



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:

6/1/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 05/31/2018

Name of Pesticide Product:

Activyl® Tick Plus for Dogs and
Puppies

Name and Address of Registrant (include ZIP Code):

Micah T. Reynolds, Agent
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:

Richard Gebken, Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

Date:

6/1/16

2. This registration is time-limited and expires 05/31/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

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

5. You are required to comply with the data requirements described in the DCIs identified below:
 - a. Indoxacarb GDCI-067710-1382
 - b. Permethrin GDCI-109701-1252

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

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

6. 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 data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. 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
- Alternate CSF 1 dated 12/12/2014

If you have any questions, please contact Eric Bohnenblust by phone at (703) 347-0426, or via email at Bohnenblust.eric@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Gebken', with a long horizontal flourish extending to the right.

Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

Enclosure

“Master Label for ACTIVYL® Tick Plus for Dogs and Puppies”:

This master label includes text for different size packages and application rates specific to pet's age and body weight.

PRIMARY CARTON - FRONT PANEL STATEMENTS

Activyl® 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

Once-A-Month Topical Flea and Tick (Spot-On)(Treatment)(Prevention)(Control) 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) ONLY
over (>) (greater than) 11 lb (pounds) (5.0 kg) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

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 PANEL FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

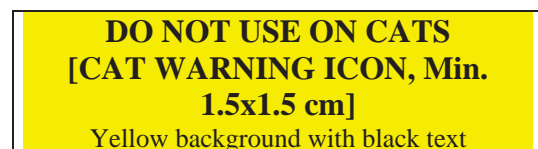
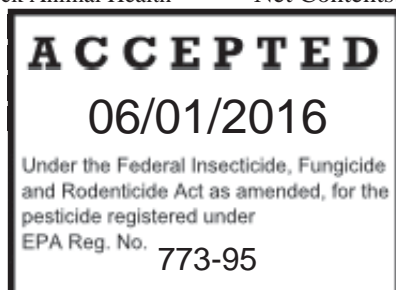
EPA Reg. No. 773-95

EPA Est. No. 618-LA-1

LOGO – Merck Animal Health

Net Contents:

X applicator(s), each 0.02 fl.oz. (0.5 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.03 fl.oz. (1.0 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.07 fl.oz. (2.0 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.14 fl.oz. (4.0 mL) {Total X fl.oz (X ml)}
X applicator(s), each 0.20 fl.oz. (6.0 mL) {Total X fl.oz (X ml)}



GRAPHIC (note to reviewer: appropriate dog picture will be presented on the front panel depending on package)

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

PRIMARY CARTON - BACK PANEL STATEMENTS

DIRECTIONS FOR USE

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

RESTRICTIONS

► DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ► TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. ► FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. ► 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 HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ► DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT

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	
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If On Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything to an unconscious person.
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.	

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.

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

PRIMARY CARTON - BACK PANEL 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 to cats or ingested by cats, contact your veterinarian immediately. [CAT WARNING ICON, Min. 1.5x1.5 cm] Yellow background with black text	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 CONTINUED ON SIDE PANELS	

PRIMARY CARTON – SIDE PANEL STATEMENTS

PRECAUTIONARY STATEMENTS (cont'd)

HAZARDS TO DOMESTIC ANIMALS

For external use on dogs and puppies only. Do not use on puppies under 8 weeks of age. Do not use on dogs weighing less than (4 lb) (11 lb) (22 lb) (44 lb) (88 lb). Consult a veterinarian before using this product on debilitated, aged, and medicated animals. Do not use on pregnant or nursing animals. Individual sensitivities may occur after using any pesticide product. If signs of sensitivity occur bathe your pet 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 animals.

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 **If empty:** Do not reuse this 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

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

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

APPLICATOR LABELING STATEMENTS

Activyl® Tick Plus 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) ONLY
over (>) (greater than) 11 lb (pounds) (5.0 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

Indoxacarb.....13.01%
Permethrin.....42.50%

**Cat Warning Icon or
DO NOT USE ON CATS**

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

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

EPA Reg. No. 773-95
EPA Est. No. 618-LA-1

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

Lot No:

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

FOIL POUCH LABELING STATEMENTS

DO NOT REMOVE APPLICATOR (TUBE) UNTIL READY TO USE

Activyl® Tick Plus 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) ONLY
over (>) (greater than) 11 lb (pounds) (5.0 g) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to) 132 lb (pounds) (60 kg) ONLY

Indoxacarb.....13.01%
Permethrin.....42.50%

Cat Warning Icon

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE USE

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

EPA Reg. No. 773-95
EPA Est. No. 618-LA-1

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

Lot No:

(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 depending 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

Once-A-Month Topical Flea and Tick (Spot-On)(Treatment)(Prevention)(Control) 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) ONLY
over (>) (greater than) 11 lb (pounds) (5.0 kg) and (up to) (less than or equal to) 22 lb (pounds) (10 kg) ONLY
over (>) (greater than) 22 lb (pounds) (10 kg) and (up to)(less than or equal to) 44 lb (pounds) (20 kg) ONLY
over (>)(greater than) 44 lb (pounds) (20 kg) and (up to)(less than or equal to) 88 lb (pounds) (40 kg) ONLY
over (>)(greater than) 88 lb (pounds) (40 kg) and (up to)(less than or equal to)132 lb (pounds) (60 kg) ONLY

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

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

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.

