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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Id # 000059-00231. Permethrin: EXspot for Dogs. Results of a target animal field safety study in dogs.

TOX CHEM No.: 652BB
PC No.: 109701
Barcode: D181581
Submission No.: S423500

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TO: George LaRocca/Linda Arrington
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I. CONCLUSION

Toxicology Branch acknowledges receipt of the report of the field study demonstrating a lack of a pattern of reactions to the use of the product EXspot For Dogs in both nursing bitches and their puppies. Since no pattern of effects following treatment were evident, no regulatory action is recommended for this product.

It is noted, however, that the Miniature Pinscher breed may be sensitive to the product particularly if an individual animal ingests the applied product. This breed, however, is regarded as sensitive to many drugs and animal care products.

II. ACTION SUBMITTED.

Coopers Animal Health Inc (refer to letter from Joseph E. Dyer dated July 23, 1992) has submitted the results of a field study which tested the usage of the product EXspot For Dogs (EPA

Reg. No.: 59-231) at its label usage rate in a population of 28 purebred dogs, two crossbreed dogs in 13 kennel locations. According to the report, the population comprised 521 nursing puppies (281 males and 240 females) in 131 litters with the pups being between the ages of 5 and 32 days. The results of the study are being submitted in accordance with 40 CFR 153.66 (a section of the CFR which sets forth the EPAs interpretation of the requirements of FIFRA section 6(a)2) but the data are not actually a 6(a)2 submission. Mr. Dyer states that the information provided is "purely supportive of subject product and is not considered required for registration purposes". The study was not conducted in accordance with GLP's and protocol and treatment records have not been included in the summary report.

III. Toxicology Branch Comments.

1. Toxicology Branch I (TB-I) acknowledges the receipt of the report entitled "Evaluation of EXspot (Permethrin 65%) in Various Breeds of Dogs and Nursing Puppies When Applied at Label Dose" by D. L. Salsbury (dated 1992, Document Number:KVRP151-65B, no MRID number was provided for this study). Since the study is not required by the GUIDELINES and does not follow GLP principles, no DER has been prepared for this study.

The experiment consisted of treating each dog with (under 33 pounds) with 1 ml of the product topically along the back line in order to maximize the amount of product applied. Dogs over 33 pounds received an additional dose over the hips. The dogs were treated only once.

2. TB-I notes that the study does not provide evidence that when used as directed for a single application, the product EXspot for Dogs results in a pattern of adverse effects in either nursing bitches or their pups.

A possible exception to this generalization may be the Miniature Pinscher breed. One female developed severe reactions ("tonic/clonic convulsion, etc.") and required medication (acepromazine and thiamylal sodium) following which the animal recovered. It is believed that this animal ingested the product while grooming the puppies. Eleven other bitches of this breed did not develop similar reactions. In addition one set of pups of this breed was said to have on occasion been "touchy" but this observation was not repeated in other litters.

According to information provided in the study report, the Miniature Pinscher breed is "notoriously" sensitive to drugs and vaccines and often exhibit severe, sometimes fatal reactions, to commonly used products. The kennel owner stated that many kennels had discontinued attempting to raise Miniature Pinschers because of excessive losses incurred due to their hypersensitive nature.