

DATE: 07/JUL/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D266030 REG./File Symbol No.: 65331-L
PRODUCT NAME: Frontline Plus for Dogs
COMPANY: Merial Limited

FROM: Shyam B. Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

S. B. Mathur
7-7-00

TO: Arnold Layne, PM 03
Insecticide Branch/RD(7505C)

INTRODUCTION

The subject product was reviewed previously (Product chemistry review dated 02-25-00). The registrant was informed of several deficiencies in the product chemistry data. The registrant responded on April 25, 2000 by submitting the additional required information and the revised CSF for the basic formulation dated April 18, 2000.

SUMMARY OF FINDINGS

1. The subject product contains Fipronil [REDACTED] and Methoprene [REDACTED] as the active ingredients with product label claims of 9.80% and 8.82% respectively.

2. The registrant has proposed a wider certified limits ($\pm 7\%$) instead of ($\pm 5\%$) for the active ingredients for the formulation requirements.

[REDACTED]

4. The CSF for basic formulation (dated 04-18-00) is filled out correctly and completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration.

5. All the inert ingredients used in the formulation are cleared by the Agency.

6. The revised information provided on the guideline reference 830.1650 (Description of formulation process) satisfy the data requirements of 40CFR§158.165.

CONCLUSION:

The TRB has reviewed the revised product chemistry data for the subject product and has concluded that:

1. The data submitted corresponding to guideline reference 830.1650 (Description of the formulation process) satisfy the data requirements of 40CFR§158.165 and are acceptable.

2. The acceptance of the revised CSF for basic formulation dated 04-18-00 is subject to the clarification of the following discrepancy on the Flash point units:

The units of Flash point given in the CSF does not agree with that provided in the study on guideline 830.6315. The CSF indicates it to 36.7 degree C, where as, in the study it is given as 36.7 degree F. This discrepancy in the units would make difference in the language on the product label. The registrant must clarify this disagreement.

3. The wider certified limits used for the active ingredients and in cases of two inert ingredients are acceptable.