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

APR 20 1990

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCESMEMORANDUM

SUBJECT: EPA Reg. No.: 59-EGR. Permethrin: Review of the registration for the product EXspot for dogs. Review of a study demonstrating the safety of the product for dogs. Comments on the label regarding the use of this product on dogs.

TOX CHEM No.: 652BB  
TOX PROJECT No.: 9-1314  
Record No.: 242235  
MRID No.: 410569-06

FROM: John Doherty *John Doherty* 7/13/89  
Section I, Toxicology Branch I (IRS)  
Health Effects Division (H7509C)

TO: George LaRocca  
Product Manager #15  
Registration Division (H7505C)

THROUGH: Robert Zendzian *Robert Zendzian* 7/13/89  
Acting Section Head  
Section I, Toxicology Branch I (IRS)  
Health Effects Division (H7509C)

The Coopers Animal Health Co. is seeking to register their product EXspot For Dogs (refer to letters from Donald A. Buss dated March 14, 1989 and March 31, 1989). The only study submitted to Toxicology Branch-I (TB-I) for review at this time was a domestic animal safety study with dogs. The studies supporting the label signal word and precautionary statements were not sent to TB-I.

TB-I has reviewed the dog safety study (refer to DER attached) and determined that this study is ACCEPTABLE and demonstrates that the product is safe for use on dogs 6 months or older at 7 day intervals. The label of this product should be written to specifically state that the product should not be used on puppies (dogs less than 6 months old) or at intervals less than 7 days. The references to puppies or to dogs of any age must be deleted from the label. If the registrant wants to

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include the term puppies on the label, a study demonstrating the safety of this product on puppies must be provided. The ages of the puppies actually tested must be included in the study report.

The label (p.6) also states that the product is not contraindicated for use with other drugs and pesticides. This statement must be deleted from the label. The reference to "a wide margin of safety" must also be deleted.

TB-I cannot further evaluate the label for this product until the acute toxicity studies supporting the label and precautionary statements are provided. According to Mr. Buss's letter of March 31, 1989, these studies were submitted to the Agency.

Reviewed by: John Doherty *John Doherty* 7/13/89  
Section I, Toxicology Branch I (H7509C)  
Secondary reviewer: Robert Zendzian *Robert Zendzian* 7/17/89  
Section I, Toxicology Branch I (H7509C)

## DATA EVALUATION REPORT

STUDY TYPE: 86-1. Domestic Animal Safety (dogs)

MRID NO.: 410569-06.

TOX. CHEM. NO.: 652BB

TEST MATERIAL: EXspot. 65% permethrin spot on formulation,  
Lot #86-0080-7, 9/1/88.TEST ANIMALS: Dogs, mixed breed, 6 months to one year of age and  
15-25 pounds in weight.

STUDY NUMBER(S): #RA112488

SPONSOR: Cooper's Animal Health, Inc.

TESTING FACILITY: Cooper's Animal Health, Inc., Kansas City,  
Kansas.TITLE OF REPORT: "Results of a Study to Determine the Safety of  
EXspot in the Target Species, Dogs"

AUTHOR(S): Julie G. Gladney

REPORT ISSUED: October 24, 1988

## CONCLUSIONS:

No reactions were evident in dogs treated with 1X and 4X the label usage rate. The study demonstrates that the product is safe for use on dogs 6 months of age or older following repeated applications with an interval of 7 days.

Classification: ACCEPTABLE

Special Review Criteria (40 CFR 154.7): N/A

## Quality Assurance Statement:

A statement signed by D.S. Seymour attested that periodic quality assurance inspections were made. No irregularities were reported by the inspector.

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## REVIEW

In this study three groups of dogs (6 months to one year of age, 15-25 pounds in weight) were dosed with either 1 cc (5 dogs), 4 cc (5 dogs) by dropping the test material (65% permethrin spot on formulation) on their shoulder blades or were untreated (2 dogs). Three applications of the test material were made: one on day 0, one on day 7 and day 14 and the dogs were observed for reactions until day 18. The behavioral reactions looked for included but were not limited to the following symptoms: diarrhea, vomiting, salivation, excessive lacrimation, muscle fasciculations, hyperactivity, depression or anorexia). Blood samples were also taken prior to treatment to help assess the general health of the dogs.

No adverse reactions were reported in any of the dogs treated at any time. No signs of local (site of application) irritation were reported.

CONCLUSION. This study is ACCEPTABLE. The study demonstrates that the product is safe for use on dogs (6 months or older) following repeated application with an interval of 7 days.

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