



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

FEB - 2 2000

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Joseph Pavelchak
Schering-Plough Animal Health Corporation
1095 Morris Avenue
P.O. Box 3182
Union, New Jersey 07083-1982

) SUBJECT: Request to Amend Label
Add Claim for Extra Large Dogs and Mites
Exspot® Insecticide
EPA Reg. No. 773-73
Your Submissions Dated November 2 and November 11, 1999

Dear Mr. Pavelchak:

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

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1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. Under PRECAUTIONARY STATEMENTS, revise the IF IN EYES section to read: "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."
 - b. Add the following statement near the first aid statements: "Have the product container or label with you when calling a poison control center or doctor or going for treatment."
 - c. The efficacy data that you submitted (MRID 44964601) indicates that for the deer tick and brown dog tick protection times, the appropriate protection claim for this

product is 3 to 4 weeks. Correct the table appearing on page 2 of the proposed label.

- d. The table on inside panel is misleading and unacceptable in that it implies product will control certain diseases of dogs. The product is for control of certain ectoparasites that may transmit certain diseases. It does not control these diseases. Therefore, delete the column under Problem in the table.
- e. Delete the pictures of children from the labeling. These pictures of children holding or hugging dogs is misleading in that the consumer may conclude that it is safe to handle the animal after treatment. The precautionary text states to avoid contact and wash after handling. We regret this was overlooked in our previous review.

3. We are accepting the mite claim on a conditional basis pending review of the efficacy data. We will notify you of any label changes necessary after that review is complete.

4. Submit two copies of your final printed labeling before you release the above referenced product for shipment.

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

A stamped copy of the labeling is enclosed for your records. If you have any questions regarding this letter, please contact Linda Werrell of my team at (703)308-8033.

Sincerely Yours,



George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division

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

Kills and Repels Fleas and Ticks, Mosquitoes, Mites and Lice on Dogs for up to 4 Weeks.

Graphics

ACTIVE INGREDIENT:

Permethrin*65%

INERT INGREDIENTS:.....35%

Total ... 100% wt/wt

*Cis/trans ration: Max 55% (+) cis and min. 45% (+) trans.

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Inside Panels for Additional Precautionary Statements

ACCEPTED FOR COMMENTS
Letter Dated
FEB -2 2000

Exclusive Patented Formula

Contains: Three 1-Month Doses
Net Contents: Three 1cc Applicators
Or
Net Contents: Three 2 cc Applicators
Or
Net Contents: Two 4 cc Applicators

Insecticide,
Available Act
Insecticide
No.
773-73

Not for Use on Cats
graphic

Or

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

Exspot[®] Insecticide for Dogs

Exspot Insecticide for Dogs Kills and Repels fleas, ticks, mosquitoes, mites and dog lice:

Insect	Problem	Protection
Fleas	Flea allergy dermatitis	Up to 4 weeks
Deer Ticks (<i>Ixodes scapularis</i>)	A vector of Lyme Disease	Up to 4 weeks
Brown Dog Ticks (<i>Rhipicephalus sanguineus</i>)	A vector of canine Ehrlichiosis	Up to 4 weeks
American Dog Ticks (<i>Dermacentor variabilis</i>)	A vector of Rocky Mountain Spotted Fever	2 to 3 weeks
Lone Star Ticks (<i>Amblyomma americanum</i>)	A vector of Babesiosis and Ehrlichiosis	2 to 3 weeks
Mosquitoes (<i>Aedes Aegypti</i>)	A vector of Heartworm	Up to 4 weeks
Dog lice (<i>Trichodectes canis</i>)	Dermatitis and secondary skin infections Degrades coat conditioning	Up to 4 weeks
Mites (<i>Cheyletiella yasguri</i>)	Dermatitis and secondary skin infections Degrades coat conditioning	Up to 4 weeks

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

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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Rev. 11/99

Exspot[®] Insecticide for Dogs

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

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.** 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. EXSPOT Insecticide for Dogs may be used on puppies as young as 4 weeks of age.

Use direction
Picture 1

Use direction
Picture 2

HOW TO APPLY:

Remove vial along perforations. Hold vial in upright position. Point tip of vial up and away from user's face and body. Cut along dotted line. Part dog's hair between the shoulder blades. Invert vial over dog. Squeeze the vial firmly to apply all of the solution to the dog's skin. Wrap the vial in newspaper and put in trash.

PACKAGE FOR PUPPIES OR SMALL DOGS

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

Apply 1 cc 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 vial) of EXSPOT Insecticide solution to the skin of the dog's back and 1 cc (1/2 of vial) 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:

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

Exspot[®] Insecticide for Dogs

**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 toxic exposure. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant 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 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.

Exspot[®] Insecticide for Dogs

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.

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. 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 and Repels Fleas, Ticks, Mosquitoes, Lice and Mites on Dogs and Puppies.

- Exclusive Patented Formula – 65% Permethrin
- Can be applied on Puppies as Young as 4 weeks of age
- Can be applied on pregnant or nursing dogs

HUMAN EMERGENCY: Contact Rocky Mountain Poison Center 303-595-4869.

(Applicator location)	(Applicator location)	(Applicator location)
(animal graphic with use directions)	(animal graphic with use directions)	(animal graphic with use directions)
Schering-Plough Animal Health	Schering-Plough Animal Health	Schering-Plough Animal Health

Exspot^R Insecticide for Dogs

Compare the approved label claims

Features	Defend Exspot
Availability	OTC
Dosing Method	Spot On
Active Ingredient	Permethrin
Kills Adult Fleas	X
Kills Ticks	X
Kills and Repels Mosquitoes	X
Kills Dog Lice*	X
Age Restrictions	X
Repels Adult Fleas	X
Repels Ticks	X
Kills Mites*	X
Age Restrictions	Over 4 weeks

Based on actual package labeling claims.

*Recently approved label claims.

Not for Use on Cats graphic

Bar code

Lot No.