



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

EPA Reg. Number:

773-73

Date of Issuance:

11/8/18

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 02/12/2020

Name of Pesticide Product:

Exspot Insecticide for Dogs

Name and Address of Registrant (include ZIP Code):

Micah Reynolds
 Consultant for Intervet, Inc.
 (d/b/a Merck Animal Health)
 c/o Technology Sciences Group, Inc.
 1150 18th St, Suite 1000
 Washington, DC 20036

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:

Elizabeth Fertich, Product Manager 04
 Invertebrate & Vertebrate Branch 1, Registration Division
 (7505P)

Date:

11/8/18

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product and is extending the two-year registration restriction. This registration is time-limited and expires 02/12/2020.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in the notice first listing the reporting requirements in the amendment letter dated 02/7/2014.
4. 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 07/13/2012
- Alternate CSF 1 dated 07/13/2012
- Alternate CSF 2 dated 07/13/2012
- Alternate CSF 3 dated 07/13/2012
- Alternate CSF 4 dated 07/13/2012

If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Enclosure

{“Master Label for Exspot® Insecticide for Dogs”}

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

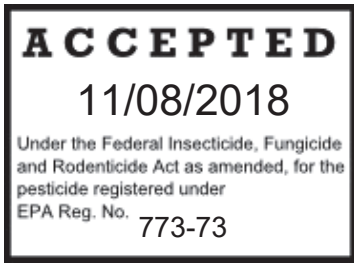
PRIMARY CARTON - FRONT PANEL STATEMENTS

Exspot® Insecticide for Dogs

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

Alternate Brand Names:

Defend® Exspot Treatment for Dogs
Defend® Exspot Insecticide for Dogs
ProTICall® Insecticide for Dogs



**For Use on Dogs and Puppies
DO NOT USE ON CATS**

Kills, repels, and prevents re-infestation of fleas on dogs for up to 5 weeks
Kills, repels, and prevents re-infestation of ticks on dogs for up to 6 weeks
Kills and repels mosquitoes, lice, and mites on dogs for up to 4 weeks

For Dogs (and) (or) puppies 4 weeks and older and
[over (>) (greater than) 17 lbs (pounds) [(7.7 kg)] and (up to) (less than or equal to) 33 lbs (pounds) [(15 kg)] ONLY]
[over (>) (greater than) 33 lbs (pounds) [(15 kg)] and (up to) (less than or equal to) 65 lbs (pounds) [(29 kg)] ONLY]
[over (>) (greater than) 65 lbs (pounds) [(29 kg)] ONLY]

Active Ingredient:

Permethrin*65%

Other Ingredients:.....35%

Total 100% wt/wt

*Cis/trans ratio: Max. 55% (±) cis and Min. 45% (±) trans

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE INSIDE PANELS FOR FIRST AID AND ADDITIONAL PRECAUTIONARY STATEMENTS

Contains: Three [Two] 1-Month Doses

Net Contents: {Note that each weight is packaged separately.}

{small dog/puppy} [Two 1cc applicators, each 0.034 fl. oz. [(1.0 mL)]] [Three 1cc applicators, each 0.034 fl. oz. [(1.0 mL)]]

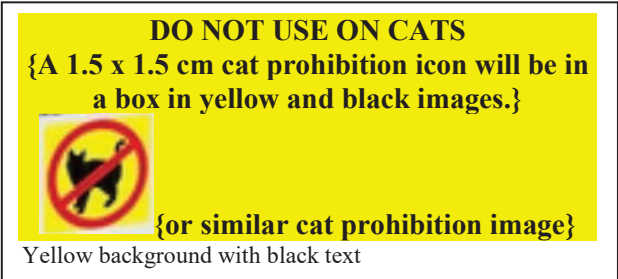
{large dog} [Four 1cc applicators, each 0.034 fl. oz. [(1.0 mL)]] [Six 1cc applicators, each 0.034 fl. oz. [(1.0 mL)]]

{extra large dog} [Eight 1cc applicators, each 0.034 fl. oz. [(1.0 mL)]] [Twelve 1cc applicators, each 0.034 fl. oz. [(1.0 mL)]]

{extra large dog} [Four 2cc applicators, each 0.068 fl. oz. [(2.0 mL)]] [Six 2cc applicators, each 0.068 fl. oz. [(2.0 mL)]]

Sold Only Through Veterinary Clinics

DOG GRAPHIC – {A large, clear picture of a dog in the weight range for the product as packaged will be included on the final printed label.}



