Registration Human Safety Review

PM: Zandrew (15)  TOX Reviewer: W. Haggan

EPA#: 2576-AC-6  Date: 6/23/76  Product Name: Chlordane  1:1 with T. Collum for Cat

Use Classification: Toxic Category

RECOMMENDATION:

Objects to the registration of the "collum" on the basis that the data submitted is insufficient to support toxicity data requirements under the section 3 regulations. Further data required can be grouped into 3 categories:

1) Human Safety Data
   a) Acute Oral
   b) Acute Inhaled
   c) Skin Irritation
   d) Skin irritation on formulation (data submitted are inconclusive)

2) Domestic Animal Safety Data
   a) Subacute Cholinesterase inhibition study - designed to determine the maximum degree of cholinesterase inhibition occurring under actual use conditions. To be done with the collum on the most sensitive species (cat or dog)

3) Other Studies
   a) Long-term repetitive exposure study in dogs
      A statistical analysis of the blood, blood urea, homologous, lymphocytes, and kidney and liver function tests indicated no significant effects due to the test collum. Blood samples were taken on days 0, 60, and 180. Collums were replaced every 30 days.

Acute Oral ( Rat )
LD50
Toxic signs:

Comments:

Acute Dermal ( Rabbit )
LD50
Toxic signs:

Comments:

Acute Inhalation ( )
LC50
Toxic signs:

Comments:

Primary Eye Irritation ( Rabbit )

Comments:

Primary Skin Irritation ( Rabbit )

Comments:

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L&EP: 6/29/76
2) Drug interaction study—cats exposed to 1570 nitrofurazone collars for 60 days were given zentane or phenothiazine tranquilizer. No drug interaction (as indicated by systemic toxicity) occurred. Unknown dosage—study is unacceptable.

3) Subacute eye irritation study on the actual use of the flea collar on cats wore a control collar for 60 days (collars replaced at 30 days). No difference in irritation occurred between the use of the test and placebo collars. Results were not quantitated.

10% sticros

1) Eye and skin irritation studies in dogs—placebo, chlor am test collar were worn for 11–37 days. The study states that no irritation was observed in the animals. This could be attributed to sticros. The test was poorly designed so the results are questionable.

2) Forced feeding study in dogs—219 collage was the dose used. Dog used.

3) Effect of mixture on skin irritation in dogs—no effect

4) Long term repeated exposure in dogs—duration 180 days, collars were replaced every 30 days. Dermatologic and irritant effects were assessed. No significant effect was observed.

5) Drug interaction study—common and veterinary drugs (Ronnel, Quercine 50%, hydron, corticosteroids, anthelmintics on trimethionyl/dilatene). Produced no deleterious effect when administered concurrently with the 10% sticros collar.

6) Liver function test on animals in #4 (induced by codeine)—no effect observed.

7) Kidney function test on animals in #4—no effect observed.

8) Effect of repeated exposure of cat to sticros collar in cats—no skin irritation was observed (length of intervention 60 days).

9) Drug interaction study—ethane (short acting barbiturate) was administered concurrently with the collar. Note animals administered the test collar recovered more slowly than did animals wearing the placebo collar.

10) Reproduction study 4 (reproductive studies).