

US EPA ARCHIVE DOCUMENT

EFFICACY REVIEW
HARTZ REFERENCE 123; EPA Reg. No. 2596-155

DATE: 10/20/05

DP BARCODE: D322282

DECISION: 361191

GLP: Yes

CHEMICAL: Dinotefuran (14.85%)

CHEMICAL NUMBER: 044312

PURPOSE: Provide efficacy data to support additional label claims.

MRID: 46660401. Slone, R. (2005) Evaluation of Efficacy of an Experimental Spot-on at 2, 6, and 12 Hours Following Topical Administration to Cats 9 Pounds or Less of Body Weight Infested with the Cat Flea (*Ctenocephalides felis*): TS# 12690, TS# 12691, Advantage (TS# 12692), Sergeant's Gold (TS# 12694). Project Number: 1815, PLRS/0529. Unpublished study prepared by Professional Laboratory and Research Services, Inc. 32 p.

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BACKGROUND:

Hartz Reference 123 is intended for the treatment and prevention of fleas on cats and kittens 12 weeks of age or older. The directions for use state to evenly apply to one spot on the cat's back the contents of one applicator tube. Upon completion of application, the cat should be held in an upright position for two minutes to prevent the loss of material. The application rate for this product is 1.2 ml for cats weighing 9 pounds or less and 2 ml for cats greater than 9 pounds. The treatment should be repeated monthly, and must never be used on other animals. Label claims include: "*Kills fleas within 24 hours*", "*Kills fleas for up to 30 days*", and "*Quick Kill*". Proposed label claims include, "*Kills 96% of fleas in 6 hours (and continues to prevent infestation for four weeks)*", and "*Kills 100% of fleas in 12 hours (and continues to prevent infestation for four weeks)*".

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

46660401. Slone, R. (2005) Evaluation of Efficacy of an Experimental Spot-on at 2, 6, and 12 Hours Following Topical Administration to Cats 9 Pounds or Less of Body Weight Infested with the Cat Flea (*Ctenocephalides felis*): TS# 12690, TS# 12691, Advantage (TS# 12692), Sergeant's Gold (TS# 12694). Project Number: 1815, PLRS/0529. Unpublished study prepared by Professional Laboratory and Research Services, Inc. 32 p.

The objective of this study was to determine the efficacy of dermal flea treatments at 2, 6 and 12 hours after application against the cat flea (*Ctenocephalides felis*) on cats weighing 9 lbs or less. The experimental design consisted of 24 cats being divided up evenly (six per group) into four groups. All the cats in one group were treated with spot-on TS# 12691 (dinotefuron), while two other groups were treated with the commercial standards Advantage and Sergeant's Gold. The final group served as a control. On the day prior to application, all cats were infested with one hundred unfed adult cat fleas. All cats used in the study were initially tested for flea host ability, and all animals exhibiting low flea holding capacities were replaced. A count of all living fleas was made 2, 6 and 12 hours after application.

Reported Results:

Table 1. Mean Counts and Percent Control for Cats Weighing 9 lbs or Less¹

	Two Hours	Six Hours	Twelve Hours
Control	22.5	18.0	63.1
TS# 12691	7.6 (66.3%)	0.6 (96.7%)	0.0 (100.0%)
Advantage	12.2 (46.0%)	6.6 (63.5%)	0.9 (98.5%)
Sergeant's Gold	6.6 (70.7%)	2.5 (86.0%)	5.2 (91.8%)

$$^1 100*(GMC-GMT)/GMC$$

Of the three "treatment" groups, TS# 12691 was the most efficacious having 96.7% control after six hours and 100% control after twelve hours. None of the "treatment" groups had an acceptable level of efficacy after only two hours.

RECOMMENDATIONS:

The submitted data do not support the proposed label claims "*Kills 96% of fleas in 6 hours (and continues to prevent infestation for four weeks)*" and "*Kills 100% of fleas in 12 hours (and continues to prevent infestation for four weeks)*". The following recommendation applies:

1. Although efficacious, the submitted data was only tested on cats weighing less than 9 pounds. To receive the claims listed above, additional data must be submitted showing that it also "holds true" for cats weighing over 9 pounds.