{text denotes notes to reviewer}; [text denotes optional text]; (denotes alternate presentation of the same claim/statement)

PRIMARY CARTON - BACK PANEL STATEMENTS

Exspot® Insecticide for Dogs

READ ENTIRE LABEL COMPLETELY BEFORE USING. USE ONLY ON DOGS AND PUPPIES 4 WEEKS AND OLDER AND

[over (>) (greater than) 17 lbs (pounds) [(7.7 kg)] and (up to) (less than or equal to) 33 lbs (pounds) [(15 kg)] ONLY]

[over (>) (greater than) 33 lbs (pounds) [(15 kg)] and (up to) (less than or equal to) 65 lbs (pounds) [(29 kg)] ONLY]

[over (>) (greater than) 65 lbs (pounds) [(29 kg)] ONLY]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS: CAUTION. Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash hands 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: Consult a veterinarian before using this product on debilitated, aged, or pregnant or nursing dogs. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated animals. Consult with a veterinarian before using on dogs with known organ dysfunction. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, discontinue use, bathe your pet with mild soap, and rinse with large amounts of water. If signs continue, seek veterinary advice immediately. This product is not a substitute for prescribed heartworm preventative.

DO NOT USE ON CATS. May be fatal if applied to or ingested by cats. 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.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call poison control center or doctor immediately for treatment advice.• Have a person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything to an unconscious person.
If on Skin or Clothing	<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 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.
HOT LINE NUMBER	
Have the product container or label with you when calling the poison control center or doctor or going for treatment. For additional information on this product (including health concerns, medical emergencies, or pesticide incidents), you may call the Rocky Mountain Poison Center at 1-303-595-4869.	

Amended Version – 5.0 (Spot-On Time-Limited Registration Renewal)

{Note to reviewer: A box labeled Side Effects will be immediately placed above the cat warning box on the back panel.}

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 or call 1-800-224-5318. Hair discoloration or hair loss at the application site may occur. Dogs may also show lethargy.

**DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.
{A 1.5 x 1.5 cm cat prohibition icon will be in a box in yellow and black images.}**



{or similar cat prohibition image}

Yellow background with black text/image

PRIMARY CARTON – INSIDE BACK PANEL

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

STORAGE AND DISPOSAL

{Note to reviewer, immediate packaging is destroyed after use, therefore inherently non-refillable.}

PESTICIDE STORAGE: Store this product in a cool, dry (preferably locked) place, away from heat or open flame, in an area that is inaccessible to children and pets. Protect from freezing.

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

Exspot® Insecticide for Dogs is an effective and easy to use product for killing, repelling, and preventing re-infestations of fleas and ticks on your dog and puppy. Exspot® Insecticide for Dogs may become less effective if dog is frequently bathed or gets wet. **DO NOT USE ON CATS.**

Exspot® Insecticide for Dogs kills, repels, and prevents re-infestation of fleas and ticks on dogs. It also kills and repels mosquitoes, dog lice, and mites:

<i>Insect</i>	<i>Protection</i>
Fleas	Up to 5 weeks
Deer Ticks a vector of Lyme disease (<i>Ixodes scapularis</i>)	Up to 6 weeks
Brown Dog Ticks (<i>Rhipicephalus sanguineus</i>)	Up to 6 weeks
American Dog Ticks (<i>Dermacentor variabilis</i>)	Up to 6 weeks
Lone Star Ticks (<i>Amblyomma americanum</i>)	Up to 6 weeks
Mosquitoes a vector of heartworm (<i>Aedes aegypti</i>)	Up to 4 weeks
Dog lice (<i>Trichodectes canis</i>)	Up to 4 weeks
Mites (<i>Cheyletiella yasguri</i>)	Up to 4 weeks

NOTICE OF WARRANTY

To the extent consistent with applicable law, Intervet Inc. makes no warranty of merchantability, fitness for any particular purpose, or otherwise, expressed or implied concerning this product or its uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label.

Lot or Batch No.: {Note to reviewer: May also be stamped directly onto container.}

{text denotes notes to reviewer}; [text denotes optional text]; (denotes alternate presentation of the same claim/statement)

PRIMARY CARTON – LEFT SIDE PANEL STATEMENTS

Exspot® Insecticide for Dogs

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label completely before using. Use only on dogs and puppies 4 weeks and older.

