b>PRECAUTIONARY STATEMENTS</b> <b>HAZARDS TO HUMANS</b> <b>CAUTION.</b> Causes moderate eye irritation. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin or 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. <b>[HAZARDS CONTINUED ON SIDE PANELS]</b></p>

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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] [11 lb] [22 lb] [44 lb] [88 lb].** Consult a veterinarian before using this product on debilitated, aged, and medicated dogs. Do not use on pregnant or nursing dogs. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated dog.

**DO NOT USE ON CATS. MAY BE FATAL.** Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided. Keep cats away from treated dogs for 24 hours. Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effect.

#### 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. Do not pour or dispose down-the-drain or sewer. Call your local solid waste Agency for local disposal options.

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



{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® Tick Plus for Dogs and Puppies  
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## {APPLICATOR LABELING STATEMENTS}

### Activyl® Tick Plus 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] 11 lb [pounds] [5.0 kg]  
over [greater than] [>] 11 lb [pounds] [5.0 kg] 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.....13.01%  
Permethrin.....42.50%

### Cat Warning Icon {or} DO NOT USE ON CATS

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



### KEEP OUT OF REACH OF CHILDREN CAUTION

{Note to reviewer: One statement will appear on the label corresponding to the appropriate package.}  
0.02 fl.oz. (0.5 mL)  
0.03 fl.oz. (1.0 mL)  
0.07 fl.oz. (2.0 mL)  
0.14 fl.oz. (4.0 mL)  
0.20 fl.oz. (6.0 mL)

EPA Reg. No. 773-95  
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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## {FOIL POUCH LABELING STATEMENTS}

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

### **Activyl® Tick Plus**

{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] 11 lb [pounds] [5.0 kg]  
over [greater than] [>] 11 lb [pounds] [5.0 kg] 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.....13.01%  
Permethrin.....42.50%

### **Cat Warning Icon {or}** **DO NOT USE ON CATS**

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



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

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

0.02 fl.oz. (0.5 mL)  
0.03 fl.oz. (1.0 mL)  
0.07 fl.oz. (2.0 mL)  
0.14 fl.oz. (4.0 mL)  
0.20 fl.oz. (6.0 mL)

EPA Reg. No. 773-95  
EPA Est. No. XXX

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

Lot No:

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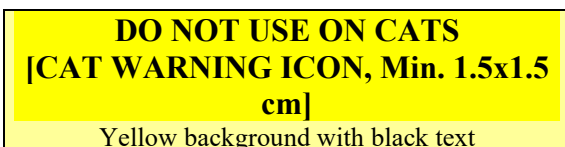
{Note to reviewer: Due to carton size this additional information is referred to on the carton and includes complete directions for use with all carton box mandatory required statements found on the primary carton }

**{For 0.5 mL, 1.0 mL, 2.0 mL, 3.0 mL, 4.0 mL, 6.0mL package sizes}**

**{Note to reviewer: appropriate dose size will depend on package}**

## {PACKAGE INSERT STATEMENTS}

### Activyl® Tick Plus For Dogs and Puppies



**{Alternate Brand Names:** Activyl® Tick Plus Spot-On for Dogs, Activyl® Tick Plus for Dogs or Puppies, Activyl® Tick Plus Spot-On for Dogs and Puppies, Activyl® Tick Plus Spot-On for Dogs or Puppies}

{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 and Tick [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] 11 lb [pounds] [5.0 kg]  
over [greater than] [>] 11 lb [pounds] [5.0 kg] 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]

#### Active Ingredients:

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.....13.01%

Permethrin\*:

3-(phenoxybenzyl)-methyl-(±) cis, trans-3-(2,2-dichloroethenyl)-2,2-

Dimethylcyclopropanecarboxylate.....42.50%

**Other Ingredients:**.....44.49%

**Total** 100.00%

\*cis/trans ratio Min. 35%(±) cis and Max. 65%(±)trans

**KEEP OUT OF REACH OF CHILDREN**  
**CAUTION**

{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)}

### CAT WARNING ICON

DO NOT USE ON CATS - MAY BE FATAL  
Keep cats away from treated dogs for 24  
hours. If applied or ingested, contact your  
veterinarian immediately.

