

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

NOV - 4 1988

**MEMORANDUM** 

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

13 port. Buly 4/03/88

SUBJECT:

Hartz Response to Review of Cholinesterase Study

Involving a Rabon-containing Collar

TO:

Mr. George LaRocca, PM 32

Registration Division (TS-767)

FROM:

Byron T. Backus, Toxicologist

Fungicide/Herbicide/Antimicrobial Toxicology Branch

HED (TS-769C)

THROUGH:

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Fungicide/Herbicide/Antimicrobial Toxicology Branch

HED (TS-769C)

and

William Burnam, Acting Branch Chief "Y "Y " Fungicide/Herbicide/Antimicrobial Toxicology Branch

HED (TS-769C)

EPA Record No. 230582

Project No. 8-1125

EPA Reg. No. 2596-62

Tox. Chem. 217A

## Action Requested:

Review a response from Hartz Mountain Corporation to a previous Toxicology Branch review.

## Background:

The Toxicology Branch previously reviewed (memorandum of March 28, 1988) a collar exposure study (including cholinesterase activity measurements) involving beagle bitches and their puppies). In that review it was concluded that, because the plasma cholinesterase activity in puppies was depressed (by about 20-30%) that:

"Labeling for this product should be revised to state that pregnant bitches, newborn puppies, and nursing puppies should not wear or otherwise be exposed to this collar. Additionally, it would also be appropriate to add a label statement that additional cholinesterase inhibiting compounds should not be used on dogs wearing this collar."

The registrant has now responded with a number of arguments as to why current labeling is adequate. As part of their submission, copies of labels for two competitors' products (Sergeant's Flea and Tick Collar, EPA Reg. No. 778-41, specially developed for small dogs and puppies; and Double Duty Plus, EPA Reg. No. 2517-24) are included.

## Comments and Recommendations:

1. After examining this material the Toxicology Branch concludes that, if labeling does not exclude pregnant bitches, newborn and nursing puppies from exposure to this collar, then there should be a statement on this collar that it contains a cholinesterase inhibitor. Both competitor's labels include this information. Also, the previously reviewed study reported significantly lower plasma cholinesterase in 1 and 2-collar puppies relative to their controls at days 30 and 42.