

DATE OUT: 02 Feb 1998

SUBJECT: EP [x] MP [] PRODUCT CHEMISTRY REVIEW
DP BARCODE No.: D240956
REG./File Symbol No.: 65331-2
PRODUCT NAME: Frontline Top Spot for Cats
COMPANY: Merial Limited

TO: PM # 03, Susan Lewis/Ann Sibold
Insecticide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist *Bruce F. Kitchens* 02 Feb 1998
Technical Review Branch
Registration Division (7505C)

INTRODUCTION:

The registrant, Merial Limited, has submitted a storage stability study (442446-01 and 442982-01) for the end-use products, Frontline Top Spot for Cats (E.P.A Reg. No. 65331-2) and Frontline Top Spot for Dogs (E.P.A. Reg. No. 65331-3). The active ingredient in these products is fipronil at 9.7% a.i. The Technical Review Branch (TRB) has been asked to review this study and determine its acceptability.

SUMMARY OF FINDINGS:

TRB has reviewed this study and reports the following findings:

- > The registrant reports the storage stability data acquired for 9, 12, 18, and 24 months of storage. The registrant states that no change of color and odor was observed over the storage period.
- > The registrant also reports no significant mass loss (> 2%) was found over the 12 month period, indicating that no evaporation occurred.

- > The average w/v percentage for the 9-month samples were 9.2435, 9.381, 9.399, 9.7589, and 9.4527 for the 0.25ml shell, 0.50 ml shell, 0.67 ml shell, 1.34 ml shell, and 2.68 ml shell, respectively. The shell is actually the package type.
- > The average w/v percentage for the 12-month samples were 9.7905, 9.7906, 9.5075, 9.8298, and 9.8059 for the 0.25ml shell, 0.50 ml shell, 0.67 ml shell, 1.34 ml shell, and 2.68 ml shell, respectively.
- > The average w/v percentage for the 18-month samples were 9.3484, 9.3628, 9.5588, 9.5053, and 9.6937 for the 0.25ml shell, 0.50 ml shell, 0.67 ml shell, 1.34 ml shell, and 2.68 ml shell, respectively.
- > The average w/v percentage for the 24-month samples were 9.9647, 9.7861, 9.7748, 9.9129, and 9.9894 for the 0.25ml shell, 0.50 ml shell, 0.67 ml shell, 1.34 ml shell, and 2.68 ml shell, respectively.

CONCLUSIONS:

TRB has reviewed this study and concludes the following:

- > The average w/v percentage for the 9, 12, 18, and 24-month samples indicate that the end-use product Frontline Top Spot for Cats is stable for the storage period at 25°C.
- > This study satisfies the data requirement for storage stability as specified in 40 CFR 158.190 for physical and chemical properties.