Format – Yellow background with black text

{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.}

## 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. For indoor use only. Application of product on pets must only be done indoors.

### 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 DOUBLE DOSE OR APPLY MORE THAN ONE TUBE/APPLICATOR PER TREATMENT FOR ONE DOG REGARDLESS OF THE DOG'S WEIGHT. ▶ DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT. ▶ DO NOT BATHE DOG FOR 24 HOURS AFTER APPLICATION.

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

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

{For 0.5 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 4 lb.

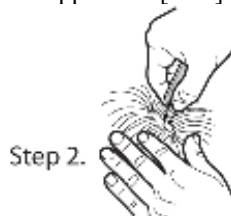
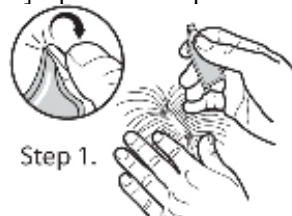
{For 1.0 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 11 lb.

{For 2.0 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 22 lb.

{For 4.0 mL package size} Do not use on dogs or puppies under 8 weeks of age. Do not apply to dogs weighing less than 44 lb.

{For 6.0 mL package size} Do not use on dogs or 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].



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



{0.5 mL size only}  
ONLY For dogs over 4 lb up to 11 lb  
(ONLY For dogs over 1.8 kg up to 5.0 kg)



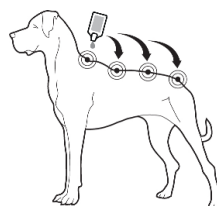
{1.0 mL size only}  
ONLY For dogs over 11 lb up to 22 lb  
(ONLY For dogs over 5.0 kg up to 10 kg)



{2.0 mL size only}  
ONLY For dogs over 22 lb up to 44 lb  
(ONLY For dogs over 10 kg up to 20 kg)



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



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

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 0.5 mL and 1.0 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 2.0 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 large dogs – packaging size 4.0 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 6.0 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 2.0 mL, 4.0 mL, and 6.0 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 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.

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{Note to reviewer: First Aid statements may be boxed if label space allows or unboxed. 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 a poison control center or doctor immediately for treatment advice.</li><li>• Have 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 a 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.

#### **PRECAUTIONARY STATEMENTS**

##### **HAZARDS TO HUMANS**

**CAUTION.** Causes moderate eye irritation. Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin or 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 8 weeks of age and older and weighing over [4 lb] [11 lb] [22 lb] [44 lb] [88 lb].** Consult a veterinarian before using this product on debilitated, aged, and medicated dogs. Do not use on pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using any pesticide product. If signs of sensitivity occur bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated dogs.

**DO NOT USE ON CATS. MAY BE FATAL.** Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided. Keep cats away from treated dogs for 24 hours. Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effect.

##### **PHYSICAL OR CHEMICAL HAZARDS**

Flammable. Keep away from heat and open flame.

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### STORAGE AND DISPOSAL

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

**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. Do not pour or dispose down-the-drain or sewer. Call your local solid waste Agency for local disposal options.

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EPA Est. No. XXX

Net Contents: X [applicator(s)] [tube(s)], each 0.02 fl.oz. (0.5 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.03 fl.oz. (1.0 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.07 fl.oz. (2.0 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.14 fl.oz. (4.0 mL) [Total X fl.oz (X ml)]  
X [applicator(s)] [tube(s)], each 0.20 fl.oz. (6.0 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).**