USE RESTRICTIONS

DO NOT USE ON CATS or other animals other than dogs – may be fatal. Do not use Exspot® Insecticide for Dogs on dogs and puppies less than 4 weeks of age. Do not allow your dog or puppy to ingest this product. Do not use on dogs or puppies weighing less than [17 lbs (7.7 kg)] [33 lbs (15 kg)] [65 lbs (29 kg)]. Do not exceed labeled dosage amount for dogs. Do not have contact or allow children to have contact with treated area until completely dry. Do not allow children to apply product. Do not use on animals other than dogs. Only apply product one time per [month (30 days)]. Do not apply more than once per month.

{Note to Reviewer: Only one of the three sizes would be present on the container label.}

{APPLICATION DIRECTIONS FOR DOGS AND PUPPIES OLDER THAN 4 WEEKS OF AGE AND WEIGHING MORE THAN 17 LBS BUT LESS THAN OR EQUAL TO 33 LBS ONLY}:

HOW TO APPLY:

1. Remove tube along perforations. 2. Hold tube in upright position. 3. Point tip of tube up and away from user's face and body. 4. Cut across tip where indicated. 5. Part dog's hair between the shoulder blades. 6. Invert tube over dog. 7. Squeeze the tube firmly and apply contents of the tube to the skin of the dog's back between the shoulder blades. SEE DOSING CHART on side panel. 8. When application is complete, follow instructions in the Storage and Disposal section.

{APPLICATION DIRECTIONS FOR DOGS AND PUPPIES OLDER THAN 4 WEEKS OF AGE AND WEIGHING MORE THAN 33 LBS BUT LESS THAN OR EQUAL TO 65 LBS ONLY}:

HOW TO APPLY:

- 1 Remove (2) (two) (1cc) tubes along perforations. 2. Peel away plastic cover from cardboard. 3. Hold in upright position and point tip of tube up and away from user's face and body. 4. Tear away tip of tube at notch where indicated. 5. Part dog's hair between the shoulder blades. 6. Invert first tube over dog. 7. Squeeze the tube firmly and apply contents of the tube to the skin of the dog's back between the shoulder blades. Apply the (second (one) (1) (cc) tube) of solution to the dog's skin directly in front of the base of the tail. SEE DOSING CHART on side panel. 8. When application is complete, follow Pesticide Disposal under Storage and Disposal section.

{APPLICATION DIRECTIONS FOR DOGS AND PUPPIES OLDER THAN 4 WEEKS OF AGE AND WEIGHING MORE THAN 65 LBS ONLY}:

HOW TO APPLY:

1. (Remove (4) (four) (1cc) (tubes) along perforations.) {or} (Remove (2) (two) (2cc) (tubes) along perforations.) 2. Peel away plastic cover from cardboard. 3. Hold in upright position and point tip of tube up and away from user's face and body. 4. Tear away tip of tube at notch where indicated. 5. Part dog's hair between the shoulder blades. 6. Invert first tube over dog. 7. Squeeze the tube firmly and apply 2cc (2-1cc tubes) (1-2cc tube) to the skin of the dog's back between the shoulder blades. Apply another 2cc (2-1cc tubes) (1-2cc tube) to the dog's skin directly in front of the base of the tail. SEE DOSING CHART on side panel. 8. When application is complete, follow Pesticide Disposal under Storage and Disposal section.

[graphic of how to open and apply product]

{text denotes notes to reviewer}; [text denotes optional text]; (denotes alternate presentation of the same claim/statement)

PRIMARY CARTON – RIGHT SIDE PANEL STATEMENTS

Exspot® Insecticide for Dogs

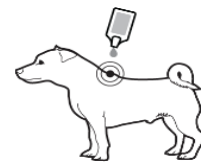
DOSING CHART

Follow the appropriate instructions

{Note to Reviewer: Only one of the three sizes would be present on the container label.}

SMALL DOGS

**Dosage for Small Dogs and Puppies
(4 weeks and older) weighing at least
17 lbs (7.7 kg) but less than 33 lbs (15 kg) only:**
Apply (1) (one) (cc) (1 tube) of
EXSPOT® Insecticide solution
to the skin of the dog's back
between the shoulder blades.



