

APR 8

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Mr. Joseph E. Dyer
Coopers Animal Health, Inc.
1201 Douglas Avenue
Kansas City, MO 66103-1438

Dear Mr. Dyer:

Subject: Submission of Target Animal Safety Data and Label
Revision
EXspot® for Dogs
EPA Registration No. 59-231
Your Application Dated July 15 1991 and
Your Notification Dated February 27, 1992

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling.

1. The proposed language for the Statement of Practical Treatment should be revised as follows:

Adverse Reactions: **Some animals may be sensitive to ingredients in this product.** Reported reaction in dogs has been skin sensitivity. Dogs may show lethargy, increased pruritus, erythema, rash and hair loss at the application site. **Dogs should be observed following treatment.** If sensitivity to EXspot® insecticide occurs, discontinue use and bathe the dog. Seek Veterinary Advice.

2. The safety data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, was also reviewed and found acceptable in support of the deletion of the claim "Do not use on dogs less than 6 months of age." Enclosed is a copy of the Toxicology Branch review for your records.

U.S.F. 2.1

This letter is also is to notify that:

a) The February 27, 1992 label revisions do not qualify as a Notification. According to PR Notice 88-6, any revisions of label language consistent with 40 CFR Part 156, which involves no change in the ingredients statement, precautionary statements or directions of use are considered a notification. Since you are changing precautionary statements, you should have submitted the revisions as a Section 3 amendment.

b) Because of the available data base on permethrin and the fact that the results of the domestic animal safety study did not show adverse effects. The Agency is classifying the study as acceptable. However in the future such a study will be classified as supplemental rather than acceptable because of the deficiencies noted in the conduct and reporting of the study. Refer to page 3 of the Toxicology Branch review for identification of these deficiencies.

Submit five copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

DRAFT
LABEL
FRONT PANEL

Contains: Two 1cc Applicators



EXspot® INSECTICIDE FOR DOGS

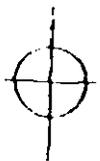
- Kills & Repels Fleas up to 4 Weeks
- Kills & Repels Deer Ticks (*Ixodes dammini*)
Vector of LYME DISEASE up to 4 Weeks
- Kills & Repels Brown Dog Ticks
(*Rhipicephalus sanguineus*) up to 4 Weeks
- Kills & Repels American Dog Ticks
(*Dermacentor variabilis*) for 2 to 3 Weeks

Contains: Two 1cc Applicators

Active Ingredient
 Permethrin (3-phenoxyphenyl) methyl (±)-cis
 trans-3-(2,2-dichloroethyl)-2,2-dimethylcy
 clopropanecarboxylate** 65%
 Inert Ingredients 35%
 ** cis/trans ratio 100%
 Max 55% (±) cis and min 45% (±) trans

Handwritten signature and date: Joseph E. Dyer 2/20/92

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



PANTONE®
3298 C



ACCEPTED
with COMMENTS
by EPA [unclear]

APR 8

Under the Federal Insecticide, and Fungicide, and Plant Repellent Act, as amended, for the registered under FIFRA 1

59-231

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DRAFT LABEL
INSIDE PANEL

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. **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.

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 administering syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person. If On Skin: Remove contaminated clothing and wash with plenty of soap and water. If In Eyes: Flush eyes with plenty of water. Call a physician if irritation persists. Adverse Reactions: An uncommon but reported reaction in dogs has been skin sensitivity. Dogs may show lethargy, increased pruritus, erythema, rash and hair loss at the application site. If sensitivity to EXspot insecticide occurs, discontinue use and bathe the dog. Seek Veterinary advice.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not add directly to water. Do not contaminate by disposing of equipment washwaters.

STORAGE AND DISPOSAL

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

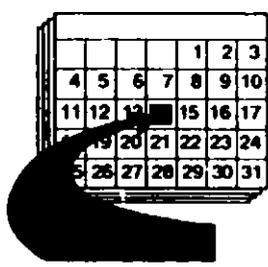
Storage: Store in a cool, dry place. Pesticide Disposal: Securely wrap original container in several layers of newspaper and discard in trash. Container Disposal: Do not reuse empty container. Wrap container and put in trash.

EXspot insecticide is an effective and easy to use product. EXspot insecticide demonstrates greater than 95% 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, yard). Consult your veterinarian or entomologist for program recommendations. If necessary, repeat applications may be made, but do not apply at intervals less than 7 days. Do not use on dogs less than 6 months of age.

DO NOT USE ON CATS.

NOTICE OF WARRANTY

COOPERS ANIMAL HEALTH, 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.



Joseph E. Dyer
2/20/92

DRAFT
LABEL
BACK PANEL



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.** 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.



HOW TO APPLY:

Hold card in upright position, cap pointing up and 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. Wrap container and put in trash.



Dosage for Dogs Weighing Less Than 33 pounds:
Apply 1 (one) cc of EXspot insecticide solution to dog's back between the shoulder blades.



Dosage for Dogs Weighing More Than 33 pounds:
Apply 1 (one) cc of EXspot insecticide solution to dog's back between the shoulder blades and apply 1 (one) cc of EXspot insecticide solution to the dog's back directly above the tail head area.

504441

Lot No.



Coopers Animal Health Inc
1201 Douglas Avenue
Kansas City, KS 66103-1438
U.S.A. 15-27-005A



KILLS & REPEATS
US Patent No. 4,020,181 - one Patent Pending
EPA Reg. No. 59-231 EPA Est. No. 47179 IL 001



Joseph E. Dyer
2-20-92