

EFFICACY REVIEW

DATE: IN 2-7-02 OUT 2-21-02

FILE OR REG. NO. 11556-RGE

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED January 7, 2002

DATE OF SUBMISSION December 31, 2002

DATE SUBMISSION ACCEPTED

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

DATA ACCESSION NO(S). 455630-11 & 455735-01; D280839; S608992;
Case# 071346; AC:166

PRODUCT MGR. NO. 03-Layne/Sproat

PRODUCT NAME(S) Advantix™ 10 for Dogs

COMPANY NAME Bayer Corporation, Agriculture Division, Animal Health

SUBMISSION PURPOSE Provide performance data in support of claims
for 4 weeks control of cat flea and brown dog
tick and lone star tick with subject product.

CHEMICAL & FORMULATION Imidacloprid: 1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine 8.8%
Permethrin: (3-phenoxyphenyl)methyl(+)cis,
trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate* 44.0%
*Cis/trans isomer ratio: (ready-to-use topical solution of 1.15 Sp.Gr.)
Maximum 55%(+)cis,
Minimum 45%(+)trans

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 455630-11, having been obtained from standard kennel testing conducted according to the requirements of § 95-9(a)(1) to (3) on p. 263 and § 95-30(b)(11)1. to 10. on pp. 280-3, and meeting the standard of § 95-9(b)(2)(i) on p. 264 and § 95-30(b)(11)10. on pp. 283-4 of the Product Performance Guidelines, and the GLP requirements of 40 CFR Part 160, are adequate to demonstrate ability of the subject product to kill and repel cat flea, *Ctenocephalides felis*, for 4 weeks or more, and brown dog tick, *Rhipicephalus sanguineus*, for 4 weeks or more, when applied according to label rates and directions to dogs. Similarly, the data in MRID No. 455735-01, having been obtained from standard kennel testing conducted according to the same requirements and meeting the same standard, are adequate to demonstrate ability of the subject product to kill and repel cat flea for 4 weeks or more and lone star tick, *Amblyomma americanum*, for up to 4 weeks, when applied (to be continued)

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according to label rates and directions to dogs. The claim for protection against blood feeding mosquitoes which may transmit dog heartworm was previously accepted for EPA Reg. No. 67505-4, "ECTO Flea and Tick Insecticide", a 45% spot-on registered on June 9, 1997. Since there are, according to REFS, no registered products containing imidacloprid as the active ingredient which carry claims for mosquitoes, we can be certain that it is the permethrin part of the subject product formulation which is responsible for effectiveness against mosquitoes. Furthermore, since there is only 1% difference between this product and the subject product as to the amount of permethrin and this product also claims protection vs. blood feeding mosquitoes for up to 4 weeks, we are assured of the effectiveness of the subject product for the same purpose for the same length of time. Relative to flea and tick claims on labeling for the subject product, the data in MRID Numbers 455630-11 and 455735-01 support the following: "Kills 98-100% of the Fleas on Dogs Within 12 Hours", "One Treatment Prevents Further Flea Infestation For At Least Four Weeks", "Kills Fleas Before They Lay Eggs" and "Repels and Kills Ticks including...Brown Dog Ticks (vector of ehrlichiosis) and Lone Star Ticks for up to Four Weeks".

RL Vern L. McFarland, IB