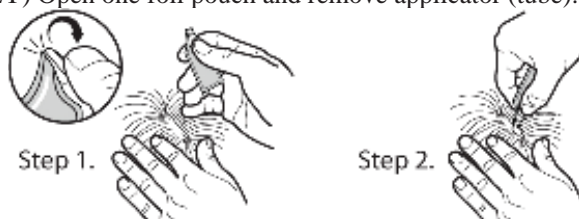
Format – Yellow background with black text

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.

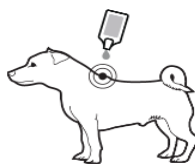
(HOW TO APPLY) Open one foil pouch and remove applicator (tube).



3. Graphics for specific dog sizes represented below – 1 graphic per package size



For dogs over 4 lb up to 11 lb ONLY
(For dogs over 1.8 kg up to 5.0 kg ONLY)
(0.02 fl.oz.(0.5 mL) size only)



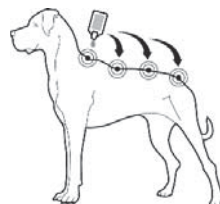
For dogs over 11 lb up to 22 lb ONLY
(For dogs over 5.0 kg up to 10 kg ONLY)
(0.03 fl.oz.(1.0 mL) size only)



For dogs over 22 lb up to 44 lb ONLY
(For dogs over 10 to 20 kg ONLY)
(0.07 fl.oz (2.0 mL) size only)



For dogs over 44 lb up to 88 lb ONLY
(For dogs over 20 kg up to 40 kg ONLY)
(0.14 fl.oz (4.0 mL) size only)



For dogs over 88 lb up to 132 lb ONLY
(For dogs over 40 kg up to 60 kg ONLY)
(0.20 fl.oz. (6.0 mL) size only)

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

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.

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 it is completely dry.

For Directions for Use - dogs over 88 lb up to 132 lb ONLY: DO NOT DOUBLE DOSE DOGS LARGER THAN THE UPPER WEIGHT ON THE PACKAGE FOR THE 88 lb to 132 lb DOG.

It is recommended to reapply every 30 days or as needed, but DO NOT apply more than 1 applicator (tube) per month. When application is complete, follow the Container Handling instructions under the Storage and Disposal section below.

(ALTERNATE Step 3 Directions for larger dogs:

Step 3. Apply entire contents of tube evenly to (two)(or)(three)(or)(four) spots on the back from between the shoulder blades to the base of the tail. 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 solution on the skin. Squeeze applicator firmly applying entire contents directly to skin. Do not apply an excessive amount of solution at any one spot. Do not allow product to run off. Do not have contact with treated area (application site) until it is completely dry.)

RESTRICTIONS

► DO NOT ALLOW CHILDREN TO APPLY PRODUCT. ► TO PREVENT HARM TO YOU AND YOUR DOG, READ ENTIRE LABEL AND DIRECTIONS BEFORE EACH USE. ► FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. ► 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 HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL IT IS COMPLETELY DRY. ► DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.

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	
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If On Skin	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.

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

If Swallowed	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to by a poison control center or doctor.• Do not give anything to an unconscious person.
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.	

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. Do not use on puppies under 8 weeks of age. Do not use on dogs weighing less than (4 lb) (11 lb) (22 lb) (44 lb) (88 lb). Consult a veterinarian before using this product on debilitated, aged, and medicated animals. Do not use on pregnant or nursing animals. Individual sensitivities, while rare, may occur after using any pesticide product. If signs of sensitivity occur bathe your pet 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 animals.

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 If empty: Do not reuse this 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. 773-95
EPA Est. No. 618-LA-1

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

Made in the USA

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

xxxxxxx Rev. xx/xxxx

(Volume varies with size of animal for which package is intended and number of applicators per package. Product may be packaged in 1, 3, 4, 6, or 12 applicators per package. Total volume will correspond to number of applicators)

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

FRONT PANEL AND/OR SIDE PANEL CLAIMS -optional

1. Kills fleas that may cause bartonellosis or transmit tapeworm.
2. Kills fleas that may cause (flea allergy dermatitis) (FAD).
3. Kills fleas that may cause flea allergy dermatitis, bartonellosis or transmit tapeworm.
4. (Activyl® Tick Plus for Dogs and Puppies) (alternate brand name) kills fleas that (may cause 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) (alternate brand name) 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 is recommended. Do not apply more than once a month.
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). Do not apply more than once a 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 against fleas and ticks for (four)(4)(weeks) (one)(1)(month).
15. Monthly treatment recommended for optimal (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)
19. (Controls)(Treatment against)(Protects against) fleas and ticks.

