

Product Performance Data Evaluation Review

by Kevin J. Sweeney, Senior Entomologist, IB

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2/22/07

Date: February 22, 2007

Reviewer: Linda DeLuise

PM: George LaRocca, PM 13

EPA Reg. Nos. 11556-132, 133, 134, 135

Product Names: K9 Advantix 10, K9 Advantix 20, K9 Advantix 100, and
K9 Advantix 55

PRIA Code: R34

PRIA due date: February 28, 2007

DPs: 334312, 334311, 334313, 334314

Active ingredients: 44% permethrin and 8.8% imidacloprid

Formulation: RTU Spot-on

Site: Dogs. Not for use on cats.

Request: Review two efficacy studies submitted in support of adding biting fly kill and repellency claims to each of the four labels.

GLP studies? No.

OPPTS Guideline: 810.3300

Submitted studies:

MRID 46978901 Assessment of the Efficacy of an Imidacloprid (10%)/Permethrin (50%) Spot-on against *Stomoxys calcitrans* on Dogs. by L.J. Fourie ClintVet Int. Ltd., South Africa 2004.

MRID 46978902 Assessment of the Efficacy of an Imidacloprid (10%)/Permethrin (50%) Spot-on against *Stomoxys calcitrans* on Dogs by L.J. Fourie and D. Stanneck of ClintVet Int. Ltd., South Africa 2005.

Study Reviews:

MRID 46978901 Assessment of the Efficacy of an Imidacloprid (10%)/Permethrin (50%) Spot-on against *Stomoxys calcitrans* on Dogs. by L.J. Fourie ClintVet Int. Ltd., South Africa 2004.

Purpose: Evaluate the efficacy of the spot-on formulation against biting flies on dogs in a laboratory assay.

Methods: 18 dogs were screened for their attraction to biting stable flies. The two least attractive subjects were removed. The remaining 16 dogs were divided into two groups. Treatments were randomized, 8 dogs were treated and 8 were untreated. Groups were balanced with regard to sexes as well. Dogs weighed between 8 and 16 kg. The application rate was 0.1ml/kg. (The subject products are sold in 2.5 ml doses and applied at the same rate.)

Individual dogs were penned and exposed to biting stable flies. The adult flies were 14 days old and fasted from blood for three days and sucrose solution for one day prior to exposure. Each dog was exposed to 25 starved flies at each exposure period (day 1, 8, 18, 22 and 29). On day 18, only 20 flies were applied. Dogs were sedated during each exposure period. The number of alive, dead, and blood-fed flies was counted at each exposure period for treated dogs. For the untreated dogs, only mortality was recorded. Lack of blood-feeding success was the equivalent of repellency.

Results:

Repellency: The data indicate that the product is more than 90% effective through 3 weeks. Repellency declined in week 4 to just 82.5%.

Kill: Kill was effective through one week. Results were poor after day 8.

Conclusions: This study is acceptable and supports a repels biting flies for three weeks claim. Kill claims are not acceptable.

MRID 46978902 Assessment of the Efficacy of an Imidacloprid (10%)/Permethrin (50%) Spot-on against *Stomoxys calcitrans* on Dogs by L.J. Fourie and D. Stanneck of ClintVet Int. Ltd., South Africa 2005.

Purpose: Evaluate the efficacy of the spot-on formulation against biting flies on dogs in a laboratory assay.

Methods: 24 dogs were screened for their attraction to biting stable flies. The least attractive subjects were removed. The remaining 20 dogs were divided into two groups. Treatments were randomized with 10 dogs treated and 10 untreated. Groups were balanced with regard to sexes as well. Dogs weighed between 8 and 16 kg. The application rate was 0.1ml/kg. (The subject products are sold in 2.5 ml doses and applied at the same rate.)

Individual dogs were penned and exposed to biting stable flies. The adult flies were 14 days old and fasted from blood for three days and sucrose solution for one day prior to exposure. Each dog was exposed to 25 starved flies at each exposure period (day 1, 8, 18, 22 and 29). On day 18, only 20 flies were applied. Dogs were sedated during each exposure period. The number of alive, dead, and blood-fed flies was counted at each exposure period for treated dogs. For the untreated dogs, only mortality was recorded. Lack of blood-feeding success was the equivalent of repellency.

Results:

Repellency: Unlike the first study, the product was less than 90% effective except for the data point collected at 22 days where repellency was 90%.

Kill: Kill was ineffective.

Conclusions: This study is rated “supplementary” in support of repel biting flies claims. Kill claims are not acceptable.

Entomologist's Recommendations:

A. Based on the submitted data, the following claims are supported:

1. Repels biting flies up to 3 weeks.
2. Repels and inhibits blood-feeding by biting flies up to three weeks.
3. Repels and prevents blood-feeding by flies up to three weeks
4. Repels (annoying) (bothersome)(nuisance) biting flies up to three weeks.
5. Inhibits (annoying) (bothersome)(nuisance) biting flies up to three weeks.
6. Prevents/Inhibits blood-feeding by biting flies up to three weeks.
7. Prevents blood-feeding by biting flies up to three weeks.

B. Remove

8. "Starts working/ repels before biting flies bite."

The study counted blood-fed flies, not number of bites.

9. All "kills flies" claims. The data do not support these claims.