



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:

3/28/22

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 02/12/2024

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 4
Invertebrate-Vertebrate Branch 1
Registration Division
Office of Pesticide Programs

Date:

3/28/22

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 02/12/2024.
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 02/07/2014.
4. Submit one copy of the final printed label for the record before you release the product for shipment.

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin Interim Decision, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

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 Vanessa Emerson by phone at 202-566-2663, or via email at emerson.vanessa@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.}

Exspot® Insecticide for Dogs
EPA Reg. No. 773-73
Amended Version – 6.5 (Spot-On Time-Limited Registration Renewal to 2022 and Permethrin Reg. Review)

DATED: February 2, 2022
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{“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

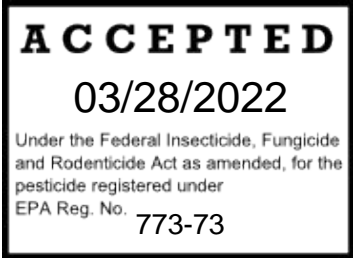
Kills, repels, and prevents re-infestation of fleas on dogs for 5 weeks
Kills, repels, and prevents re-infestation of ticks on dogs for 6 weeks
Kills and repels mosquitoes, lice, and mites on dogs for 4 weeks

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 >17-33 lb} 1 [applicator][tube]: 0.034 fl. oz. [1.0 mL] [1cc]
2 [applicators] [tubes]: each 0.034 fl. oz. [1.0 mL] [1cc] Total 0.068 fl. oz. [2.0 mL] [2cc]
3 [applicators] [tubes]: each 0.034 fl. oz. [1.0 mL] [1cc] Total 0.102 fl. oz. [3.0 mL] [3cc]

{large dog >33-65 lb} 1 [applicator][tube]: 0.068 fl. oz. [2.0 mL] [2cc]
2 [applicators] [tubes]: each 0.068 fl. oz. [2.0 mL] [2cc] Total 0.136 fl. oz. [4.0 mL] [4cc]
3 [applicators] [tubes]: each 0.068 fl. oz. [2.0 mL] [2cc] Total 0.204 fl. oz. [6.0 mL] [6cc]

{extra large dog >65 lb} 1 [applicator][tube]: 0.136 fl. oz. [4.0 mL] [4cc]
2 [applicators] [tubes]: each 0.136 fl. oz. [4.0 mL] [4cc] Total 0.272 fl. oz. [8.0 mL] [8cc]
3 [applicators] [tubes]: each 0.136 fl. oz. [4.0 mL] [4cc] Total 0.408 fl. oz. [12.0 mL] [12cc]

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Amended Version – 6.5 (Spot-On Time-Limited Registration Renewal to 2022 and Permethrin Reg. Review)

{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 with multiple applicators per package. Total volume will correspond to number of applicators.}

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 front panel of the final printed label.}

DO NOT USE ON CATS
{A 1.5 x 1.5 cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow with black images and text.}



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{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 dogs. If signs of sensitivity occur, discontinue use, bathe your dog 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 by mouth 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.

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{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 located at the lower right hand corner of the back panel in yellow with black images and text.}



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{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:** Do not pour or dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options. 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	5 weeks
Deer Ticks a vector of Lyme disease (<i>Ixodes scapularis</i>)	6 weeks
Brown Dog Ticks (<i>Rhipicephalus sanguineus</i>)	6 weeks
American Dog Ticks (<i>Dermacentor variabilis</i>)	6 weeks
Lone Star Ticks (<i>Amblyomma americanum</i>)	6 weeks
Mosquitoes a vector of heartworm (<i>Aedes aegypti</i>)	4 weeks
Dog lice (<i>Trichodectes canis</i>)	4 weeks
Mites (<i>Cheyletiella yasguri</i>)	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.}

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{PRIMARY CARTON – 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. For indoor use only. Application of product on dogs must only be done indoors. Use only on dogs and puppies 4 weeks and older and weighing [over 17 lbs and less than 33 lbs] [over 33 lbs and less than 65 lbs] [over 65 lbs] ONLY.

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 one tube regardless of the dog's weight.

