(8) (38)

472369-01
ltr of 9/20/2007

EFFICACY REVIEW

PRODUCT:	Kaput Field Rodent Bait B
FILE SYMBOL:	72500-RR
DATE:	November 13, 2007
GLP:	Yes
BARCODE:	D345949
DECISION:	371602
CHEMICAL:	Diphacinone (0.0025%) Imidacloprid (0.025%)
CHEMICAL NUMBER:	Diphacinone.....067701 Imidacloprid.....129099
PURPOSE:	Review data to determine if it supports product registration.
MRIDS:	47236901. Borchert, J. (2007) Determining the Blood Titer Levels and the Effectiveness of Genesis Formulations Against *Oropsylla hirsute* Fleas on Black-Tailed Prairie Dogs (*Cynomys ludovicianus*): Kaput Field Rodent Bait B. Project Number: 07013. Unpublished study prepared by Genesis Laboratories, Inc. 105 p.
TEAM REVIEWER:	Dan Peacock
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11-13-07

BACKGROUND:

Kaput Field Rodent Bait B is a ready-to-use pesticide bait intended for the control of wild squirrels (genus *Spermaphilus*), prairie dogs (genus *Cynomys*) and rabbits (genus *Sylvilagus* and *Lepus*) and their infesting fleas.

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.

47236901. Borchert, J. (2007) Determining the Blood Titer Levels and the Effectiveness of Genesis Formulations Against *Oropsylla hirsute* Fleas on Black-Tailed Prairie Dogs (*Cynomys ludovicianus*): Kaput Field Rodent Bait B. Project Number: 07013. Unpublished study prepared by Genesis Laboratories, Inc. 105 p.

The experimental design was constructed as to "mimic the 'one-feeding' consumption of 1g of rodent bait containing 250 mg/kg imidacloprid and one rodent bait containing 250 mg/kg imidacloprid with 25 mg/kg diphacinone." Sixteen prairie dogs were divided into two treatment groups and one control group (see table 1). All prairie dogs were assessed for disease, abnormalities and overall health prior to treatment.

Table 1. Treatment Group Designations

Group	Quantity Orally Gavaged (equivalent of orally ingesting)
Treatment 1	1 g of bait containing 250 mg/kg imidacloprid (~0.25 mg imidacloprid)
Treatment 2	1 g of bait containing 250 mg/kg imidacloprid (~0.25 mg imidacloprid) and 25 mg/kg diphacinone (~0.025 mg diphacinone)
Control	No Active Ingredient

Three hours after oral gavage, all prairie dogs were infested with 10-15 unfed *O. hirsuta* fleas via an on-rodent flea feeding apparatus secured to the with tape. Fleas were allowed to feed for a minimum of three hours, upon which time the apparatuses were removed. Observations on flea mortality were taken at 24 and 48 hours (see table 2). In addition, upon completion of flea exposure, all rats were euthanized and blood samples were taken to determine the concentration of active ingredient (see table 3).

Results:

Flea Mortality-

Table 2. Percent Mortality of Fleas Exposed to Prairie Dogs Within Two Treatment Groups and One Control

	Percent Flea Mortality	
	24-Hours	48-Hours
Treatment 1	30.0%	51.7%
Treatment 2	41.7%	53.3%
Control	4.3%	17.4%[1]

[1] *unacceptable level of control percent mortality*

The percent flea control after 24 hours ranged from 30.0% (Treatment 1) to 41.7% (Treatment 2), while the percent flea control after 48 hours ranged from 51.7% (Treatment 1) to 53.3% (Treatment 2). It should be noted that there was an unacceptable level of control mortality (>10%) observed at 48 hours. The registrant explained that they feel this was due to "flea stress".

Blood Titer-

Table 3. Concentration (ug/ml) of Imidacloprid in Blood Taken From Prairie Dogs

	Concentration of A.I. in Blood
Treatment 1	0.16 ± 0.07
Treatment 2	0.14 ± 0.02
Control	0.03 ± 0.05

The concentration of imidacloprid within the blood of rats within each of the treatment groups ranged from 0.16 ug/ml (treatment group 1) to 0.14 ug/ml (treatment group 2).

RECOMMENDATIONS

The submitted data do not support the registration of Kaput Field Rodent Bait B (EPA File Symbol 72500-RR). The following recommendations apply:

1. The submitted efficacy data are not adequate to support the addition of claims regarding the kill of fleas infesting prairie dogs. To have these pests added on in the future, acceptable data (increased percent mortality and decreased control mortality) must be submitted.

2. It should be noted that efficacy data for fleas infesting squirrels and rabbits are still outstanding.