



773-73

12/12/2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 12 2002

Ms. Diane deBruin
Schering-Plough Animal Health Corp.
1095 Morris Avenue
Union, NJ 07083-1982

Subject: Amendment Updating Disposal per PR Notice 2001-6 and Revising Application
Directions
Exspot® Insecticide for Dogs
EPA Reg. No. 773-73
Your Submission Dated September 23, 2002, as Amended by Email on
December 6, 2002 and December 12, 2002

Dear Ms. deBruin:

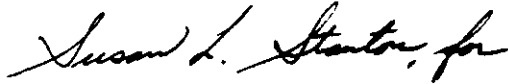
The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. The general misuse statement ("It is a violation of Federal law to use this product in a manner inconsistent with its labeling") must appear immediately after the "Directions for Use" heading in accordance with 40 CFR §156.10.
2. The statement "Do not use this product in or on electrical equipment due to the possibility of shock hazard" must be moved to the "Physical or Chemical Hazards" section of the label.
3. In the First Aid Statements, change "If On Skin" to "If On Skin or Clothing" as specified in PR Notice 2001-1.
4. In the "Storage and Disposal" section, delete the "Pesticide Disposal" instructions and change the heading "Container Disposal" to "Disposal" in accordance with PR Notice 2001-6.

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If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,



George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

FRONT PANEL

Exspot® Insecticide for Dogs

Alternate Brand Names: Defend® Exspot Treatment for Dogs, Defend® Exspot Insecticide for Dogs or 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

Graphics

ACTIVE INGREDIENT:

Permethrin*65%

OTHER INGREDIENTS:35%

Total.....100% wt/wt

*Cis/trans ratio: Max 55% (+) cis and min. 45% (+) trans; CAS #52645-53-1

**KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE INSIDE PANELS FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

**ACCEPTED
with COMMENTS
In EPA Letter Dated:
DEC 12 2002**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
773-73**

EXCLUSIVE PATENTED FORMULA

Contains: Three (or Two) 1- Month Doses
Net Contents: Three 1cc Applicators
Or
Net Contents: Three 2 cc Applicators
Or
Net Contents: Two 4 cc Applicators
Or
Net Contents: Twelve 1 cc Applicators

**DO NOT USE ON
CATS
Graphic (Cat Icon)**

Or

Sold Only Through Veterinary Clinics
Net Contents: Six 1 cc Applicators

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Exspot® Insecticide for Dogs

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
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

If you have any questions, call Schering-Plough Animal Health Technical Services at 1-800-TIC-FLEA or 1-800-842-3532. Or visit our web site at www.defendpets.com

U.S. Patent Nos. 5,344,018 & 5,236,954.

EPA Reg. No. 773-73
EPA Est. No. 6175-LA-1

Schering-Plough Animal Health Corp.
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Exspot® Insecticide for Dogs**DIRECTIONS FOR USE**

Use direction Picture 1

Use direction Picture 2

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 recommended 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 RECOMMENDED DOSING GUIDELINES BELOW.
8. When application is complete, follow Pesticide Disposal under 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 recommended 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 RECOMMENDED DOSING GUIDELINES BELOW.
9. When application is complete, follow Pesticide Disposal under Storage and Disposal section.

PACKAGE FOR PUPPIES OR SMALL DOGS

Dosage for dogs weighing 33 lbs. (15 kg) or less:

Apply 1 cc (1 tube) of EXSPOT Insecticide solution to the skin of the dog's back between the shoulder blades.

PACKAGE FOR LARGE DOGS

Dosage for dogs weighing 33 to 65 lbs. (15 to 29 kg):

Apply 1 cc (1/2 of 2cc tube) of EXSPOT Insecticide solution to the skin of the dog's back and 1 cc (1/2 of 2cc tube) to the skin of the dog's back directly in front of the base of the tail.

PACKAGE FOR EXTRA LARGE DOGS

Dosage for dogs weighing 66 lbs. (30 kg) or more:

INSIDE PANELS

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Apply 2 cc (1/2 of 4cc tube of EXSPOT Insecticide solution to the skin of the dog's back and 2 cc (1/2 of 4cc tube) to the skin of the dog's back directly in front of the base of the tail.

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Exspot® Insecticide for Dogs

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

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
DO NOT ON CATS. May be toxic and potentially fatal if applied to or ingested by cats. Do not use this product in or on electrical equipment due to the possibility of shock hazard.
EXSPOT Insecticide for Dogs may be used on puppies as young as 4 weeks of age.

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

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation.
Avoid contact with the skin, eyes or clothing. Wash thoroughly with soap and water **after handling**.

DO NOT USE ON CATS. Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effect. 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.

Exspot® Insecticide for Dogs

FIRST AID	
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 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 physician if irritation persists.
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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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.	

Adverse Reactions:

Some animals may be sensitive to ingredients in this product. Reported reactions in dogs have included skin sensitivity, increased itchiness, redness or rash. Hair discoloration or hair loss at the application site

may occur. Dogs may also show lethargy. Observe the dog following treatment. 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.

ENVIRONMENTAL HAZARDS

The product is extremely toxic to fish. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in cool, dry place. Protect from freezing. **Pesticide Disposal:** Securely wrap original container in several layers of newspaper and discard in trash.

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 or 1-800-XXX-XXXX for disposal instructions. Never place unused product 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. Defend® EXSPOT Insecticide 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.**

NOTICE OF WARRANTY

Schering-Plough Animal Health Corp. 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.

Kills, Repels and Prevents Re-infestation of Fleas and Ticks, Kills and Repels Mosquitoes, Lice and Mites on Dogs and Puppies

- Exclusive Patented Formula – 65% Permethrin
- 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 upon size of the dog.

(Applicator location)	(Applicator location)	(Applicator location)
(Cat Icon and/or use directions) Do Not Use on Cats	(Cat Icon and/or use directions) Do Not Use on Cats	(Cat Icon and/or use directions) Do Not Use on Cats
Schering-Plough Animal Health Corp.	Schering-Plough Animal Health Corp.	Schering-Plough Animal Health Corp.

Exspot® Insecticide for Dogs

Approved label claims

Features	Defend Exspot
Availability	OTC
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

DO NOT
USE ON
CATS
Cat Icon

Bar Code

Lot No

APPLICATOR TUBE (Size: 1.25in x .50in)

Front Tube Panel Text:

Permethrin
Insecticide 65%

Back Tube Panel Text:

KEEP OUT OF REACH OF CHILDREN
Read Directions and
Precautions Before Use

APPLICATOR PACKAGE (Size: 3.50in x 1.50in)

Front: Applicator visible through clear plastic.

Back:

DEFEND EXspot treatment for Dogs/Contents: 1 cc of 65% Permethrin per tube.
Exspot Administration: 1 tube for Puppies and Small Dogs; 2 tubes for Large Dogs;
Treatment for 4 tubes for XL Dogs. See Package Label for Details
Dogs
Read the entire label before using (Cat warning icon). **DO NOT USE ON CATS**
LOGO May be harmful if applied or
Schering-Plough Animal Health ingested by cats