

773-73

3/19/2015

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 19, 2015

Mr. Micah T. Reynolds
Regulatory Consultant for
Intervet, Inc. (d/b/a Merck Animal Health)
c/o Technology Sciences Group, Inc.
1150 18th Street N.W., Suite 1000
Washington, DC 20036-3840

Subject: Amended Reregistration Label
Product Name: Exspot® Insecticide for Dogs
EPA Registration Number: 773-73
EPA Decision Number(s): D413185
Your E-Submissions Dated March 10, 2015 & March 18, 2015

Dear Mr. Reynolds:

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 reregistration of the referenced product in connection with the **RED for Permethrin**, and has concluded that your submission is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

PLEASE NOTE: This product is not being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR §152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR §152.3.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

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If you have any questions about this letter, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov during the hours of 9:00 A.M. to 5:30 P.M. EST.

Sincerely Yours,



Richard J. Gebken
Product Manager (10)
Invertebrate & Vertebrate Branch 2
Registration Division (7504P)

Enclosure: Label stamped "Accepted," dated March 19, 2015

000773-00073 D413185

3/11

“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

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

Only for use on puppies and dogs over (>) (greater than) 17 lbs (pounds) (7.7 kg). Use only on puppies 4 weeks and older.

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 ADDITIONAL PRECAUTIONARY STATEMENTS

Contains: Three (or Two) 1-Month Doses

Net Contents: Three 1cc applicators, [each 0.034 fl. oz. (1.0 mL)]
Three 2cc applicators, [each 0.068 fl. oz. (2.0 mL)]
Two 4cc applicators, [each 0.135 fl. oz. (4.0 mL)]
Twelve 1cc applicators, [each 0.034 fl. oz. (1.0 mL)]

[Sold Only Through Veterinary Clinics]

[Net Contents: Six 1cc applicators, each 0.034 fl. oz. (1.0 mL)]

ACCEPTED
March 19, 2015
Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for the
pesticide registered under:

EPA. Reg. No: 773-73

DO NOT USE ON CATS
[CAT WARNING ICON, Min.
1.5x1.5 cm]
Yellow background with black text/image

EXCLUSIVE PATENTED FORMULA

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.

4/11

PRIMARY CARTON - BACK PANEL STATEMENTS

Exspot® Insecticide for Dogs

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

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: Do not use this product in households with both dogs and cats. Consult a veterinarian before using this product on debilitated, aged, or 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.

DO NOT USE ON CATS. May be toxic or potentially 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. 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.	

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.
[CAT WARNING ICON, Min. 1.5x1.5 cm]
Yellow background with black text/image

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

5/11

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.

CONTAINER DISPOSAL: 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.

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. Repeat applications may be made as necessary, but do not apply at intervals less than 7 days. **DO NOT USE ON CATS.**

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

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

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

6/11

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. **DO NOT USE ON CATS.** Exspot® Insecticide for Dogs may be used on puppies as young as 4 weeks of age. Do not allow your dog to ingest this product. Do not apply to dogs weighing less than 17 lbs (7.7 kg).

HOW TO APPLY:

1. Remove tube(s) 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 the specified amount of solution to the skin of the dog's back between the shoulder blades. For large and extra large dogs, another application of the solution to the dog's skin directly in front of the base of the tail is also required. SEE DOSING CHART on other panel.
8. When application is complete, follow instructions in the Storage and Disposal section.

OR

HOW TO APPLY:

1. Remove tube(s) 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 tube over dog.
7. Squeeze the tube gently and apply the specified amount of solution to the skin of the dog's back between the shoulder blades. For large and extra large dogs, another application of the solution to the dog's skin directly in front of the base of the tail is also required. SEE DOSING CHART on other panel.
8. When application is complete, follow Pesticide Disposal under Storage and Disposal section.

(graphic of how to open and apply product)

7/11

PRIMARY CARTON – RIGHT SIDE PANEL STATEMENTS

Exspot® Insecticide for Dogs

DOSING CHART

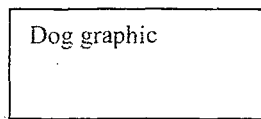
Follow the appropriate instructions
Based on your pet's weight

PUPPIES

Dosage for Puppies

**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.



(large puppy graphic)

SMALL DOGS

Dosage for Small Dogs

**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.



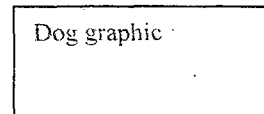
(or similar image)

LARGE DOGS

Dosage for Large Dogs

**weighing greater than 33 (15 kg)
up to 65 lbs (29 kg) only:**

Apply 1 cc (1 tube) of
EXSPOT® Insecticide
solution to the skin of the dog's back
and 1 cc (1 tube) to the skin of the dog's
back directly in front of the base of the tail



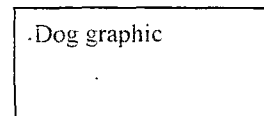
(large dog graphic w/ two application sites)

EXTRA LARGE DOGS

Dosage for Extra Large Dogs

weighing 66 lbs (30 kg) or more only:

Apply 2 cc (2 tubes or 1-2cc tube) of
EXSPOT® Insecticide
solution to the skin of the dog's back
and 2 cc (2 tubes or one-2cc tube) to the skin of
the dog's back directly in front of the base of the tail



(X-large dog graphic w/ two application sites)

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

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

8/11

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), Summit, NJ 07901 (LOGO Merck Animal Health)
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9/11

APPLICATOR TUBE LABELING

(Size: 1.25 in x 0.50 in)

Exspot® Insecticide for Dogs

Administration: 1 tube for Puppies and Small Dogs; 2 tubes for Large Dogs; 4 tubes for XL Dogs.
Only for use on puppies and dogs over (>) (greater than) 17 lbs (pounds) (7.7 kg). Use only on puppies 4 weeks and older.

Cat Warning Icon and/or DO NOT USE ON CATS

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)
 - 4cc (0.135 fl. oz.) (4.0 mL)

LOGO Merck Animal Health

Lot No:

Exp:

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

10/
11

APPLICATOR PACKAGE LABELING

(Size: 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

Administration: 1 tube for Puppies and Small Dogs; 2 tubes for Large Dogs; 4 tubes for XL Dogs.
Only for use on puppies and dogs over (>) (greater than) 17 lbs (pounds) (7.7 kg). Use only on puppies 4 weeks and older.

Cat Warning Icon and/or DO NOT USE ON CATS

Net Contents: Three 1cc applicators, [each 0.034 fl. oz. (1.0 mL)]
Three 2cc applicators, [each 0.068 fl. oz. (2.0 mL)]
Two 4cc applicators, [each 0.135 fl. oz. (4.0 mL)]
Twelve 1cc applicators, [each 0.034 fl. oz. (1.0 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:

11/11

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
- Can be used on pregnant or nursing dogs
- 12 applicator package provides 3 to 12 months protection depending on size of the dog

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

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