

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

September 24, 2002

MEMORANDUM

Product Name: FRONTLINE® TOP SPOT® FOR CATS
EPA Reg. No.: 65331-2
DP Barcode: D282329
Case No: 046906
Submission: S613891
Chemical: 129121 Fipronil

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505C)

Byron T. Backus
9/27/2002

To: Ann Sibold/Arnold Layne, PM 03
Insecticide Branch
Registration Division (7505C)

Registrant: MERIAL LIMITED

ACTION REQUESTED: "In connection with your review of D282326, please also review this label, which contains claims supported by data submitted under that barcode..."

BACKGROUND: This registered product has the following label ingredient declaration:

Active Ingredients:	
Fipronil.....	9.7%
Inert Ingredients:.....	90.3%

The registrant is citing data developed for EPA Reg. No. 65331-4, which has the following label ingredient declaration:

Active Ingredients:

Fipronil.....	9.8%
(S)-methoprene.....	11.8%
Inert Ingredients:.....	78.4%

According to the revised labeling for EPA Reg. No. 65331-2 which TRB has received the registrant is requesting 1) a lowering of the age limitation for kittens from 12 weeks to 8 weeks (citing as supporting data the companion animal safety study in MRID 44942009) and 2) allowing the use of this product on breeding, lactating and pregnant queens (female cats); citing a study submitted to the Agency 2/15/2002 [MRID 45618502]. These studies were conducted on the formulation registered under EPA Reg. No. 65331-4, which, as indicated above, contains 11.8% (S)-methoprene in addition to 9.8% Fipronil.

COMMENTS AND RECOMMENDATIONS:

1. The study titled: "ML-2,095,988 508Q/CAT/SOLUTION/TOPICAL SAFETY/TOLERANCE/REPRODUCTION, REACTIONS" (in MRID 45618502) has been reviewed by TRB (DP Barcode D282326; memorandum dated September 23, 2002 for EPA Reg. No. 65331-4). The findings of that study are adequate to support a label claim for use of EPA Reg. No. 65331-2 FRONTLINE® TOP SPOT® FOR CATS on breeding, nursing (lactating) and pregnant female cats (queens) at the dosage rate of 0.5 mL/cat at 28-day intervals.
2. The study in MRID 44942009 has been previously reviewed by TRB (memorandum dated 12 April 2000); and the review includes comments incorporated from the HED Companion Animal Safety Committee. This study utilized groups of 6 male and 6 female kittens which ranged in age from 52 to 59 days old at the initiation of the study. This study is adequate as supporting data to support a lowering of the age limitation on kittens from 12 weeks to 8 weeks for EPA Reg. No. 65331-2 at the dosage rate of 0.5 mL/cat (kitten) at 28-day intervals.