**[LOGO Merck Animal Health]**

2 Giralda Farms, Madison, NJ 07940

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

1. Kills fleas that may cause bartonellosis or transmit tapeworm.
2. 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.}
3. Kills fleas that may cause flea allergy dermatitis, bartonellosis or transmit tapeworm.
4. [Activyl® Tick Plus for Dogs and Puppies] Kills fleas that [may cause flea bite anemia] [may transmit tapeworms].
5. 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® Tick Plus for Dogs and Puppies kills fleas.
6. For the prevention [and] [treatment] of flea and tick infestations on [dogs] [and] [puppies] 8 weeks and older and [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs] for [four] [4] [weeks] [one] [1] [month].
7. Once monthly application.
8. Prevents and controls re-infestations of fleas [and] [&] ticks.
9. Controls and prevents flea and tick infestations on dogs [and/or] [puppies 8 weeks and older] [and] [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs]] for [four] [4] [weeks] for [one] [1] [month].
10. Prevents [and] [protects] against [re-]infestation [of fleas and ticks] for [four] [4] [weeks].
11. Prevents [and] [protects] against [re-]infestation [of fleas and ticks] for [one] [1] [month].
12. One treatment prevents flea [and] [tick] [infestations] [on] [dogs] [and] [puppies] 8 weeks and older and [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs] for [four] [4] [weeks] for [one] [1] [month].
13. Protects your dog [and/or] [puppy] 8 weeks and older and [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs] from [fleas] [and] [ticks] for [four] [4] [weeks] [one] [1] [month].
14. Provides ongoing protection for your dog against fleas and ticks for [four] [4] [weeks] [one] [1] [month].
15. Monthly treatment for control [and] [prevention] [of fleas and ticks] [on your] [dog] [and] [puppy] 8 weeks and older and [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs].
16. Effective monthly control [prevention] [and] [treatment] of [fleas] [and] [tick] [on] [dogs] [and] [puppies] 8 weeks and older and [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs].
17. Kills and repels ticks for [four] [4] [weeks] [one] [1] [month]
18. Flea [and] [tick] control [prevention] [and] [treatment] formulated for [dogs] [and] [puppies] 8 weeks and older and [weighing] greater than [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs]



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19. Controls [Treatment against] [Protects against] fleas and ticks.
20. Monthly treatments for [control] [and] [prevention] of [flea] [and] [tick] [infestations].
21. After application, Activyl® Tick Plus for Dogs and Puppies [This product] spreads over the dog's body to provide [full body] [all over] protection for your dog against fleas and ticks
22. Contains permethrin, an effective insecticide/acaricide that provides efficacy against ticks
23. Repels and kills ticks that may transmit Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis and bartonellosis.
24. Repels and kills ticks including those that may [cause] [transmit] Lyme disease, Rocky Mountain spotted fever, babesiosis, ehrlichiosis, anaplasmosis, tularemia and Southern tick-associated rash illness (STARI).
25. Repels and kills Brown Dog ticks (*Rhipicephalus sanguineus*) [that may transmit ehrlichiosis, Rocky Mountain spotted fever and babesiosis] American dog ticks (*Dermacentor variabilis*) [that may transmit Rocky Mountain spotted fever], Deer ticks (*Ixodes scapularis*) [that may transmit Lyme disease] and Lone Star ticks (*Amblyomma americanum*) [that may transmit ehrlichiosis, rickettsiosis - Rocky Mountain spotted fever and Southern tick-associated rash illness (STARI) and tularemia] [for one month]
26. Repels and kills ticks that may transmit [Lyme Disease] [babesiosis] [ehrlichiosis] [Rocky Mountain spotted fever] [anaplasmosis].
27. Repels and kills ticks that may cause tick paralysis.
28. Fleas [and] [Ticks] can be a year-round problem!
29. [Activyl® Tick Plus for Dogs and Puppies] is a monthly treatment that can be used throughout the year.
30. Controls flea feeding, followed [closely] by paralysis and death following exposure to the product.
31. Activyl® Tick Plus for Dogs and Puppies [This product] Remains effective against fleas and ticks even after [swimming] [water immersion], [or] [exposure to rain] [or] [sunlight].
32. For treatment [control] and prevention of flea and tick infestations, treat monthly throughout the year.
33. Prevents [annoying] [bothersome] [nuisance] blood-feeding by biting fleas [and] [ticks] for [up to] [four] [4] [weeks] [one] [1] [month].
34. [Activyl® Tick Plus for Dogs and Puppies] kills all flea life stages (egg, larvae, and adult).

