

773-73

2 / 7 / 2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Donna Martino
Intervet, Inc.
556 Morris Ave, S5-2145A
Summit, New Jersey 07901

FEB / 7 2014

Subject: Proticall Insecticide for Dogs
EPA Reg. No. 773-73
Submission dated 4/27/2012 implementing label changes to pet spot-on products
EPA Decision No. 472578

Dear Ms. Martino,

The labeling referred to above submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is **acceptable**. With this letter, the label requirements listed in the EPA letter "Implementation of Label Changes to Pet Spot-On Products" dated September 30, 2011, are fulfilled. 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. This registration is now time-limited and expires two years from the date of this letter.

Per email correspondence of January 15, 2014, it is our understanding that this product is not currently marketed by Intervet. If Intervet intends to market this product in the future, the additional requirements of September 30, 2011 must be fulfilled. These requirements include the submission of final printed labels, quarterly enhanced incident reports, and quarterly sales information in doses sold for this product, along with an analysis of the incidents reported. The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the attention of Kaitlin Keller, Pesticide Re-evaluation Division, Mail Code 7508P.

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

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 dogs and table for cats 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.
- 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

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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.

- Table showing number of incidents for each dog breed.
- 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.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this label, please contact Kaitlin Keller at (703) 308-8172 via email at keller.kaitlin@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Insecticide Branch
Registration Division (7504P)

Enclosure: Label stamped "Accepted"

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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

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

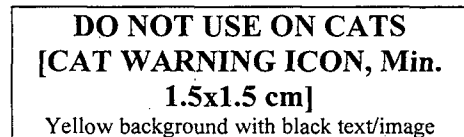
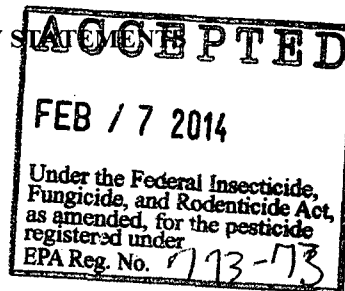
*Cis/trans ratio: Max. 55% (±) cis and Min. 45% (±) trans

**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)]



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.

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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.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, 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. 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. 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 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.

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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.]

STORAGE: Store in a cool, dry place inaccessible to children and pets. Protect from freezing.

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. Exspot® Insecticide demonstrates greater than 92% control of fleas within 3 days of application. As with all flea and tick control products. EXSPOT® Insecticide should be used as part of a control program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel and yard). Consult your veterinarian or entomologist for program recommendations. 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.

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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)

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

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PRIMARY CARTON – RIGHT SIDE PANEL STATEMENTS

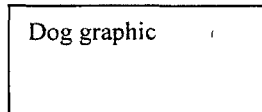
Exspot® Insecticide for Dogs

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

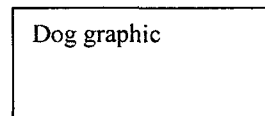
Dosage for Small Dogs
weighing at least 17 lbs (7.7 kg)
but less than 33 lbs (15 kg) only:
Apply 1 (one) cc (1 tube) of
EXSPOT® Insecticide solution
to the skin of the dog's back
between the shoulder blades.



(or similar image)

LARGE DOGS

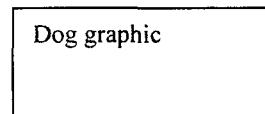
Dosage for Large Dogs
weighing greater than 33 (15 kg)
up to 65 lbs (29 kg) only:
Apply 1 cc (1 tube) of
EXSPOT® Insecticide
solution to the skin of the dog's back
and 1 cc (1 tube) to the skin of the dog's
back directly in front of the base of the tail



(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.

Or visit our web site at www.defendpets.com

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

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

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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:

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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:

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

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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
- 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.