



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

JUL 22 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Protocol for Domestic Animal Safety Testing of a
Methoprene-Containing Collar for Dogs

TO: Mendelsohn/Hutton, PM 18
Registration Division (H7505C)

FROM: Byron T. Backus, Ph.D., Toxicologist
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7/14/92

THROUGH: K. Clark Swentzel
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and

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J. M. Bannan for
7/14/92

DP Barcode D179369

Submission S418845

Chemical No. 105402

Case 037664

Action Requested:

Review a protocol for a domestic animal safety study on a methoprene-containing collar for dogs.

COMMENTS AND RECOMMENDATIONS:

1. It is recommended that there be 4 animals/sex/dose (number of collars) group rather than the 3/sex/dose indicated (p. 4). However, it would not be necessary to have a 3X dose group, so there could be 3 groups (control, 1X and 5X), each with 4 males and 4 females.
2. After weeks 1 and 2 it would not be necessary to do hematology/clinical chemistry and/or serum chemistry measurements on a weekly or biweekly basis; it would be adequate to measure these parameters every 3-4 weeks and at the end of the study (removal of collars). If there are any abnormal measurements at the time

collars are removed then it would be appropriate to measure the affected parameter 2-4 weeks later and see if it has returned to the normal range.

3. There is no problem with the proposed duration of the study (3 months or more).
4. There should be some information as to the rate of release of the active ingredient from collars. This could be done by analyzing collars (worn by 1X dogs which are not in the main study) after 1, 2, and 4 weeks, as well as some representative collars from the 1X and 5X groups worn for the duration of the main study. Three collars/dose group/sampling time should be sufficient.