

PM 03

773-73

4-28-98

10/4

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 05-31-98

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number 258055
	<b>Application for Pesticide - Section I</b>		

1. Company/Product Number <b>773-73</b>	2. EPA Product Manager <b>S. LEWIS GEORGE T. LARocca</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>EXSPOT<sup>®</sup> INSECTICIDE FOR DOGS</b>	PM# # <b>03</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>SCHERING-PLOUGH ANIMAL HEALTH CORP. 1095 MORRIS AVENUE UNION, N.J. 07083-7143</b>	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <b>NOTIFICATION</b> Product Name <b>APR 28 1998</b>	
<input type="checkbox"/> Check if this is a new address		

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

SEE FOLLOWING PAGE      ADD PEST

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If "Yes" Unit Packaging wgt. <b>1cc</b>	No. per container <b>2 &amp; 6</b>	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
Certification must be submitted		If "Yes" Package wgt. _____ No. per container _____	If "Yes" Package wgt. _____ No. per container _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <b>2x1cc and 6x1cc</b>		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled			<input checked="" type="checkbox"/> Other <b>THE LABEL IS CARBOARD AND THE RETAIL PACKAGE TO WHICH THE AMPOULES ARE FIXED</b>		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name <b>DR. IAIN WEATHERSTON</b>	Title <b>SENIOR REGULATORY CONSULTANT</b>	Telephone No. (Include Area Code) <b>(847)-265-9840</b>
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Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title <b>SENIOR REGULATORY CONSULTANT</b>	
4. Typed Name <b>IAIN WEATHERSTON</b>	5. Date <b>APRIL 15, 1998</b>	

EPA FORM 8570-1

SECTION - II

Explanation:

This is a notification of the addition of a claim for the control of the dog louse [*Trichodectes canis*] to the label of EXspot® Insecticide for Dogs, as per PR-Notice 95-2.

"This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. §1001 to wilfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under §§ 12 and 14 of FIFRA."

# Defend<sup>®</sup>

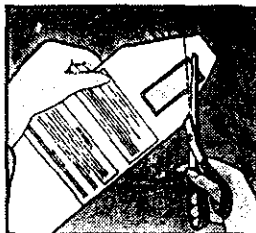
EXspot<sup>®</sup> INSECTICIDE FOR DOGS

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS.

DIRECTIONS FOR USE

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



**HOW TO APPLY**

Hold card in upright position. Point tip of tube cap up and away from user's face and body, then cut along dotted line. Invert card over dog and use point of card to part the hair of dog. Squeeze the tube firmly to apply all of the solution to the dog's skin. Wrap container and put in trash.

**Dosage for Dogs Weighing 33 Pounds or Less:**

Apply 1 (one) cc of Defend<sup>®</sup> EXspot<sup>®</sup> Insecticide solution to the skin of the dog's back between the shoulder blades.

**Dosage for Dogs Weighing More than 33 Pounds:**

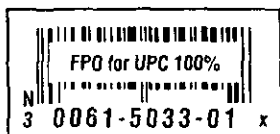
Apply 1 (one) cc of Defend<sup>®</sup> EXspot<sup>®</sup> Insecticide solution to the skin of the dog's back between the shoulder blades and apply 1 (one) cc of Defend<sup>®</sup> EXspot<sup>®</sup> Insecticide solution to the skin of the dog's back directly in front of the base of the tail.

If you have any additional questions, phone 1-800-TIC-FLEA or 1-800-842-3532.



Schering-Plough Animal Health

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KILLS & REPELS\*  
\*U.S. Patent No. 5,236,954  
& other Patent Pending  
EPA Reg. No. 773-73  
EPA Est. No. 6175-LA-1

Contains: Two 1 cc Applicators

0061-5033-01



# Defend<sup>®</sup>

EXspot<sup>®</sup> INSECTICIDE FOR DOGS

FOR USE ON DOGS AND PUPPIES  
KILLS AND REPELS\*

**Kills and Repels fleas up to 4 Weeks**

**Kills and Repels Deer Ticks (Ixodes scapularis)  
Vector of LYME DISEASE up to 4 Weeks**

**Kills and Repels Mosquitoes  
Aids in Prevention of Blood Feeding by Mosquitoes  
(Vector of HEARTWORM) up to 4 Weeks**

**Kills and Repels Dog Lice  
(Trichodectes canis) for up to 4 Weeks**

**Kills and Repels Brown Dog Ticks  
(Rhipicephalus sanguineus) up to 4 Weeks**

**Kills and Repels American Dog Ticks  
(Dermacentor variabilis) for 2 to 3 Weeks**

**Kills and Repels Lone Star Ticks  
(Amblyomma americana) for 2 to 3 Weeks**

Contains: Two-1cc Applicators

**Active Ingredients**

Permethrin, [3-phenoxyphenyl] methyl (z)-cis, trans-3-(2, 2-dichloro-ethyl)-2, 2-dimethylcyclopropane-carboxylate

Inert Ingredients

Total 100% wt./wt.

\*CIS:trans ratio: Max 55% (z) cis and min. 45% (z) trans

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

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NOTIFICATION  
APR 28 1998

3044

### STORAGE AND DISPOSAL

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

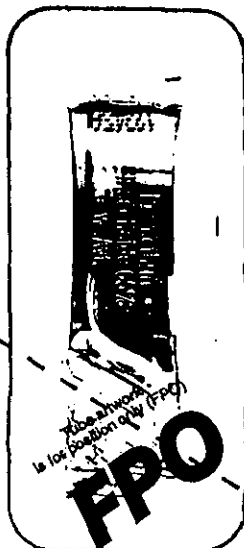
**Storage:** Store in cool, dry place. Protect from freezing. **Pesticide Disposal:** Securely wrap original container in several layers of newspaper and discard in trash. **Container Disposal:** Do not reuse empty container. Wrap container and put in trash.

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

**EMERGENCY:** Contact Rocky Mountain Poison Center (303) 595-4869.



Package  
Patent  
Pending



Package  
Patent  
Pending



CUT  
HERE

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

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with 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 toxic exposure. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing 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, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

### STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger or, if available, by administration of syrup of ipecac. **DO NOT INDUCE VOMITING OR GIVE ANYTHING BY MOUTH TO ANY UNCONSCIOUS PERSON.** If On Skin: Remove contaminated clothing and wash with plenty of soap and water. Call a physician if irritation persists. If In Eyes: Flush eyes with plenty of water. Call a physician if irritation persists. **Adverse Reactions:** Some animals may be sensitive to ingredients in this product. Reported reactions in dogs have included skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site may occur. Dogs may also show lethargy. Observe the dog following treatment, if sensitivity to Defend® EXspot® Insecticide For Dogs occurs, discontinue use and bathe the dog. 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.

KEEP OUT OF REACH OF CHILDREN  
CAUTION

4/98