

PRODUCT PERFORMANCE / EFFICACY REVIEW

Mark Suarez, Entomologist - IB

Mark E S
8 August 2007

DATE: 8 August 2007

EPA REG. NUMBER: 11556-132
11556-133
11556-134
11556-135

PRODUCT NAME: K9 Advantix 10 [11556-132]
K9 Advantix 20 [11556-133]
K9 Advantix 100 [11556-134]
K9 Advantix 55 [11556-135]

REGISTRANT: Bayer Healthcare LLC

PM: George LaRocca, PM 13
REVIEWER: BeWanda Alexander

DECISION #.: 378322 [11556-132]
378323 [11556-133]
378324 [11556-134]
378325 [11556-135]

DP BARCODE: 339551 [11556-132]
339552 [11556-133]
339556 [11556-134]
339555 [11556-135]

ACTION: R34

ACTIVE INGREDIENT(S): 109701, Permethrin.....44%
129099, Imidacloprid.....8.8%

TYPE: Spot-On for Dogs

OPPTS GUIDELINE(S): 810.3100
810.3300

MRID: 47109101 Submitted GLP? No

SITES & PESTS Dogs Fleas, Ticks, Mosquitoes, &
Biting Flies

LABEL APPLICATION RATE: >0.05 mL/lb for dogs less than 80 lbs

STUDY APPLICATION RATE: Variable (per label by weight class)

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The registrant submitted data in support of label claims that the product will remain efficacious even after the dog is bathed, swims, or is out in the rain. Trials were conducted in the laboratory where dogs were intentionally infested with brown dog ticks or fleas on various days and the number of live parasites recorded on subsequent days.

The registrant has reported adequate efficacy after both washing and wetting for the duration of the trial (26 days). However, dogs were treated according to weight class, not minimum treatment rate, and only treatment means were reported. The raw data were not provided with the study. Without the raw data for each dog, the data can not be fully evaluated.

The data appear to confirm the water repellency, but the complete data – including raw data sheets are to be submitted within 3 months of the data of registration.

Additional label comments are provided below:

- “Inert ingredients” should be changed to “Other ingredients”

Enclosure
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