EFFICACY REVIEW

by Mark Suarez, Entomologist - IB

Mark E. S. 20 DECEMBER 2004

DATE:	18 December 2004
EPA REG. NUMBER:	69332-3
PRODUCT NAME:	SPI #8208-55D
REGISTRANT:	Pet Logic, LLC
PM:	George LaRocca, PM 13
DECISION #.:	345778
DP BARCODE:	311196
ACTION:	R34; Non-Fast-Track
ACTIVE INGREDIENT(S):	128965, Etofenprox.....55.00% 129032, Pyriproxyfen.....2.20%
TYPE:	Spot-On Cat Treatment
OPPTS GUIDELINE(S):	810.1000 810.3000 810.3300
MRID:	46307401
GLP ?:	No.
SITES:	Cats
PESTS:	Fleas and Ticks
STUDY APPLICATION RATE:	372±3 and 494±3 mg/kg bodyweight; 56.0% Etofenprox, 2.26% Pyriproxyfen
LABEL APPLICATION RATE:	330 mg or 440 mg/kg body weight; 55.00% Etofenprox, 2.20% Pyriproxyfen

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STUDY SUMMARIES:

The study examined the repellency of the registrant's spot-on for cats at two dose rates 330 and 440 mg/kg body weight. Five (5) cats of undisclosed hair length were assigned to each of three groups: control, treatment A (mean application rate of 372 mg/kg bodyweight), or treatment B (mean application rate of 494 mg/kg bodyweight). Cats were infested with both cat fleas, *Ctenocephalides felis*, and the Brown Dog tick, *Rhipicephalus sanguineus*, one day prior to the initiation of the experiment. Cats were re-infested with fleas at approximately weekly interval though 4 weeks. Pests were counted by hand on Days 1 and 2 following infestation and by comb count on Day 3. Cats were fitted with Elizabethan collars, to prevent pest removal through grooming. The collars remained in place for 72 hours following each infestation.

Efficacy of the product against fleas was determined by counting fleas on days 1 and 3, after Cats were re-infested. Following the initial application, a count was done on Day 2 post-treatment, as well. The day 1 (and 2) counts were hand counts; the day 3 counts were comb counts. The product proved consistently efficacious at 90% or greater though nine (9) days for the higher (494 mg/kg bodyweight) treatment group. The product was marginally efficacious ($\geq$ 80%) at both application rates through twenty-two (22) days.

The product proved efficacious against *R. sanguineus*. Ticks were applied and counted on the same days as fleas. Control infestations were minimal, ranging from 1.6 ± 1.1 to 3.8 ± 2.5 ticks per animal. No ticks were recorded on any treated animal at either application rate through the 30 day trial.

Efficacy was calculated as the percent decrease in pests in comparison to the mean control pest count at each time for each treatment. The treatment mean ± SD was calculated from the individual percent efficacy.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS

It should be noted that the label application rates may be far below those examined in this study. Tests were performed at 372 and 494 mg/kg bodyweight. The label directions are likely to result in application rates at or below 179 mg/kg bodyweight. The submitted flea efficacy data do not support the current label claims. Previously submitted data were sufficient for flea claims, however. The product proved efficacious against the Brown Dog tick. Cats are not the preferred host of these insects, as noted in a previous efficacy review (see enclosed 21 April 2004 Efficacy Review by Kevin Sweeney). The low number of ticks recorded for the control groups is also troubling.

Recommendations:

The submitted data for tick efficacy do not meet the established efficacy requirements.

In an earlier review of submitted efficacy data (dated 21 April 2004) the reviewer found that general tick kills, repels, and controls claims to be unacceptable. The cause for this determination was partially the use of Brown Dog ticks in the assay. The registrant was instructed to provide the following study for consideration of general tick control claims:

"For a tick control claim on cats to be considered, the registrant should provide additional *in vivo* study data on cats and *in nitro* data with clipped hair removed from treated and untreated cats against Lone Star ticks and American dog ticks at a minimum. Only the label rate treatment should be tested because this is the rate that will be applied. The number of replicates should be at least five for the treatment."

The registrant has submitted no new data that would support the addition of a general tick claim to the label.

Enclosure
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