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**{ALTERNATE OPTIONAL MARKETING TEXT – on label or other web/print materials}**

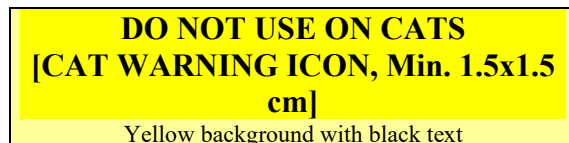
1. Activyl® Tick Plus for Dogs and Puppies [This product] kills fleas for four weeks. After ingestion, enzymes of susceptible insects metabolize indoxacarb into its paralyzing and lethal metabolite. This process is known as bioactivation. The product is convenient and easy to apply.
2. Intended to be sold through veterinarians.
3. Intended to be dispensed [and] [or] sold through [by] licensed veterinarians and to their clients for dogs under a direct vet-client-patient relationship.
4. Product availability intended through licensed veterinarians.
5. Indoxacarb [an active] [in Activyl® Tick Plus for Dogs and Puppies] [in this product] blocks the channels that regulate the flow of sodium through the insect's nervous system.
6. Through the metabolic activation process (bioactivation), the insect's enzymes remove the carbomethoxy group, converting indoxacarb [an active in] [Activyl® Tick Plus for Dogs and Puppies] to the more insecticidally active compound.
7. Activyl® Tick Plus for Dogs and Puppies [This product] [It] may also be used to [control] [prevent] infestation on flea-free [dogs] [and] [or] [puppies 8 weeks and older and greater than 4 lbs] taken into a flea-contaminated environment.
8. Permethrin is a synthetic pyrethroid and tick repellent.
9. Permethrin is an adulticide
10. Reapplication at monthly intervals [Monthly reapplications] depending upon [the level of flea challenge] [and] [animal sensitivities (i.e., flea allergy dermatitis)].
11. X applicators [in] [monthly] [doses] [applications] [treatments]
12. Long Lasting [Effective] [Protection] for 1 month [30 days] formulated for dogs [and] [puppies 8 weeks and older] [and] weighing [more than] [greater than] [4 lbs] [11 lbs] [22 lbs] [44 lbs] [88 lbs].
13. Convenient [Easy] [to apply] [to use] [spot-on] [topical] [application] treatment.
14. No fragrance added
15. No noticeable odor
16. [Manufacturer] [Satisfaction] Guaranteed or your money back

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



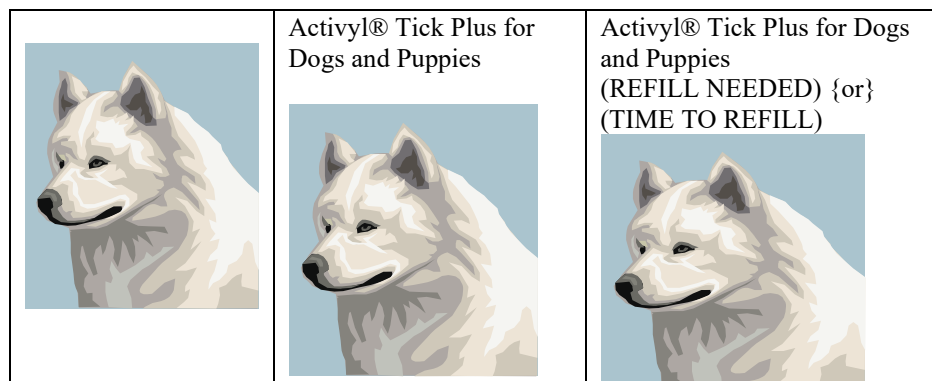
Use these handy stickers to help remember when your dog’s next application is due. When you use the last tube in this package, call your veterinarian immediately to order more [product] [Activyl® Tick Plus for Dogs and Puppies] Attach these [stickers] [reminders] to your [wall] [desk] calendar [daily planner] on the days of the first application, and on the same date for each of the remaining months.

It may be hard to remember when your dog’s [and/or][(puppy’s] 8 weeks and older next application is due. The following has been developed as a tool to help you keep track of every application. When you use the last tube in this package, call your veterinarian immediately to order more [product] [Activyl® Tick Plus for Dogs and Puppies]

Attach these [stickers] [reminders] to your [wall] [desk] calendar [daily planner] on the days of the first application, and on the same date for each of 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.}  
**{Up to 12 sticker count consistent with package}**



**{CARD Prototype:}**

<b>Dog’s NAME</b>
<b>PRODUCT: (preprinted product name)</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, including cat warning icon images used throughout the label:**



[large dog]



[medium dog]



[toy dog]



[X-large dog]

/



[small dog]