

EFFICACY REVIEW

DATE: IN 2-23-94 OUT 8- 3-94

FILE OR REG. NO. _____

PETITION OR EXP. PERMIT NO. 65331-EUP-R

DATE DIV. RECEIVED February 8, 1994

DATE OF SUBMISSION February 8, 1994

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): (I,)D, H, F, N, R, S _____

DATA ACCESSION NO(S). 431211-14,-15,-16,-17,-18,-19,-20,-21 & -22;
D199700; S458528; Case# 040837; AC:700

PRODUCT MGR. NO. 10-Brennis/Waldo

PRODUCT NAME(S) FIPRONIL 0.25% Topical Spray

COMPANY NAME Rhône Merieux, Incorporated

SUBMISSION PURPOSE Original application for permit to ship and use
experimental material in a program to evaluate
flea & tick control on pets as stand-alone.

CHEMICAL & FORMULATION Fipronil: 5-amino-1-[2,6-dichloro-4-(tri-
fluoromethyl)phenyl]-4-[(1,R,S)-(trifluoromethyl)sulfinyl]-1-H-py-
razole-3-carbonitrile 0.25%
(0.859 Sp. Gr. non-aqueous, ready-to-use pump spray)

CONCLUSIONS & RECOMMENDATIONS The proposed, quite modest program is
acceptable from the standpoint of supervision, scope of application
and number of test subjects, types of evaluations, geographic dis-
tribution of pests, replications, method of application, dosage
rates (as established by previous testing under practical condi-
tions closely simulating actual use, results of which were submit-
ted along with the application for the use permit and will be dis-
cussed in a separate paragraph below), spray application volume,
number and timings. The amount of active ingredient requested is
so modest as to hardly require comment and the preliminary work in
establishing dosage rates and concentrations is some of the finest
and most thoroughly conducted ever seen by this reviewer. The reg-
istrant should be commended on developing this new a.i. as a stand-
alone seasonal treatment for ectoparasite control on pets.

Eight of the nine volumes submitted to support the rates of
application to be used for ectoparasite (= fleas and ticks) control
in the experimental program were conducted according to require-
ments of the Good Laboratory Practices regulations of (continued)

40 CFR 160. Briefly discussing each of these volumes in order, the data enclosed in EPA Accession (MRID) Number 431211-14, having been obtained from standard kennel testing meeting the requirements of § 95-9(a)(1), (2) and (3) on p. 263 and the standard of § 95-9(b)(2) subpart (i) on p. 264 of the Product Performance Guidelines, are adequate to establish satisfactory control of fleas for up to 10 weeks and ticks for up to 6 weeks when the subject product is applied to dogs at the lowest rate on the label. MRID No. 431211-15 is adequate to establish satisfactory control of both fleas and ticks for 37 days when the subject product is applied to dogs at the lowest label rate. MRID No. 431211-16 is adequate to establish satisfactory control of the cat flea, Ctenocephalides felis, for up to 107 days when the subject product is applied to dogs at either of the rates on the label. MRID No. 431211-17 is adequate to establish satisfactory control of the American dog tick, Dermacentor variabilis, and the brown dog tick, Rhipicephalus sanguineus, for up to 44 days when the subject product is applied to dogs at the higher label rate of 6 ml per kg of body weight. MRID No. 431211-18 is adequate to establish satisfactory control of cat flea for up to 51 days when the subject product is applied to dogs at the 3 ml per kg of body weight rate, even when the dogs were subsequently subjected to bathing, shampooing or water immersion, and of brown dog tick for up to 23 days under the same treatment and exposure regime as for fleas. MRID No. 431211-19, the only data not derived from testing conducted according to GLP requirements, is adequate to establish satisfactory control of cat flea for up to 46 days on cats with one formulation of the subject product identified as Batch G01.00 and for up to 44 days with another formulation of the subject product identified as Batch G01.01 when applied at the 3 ml per kg of body weight rate. MRID No. 431211-20 is adequate to establish satisfactory control of cat flea for only 2 days whether applied at the 3 or 6 ml per kg body weight rate and flea counts on cats were obtained by means of combing. The 6 ml rate produced substantial reductions below the level of control for up to 30 days when counts were obtained either by hand or by combing. MRID No. 431211-21 is adequate to establish satisfactory control of cat flea for up to 43 days when the subject product is applied to cats at 3 ml per kg, for up to 50 days when applied at 6 ml per kg, and for up to 50 days when applied at a higher rate of 12 ml per kg. The only difference in results with the 12 ml rate compared to the 6 ml rate was a substantial reduction below the level of control for up to 57 days for 12 ml when the 3 ml and 6 ml rates produced little if any reduction. MRID No. 431211-22 is adequate to establish satisfactory control of nymphs of D. variabilis, R. sanguineus, Amblyomma americanum and Ixodes scapularis/dammini as well as adult C. felis within 2 days after exposure to hair clipped from dogs treated with either the 3 ml or 6 ml per kg body weight rate using the subject product. In fact, the 3 ml rate produced control of all but the Ixodes nymphs within 24 hours and the 6 ml rate control of all but the Amblyomma nymphs within the same period of time.

In summary, the registrant has more than satisfied required performance data to support the use of the subject product on dogs and cats at label rates in the 4 states under the use permit.

NAC Vern L. McFarland, IRB