{Note to Reviewer: Only one of the sets of directions corresponding to dog size/applicator volume will appear on the container label.}

{1.0 ML TUBE DIRECTIONS FOR DOGS AND PUPPIES OLDER THAN 4 WEEKS OF AGE AND WEIGHING > 17 LBS BUT ≤ 33 LBS ONLY}: HOW TO APPLY:

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

{2.0 ML TUBE DIRECTIONS FOR DOGS AND PUPPIES OLDER THAN 4 WEEKS OF AGE AND WEIGHING > 33 LBS BUT ≤ 65 LBS ONLY}: HOW TO APPLY:

Remove tube along perforations. Hold tube in upright position. Point tip of tube up and away from user's face and body. Cut across tip where indicated. Part dog's hair between the shoulder blades until skin is visible. Invert tube over dog. Squeeze the applicator [tube] firmly and apply entire contents of tube evenly to two spots on the back starting between the shoulder blades and ending at the base of the tail. SEE DOSING CHART on side panel. Place the tip of the applicator [tube] on the skin and gently squeeze half of the contents at each spot ensuring applicator is emptied at the second spot. Do not apply an excessive amount of solution at either spot. Do not allow product to run off. When application is complete, follow instructions in the Storage and Disposal section.

{4.0 ML TUBE DIRECTIONS FOR DOGS AND PUPPIES OLDER THAN 4 WEEKS OF AGE AND WEIGHING MORE THAN 65 LBS ONLY}: HOW TO APPLY:

Remove tube along perforations. Hold tube in upright position. Point tip of tube up and away from user's face and body. Cut across tip where indicated. Part dog's hair between the shoulder blades until skin is visible. Invert tube over dog. Squeeze the applicator [tube] firmly and apply entire contents of tube evenly to four spots on the back starting from between the shoulder blades and ending at the base of the tail. SEE DOSING CHART on side panel. Place the tip of the applicator [tube] on the skin and gently squeeze a quarter 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. When application is complete, follow instructions in the Storage and Disposal section.

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DOSING CHART

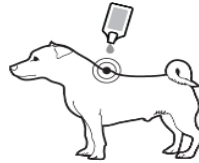
{Note to Reviewer: Only one of the three sizes would be present on the container label.}

{1.0 mL size only}

SMALL DOGS

Dosage for Small Dogs and Puppies

(4 weeks and older) weighing [at least] [greater than] [>]
17 lbs (7.7 kg) [up to] [-] 33 lbs (15 kg) only:



{2.0 mL size only}

LARGE DOGS

Dosage for Large Dogs and Puppies

(4 weeks and older) weighing [at least] [greater than] [>]
33 lbs (15 kg) [up to] [-] 65 lbs (29 kg) only:

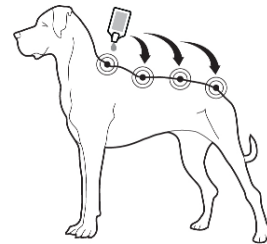


{4.0 mL size only}

EXTRA LARGE DOGS

Dosage for Extra Large Dogs

(4 weeks and older) weighing [greater than] [more than] [>]
65 lbs (29 kg) only:



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. XXX 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
Copyright XXXX, Intervet Inc. All rights reserved. Rev. xxx

{Optional LOGO Merck Animal Health – see below}



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

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

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

0.136 fl. oz. (4.0 mL) [4cc]

{Optional LOGO Merck Animal Health – see below}



Lot No:

Exp:

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{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}



{Note to reviewer: The cat prohibition icon, yellow background with black images and text, will appear on the applicator packaging and/or the applicator itself.}

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

0.034 fl. oz. (1.0 mL) [1cc]
0.068 fl. oz. (2.0 mL) [2cc]
0.136 fl. oz. (4.0 mL) [4cc]

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

EPA Reg. No. 773-73 EPA Est. No. XXX

Lot No:

Exp:

{Optional LOGO Merck Animal Health – see below}



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{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 and weighing [over 17 lbs and less than 33 lbs] [over 33 lbs and less than 65 lbs] [over 65 lbs] ONLY]

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