(or similar image)

LARGE DOGS

**Dosage for Large Dogs and Puppies
(4 weeks and older) weighing greater than
33 lbs (15 kg) up to 65 lbs (29 kg) only:**
Apply (1) (one) (cc) (1 tube) of
EXSPOT® Insecticide solution to the skin of the dog's
back between the shoulder blades and (1 cc) (1 tube) to the
skin of the dog's back directly in front of the base of the tail

Dog graphic
(large dog graphic with two
application sites – shoulder
and base of tail)

EXTRA LARGE DOGS

**Dosage for Extra Large Dogs
weighing more than 65 lbs (29 kg) only:**
When packaged with 1cc tubes, apply 2 cc (2-1cc tubes) of EXSPOT®
Insecticide solution to the skin of the dog's back between the shoulder
blades and 2cc (2-1cc tubes) to the skin of the dog's back directly in front of the base of the tail
--or--
When packaged with 2cc tubes, apply 2cc (1-2cc tube) of EXSPOT® Insecticide Solution to the skin of the dog's
back between the shoulder blades and 2cc (1-2cc tube) to the skin of the dog's back directly in front of the base of
the tail

Dog graphic
(extra large dog graphic with
two application sites –
shoulder and base of tail)

If you have any questions, call Technical Services at 1-800-TIC-FLEA or 1-800-842-3532.

Or visit our web site at www.defendpets.com

EPA Reg. No. 773-73 EPA Est. No. 618-LA-1 Made in the USA
U.S. Patent Nos. 5,344,018 & 5,236,954.
Intervet Inc (d/b/a Merck Animal Health), 2 Giralda Farms, Madison, NJ 07940 (LOGO Merck Animal
Health)

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{text denotes notes to reviewer}; [text denotes optional text]; (denotes alternate presentation of the same claim/statement)

APPLICATOR TUBE LABELING
{Labeling Text Printed directly onto the applicator tube}
{Size of tube: 1.25 in x 0.50 in}

Exspot® Insecticide for Dogs

Administration: Refer to outer container and package insert for dosing instructions.

For Dogs (and) (or) puppies 4 weeks and older and
[over (>) (greater than) 17 lbs (pounds) [(7.7 kg)] and (up to) (less than or equal to) 33 lbs (pounds) [(15 kg)]
ONLY]

[over (>) (greater than) 33 lbs (pounds) [(15 kg)] and (up to) (less than or equal to) 65 lbs (pounds) [(29 kg)]
ONLY]

[over (>) (greater than) 65 lbs (pounds) [(29 kg)] ONLY]

DO NOT USE ON CATS – May be Fatal

See Package Label for Details. Read the entire label before using.

Net Contents: [1cc (0.034 fl. oz.) [(1.0 mL)]]

[2cc (0.068 fl. oz.) [(2.0 mL)]]

LOGO Merck Animal Health

Lot No:

Exp:

FOIL POUCH LABELING

{Labeling text printed on pouch containing applicator}
{Size of applicator foil pouch: 3.50 in x 1.50 in}

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

Exspot® Insecticide for Dogs

For Use on Dogs and Puppies Only

Permethrin.....65%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ ENTIRE LABEL BEFORE USE

For Dogs (and) (or) puppies 4 weeks and older and

[over (>) (greater than) 17 lbs (pounds) [(7.7 kg)] and (up to) (less than or equal to) 33 lbs (pounds) [(15 kg)] ONLY]

[over (>) (greater than) 33 lbs (pounds) [(15 kg)] and (up to) (less than or equal to) 65 lbs (pounds) [(29 kg)] ONLY]

[over (>) (greater than) 65 lbs (pounds) [(29 kg)] ONLY]

DO NOT USE ON CATS – May be Fatal

OR



Net Contents: [1cc applicator (0.034 fl. oz.) [(1.0 mL)]]
[2cc applicator (0.068 fl. oz.) [(2.0 mL)]]

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

EPA Reg. No. 773-73

EPA Est. No. 618-LA-1

Lot No:

Exp:

{text denotes notes to reviewer}; [text denotes optional text]; (denotes alternate presentation of the same claim/statement)

{OTHER APPROVED LABEL CLAIMS}

-[Exclusive Patented Formula – 65% Permethrin]

-[Kills, repels, and prevents re-infestation of fleas and ticks, kills and repels mosquitoes, lice, and mites on dogs and puppies.]

-[Can be used on puppies as young as 4 weeks of age]

Features	Proticall® Insecticide
Dosing Method	Spot On
Active Ingredient	65% Permethrin
Kills, Repels and Prevents Re-infestation of Adult Fleas	For up to 5 weeks
Kills, Repels and Prevents Re-infestation of Ticks	For up to 6 weeks
Kills and Repels Mosquitoes, Dog Lice and Mites	For up to 4 weeks
Age Restrictions	Over 4 weeks