-
20. Monthly treatments are recommended for optimal (control) (and) (prevention) of (flea)(and)(tick) (infestations). Do not apply more than once a month.
 21. After application, (Activyl® Tick Plus for Dogs and Puppies)(Alternate brand name)(This product) (spreads over the dog's body to provide (full body) (all over) protection 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) (Alternate brand name) is a monthly treatment that can be used throughout the year.
 30. Stops flea feeding, followed (closely) by paralysis and death following exposure to the product.
 31. (Activyl® Tick Plus for Dogs and Puppies)(Alternate brand name)(This product) Remains effective against fleas and ticks even after (swimming) (water immersion), (or) (exposure to rain) (or) (sunlight).
 32. For optimum treatment (control) and prevention of flea and tick infestations, treat monthly throughout the year.
 33. (Prevents)(annoying)(bothersome)(nuisance) (blood-feeding) (by)(biting fleas)(by) (killing)(and) (biting fleas) for (up to)(four)(4)(weeks)(one)(1)(month).
 34. (Activyl® Tick Plus for Dogs and Puppies) (Alternate brand name) kills all flea life stages (- egg, larvae, and adult).
 35. Flea eggs and flea larvae in (the pet's) (your dog's) surroundings are killed following contact with (Activyl® Tick Plus)(Alternate brand name) treated pets.

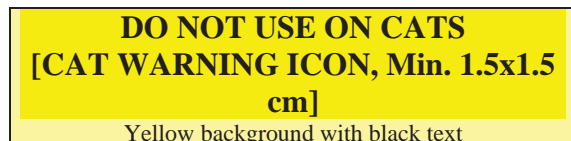
ALTERNATE MARKETING TEXT - optional

1. (Activyl® Tick Plus for Dogs and Puppies)(Alternate brand name)(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 pets 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 brand name)(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) (brand name) to the more insecticidally active compound.
7. Indoxacarb is an active ingredient from the oxadiazine chemical class.
8. (Activyl® Tick Plus for Dogs and Puppies)(Alternate brand name)(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.
9. (Indoxacarb is a) voltage-dependent sodium channel blocker.
10. Permethrin is a synthetic pyrethroid and tick repellent.
11. Permethrin is a voltage-dependent sodium channel blocker.
12. Permethrin is an adulticide
13. (Reapplication at monthly intervals) (Monthly reapplications) may be appropriate depending upon (the level of flea challenge) (and) (animal sensitivities)(i.e., flea allergy dermatitis). Do not apply more than once a month.
14. X (applicators)(monthly doses) (applications)(treatments)
15. (Long Lasting) (Effective) (Protection) for 1 month (30 days) (Specifically) 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).
16. (Convenient)(Easy)(to apply)(to use) (spot-on) (topical) (application) (treatment).
17. No fragrance added
18. No noticeable odor

Amended Version - 1.5.6 (2016 Pet Spot-On Registration Extension)

19. Questions (or)(comments) call (1-800-Tel. Number)(or)(Tel. No.)
20. For more information call (1-800- Tel. Number)(or Tel. No.)For emergencies call (1-800- Tel. Number)(or)(Tel. No.)
21. If you have any questions, call Merck Animal Health Technical Services at (1-800- Tel. Number)(or)(Tel. No.)
22. Shampooing decreases efficacy.
23. (Manufacturer) (Satisfaction) Guaranteed
24. Effectively controls fleas and ticks on dogs in a home environment.

NEXT DOSE STICKERS/ TREATMENT REMINDER (prototype)



Use these handy stickers to help remember when your pet'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)(alternate brand name).

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.

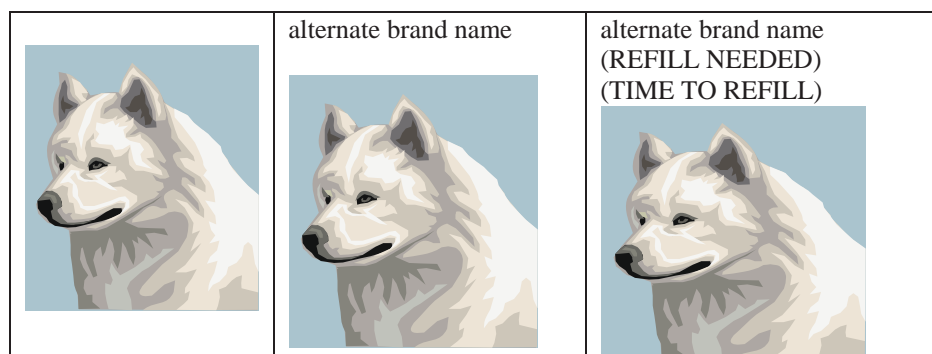
Alternate text

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)(alternate brand name).

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:

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



CARD Prototype:

PET'S NAME
PRODUCT: (preprinted alternate brand name)
DATE OF 1st APPLICATION:
DATE OF 2nd APPLICATION:
DATE OF 3rd APPLICATION

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