

EFFICACY REVIEW

PRODUCT: Kaput Field Rodent Bait B

FILE SYMBOL: 72500-RR

DATE: November 27, 2007

GLP: Yes

BARCODE: D346846

DECISION: 371602

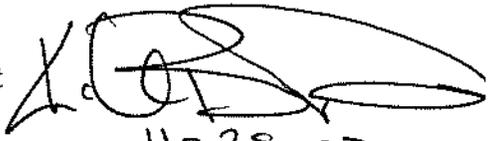
CHEMICAL: Diphacinone (0.0025%)
Imidacloprid (0.025%)

CHEMICAL NUMBER: Diphacinone.....067701
Imidacloprid.....129099

PURPOSE: Review data to determine if it supports product registration.

MRIDS: 47256401. Bruening, J. (2007) Determining the Blood Titer Levels and the Effectiveness of Genesis Formulations Against *Oropsylla idahoensis* Fleas on Wyoming Ground Squirrels (*Spermophilus elegans*). Project Number: 07015. Unpublished study prepared by Genesis Laboratories, Inc. 102 p.

TEAM REVIEWER: Dan Peacock

EFFICACY REVIEWER: Kable Bo Davis, M.S., Entomologist 

SECONDARY EFFICACY REVIEWER: Joanne Edwards, M.S., Entomologist
11-29-07

BACKGROUND:

Kaput Field Rodent Bait B is a ready-to-use pesticide bait intended for the control of wild squirrels (genus *Spermophilus*), 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.

47256401. Bruening, J. (2007) Determining the Blood Titer Levels and the Effectiveness of Genesis Formulations Against *Oropsylla idahoensis* Fleas on Wyoming Ground Squirrels (*Spermophilus elegans*). Project Number: 07015. Unpublished study prepared by Genesis Laboratories, Inc. 102 p.

The experimental design was constructed as to “mimic the ‘one-feeding’ consumption of 1g and 2g of rodent bait containing 250 mg/kg imidacloprid. Thirteen ground squirrels were divided into two treatment groups and one control group (see table 1). All squirrels 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 (5 squirrels)	1 g of bait containing 250 mg/kg imidacloprid (~0.25 mg imidacloprid)
Treatment 2 (4 squirrels)	2 g of bait containing 250 mg/kg imidacloprid (~0.50 mg imidacloprid)
Control (4 squirrels)	No Active Ingredient

Three hours after oral gavage, all ground squirrels were infested with 2-23 unfed *O. idahoensis* or *O. montana* fleas via an on-rodent flea feeding apparatus secured to the with tape. A total of 137 *O. idahoensis* and 35 *O. montana* fleas were used in total throughout the study. 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, 48 and 72 hours (see tables 2 & 3). In addition, upon completion of flea exposure, squirrels were euthanized and blood samples were taken to determine the concentration of active ingredient (see table 2).

Results:

Table 2. Percent Mortality of fleas (*O. idahoensis*) Exposed to Ground Squirrels Within Two Treatment Groups and One Control Group

	24-hr	48-hr	72-hrs	Mean ai Blood titer (ug/ml)
Treatment 1	67.6%	75.7%	81.1%	0.212 ± 0.122
Treatment 2	88.0%	92.0%	92.0%	0.188 ± 0.075
Control	4.2%	10.4% ¹	16.7% ¹	0.000

¹ unacceptable level of control mortality

The percent mortality of *O. idahoensis* fleas exposed to squirrels fed bait containing imidacloprid ranged from 81.1% (treatment 1) to 92% (treatment 2) after 72 hours. 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”.

Table 3. Percent Mortality of fleas (*O. montana*) Exposed to Ground Squirrels Within Two Treatment Groups and One Control Group

	24-hr	48-hr	72-hrs
Treatment 1	100%	100%	100%
Treatment 2	75.0%	75.0%	91.7%
Control	4.2%	10.4% ¹	16.7% ¹

¹ unacceptable level of control mortality

The percent mortality of *O. montana* fleas exposed to squirrels fed bait containing imidacloprid ranged from 91.7% (treatment 2) to 100% (treatment 1) after 72 hours. 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". In addition it should be also noted that only 35 *O. montana* fleas were used throughout the study.

RECOMMENDATIONS:

The submitted data support the addition of an "aids in the reduction of populations of fleas infesting squirrels" claim. The following recommendations apply:

1. To date, no data have been submitted to support the addition of rabbits (and their infesting fleas). All references to rabbits must be deleted from the label. ✓

In addition, it should be noted that in an Agency review dated November 13, 2007 (D345949) the submitted data were inadequate to support the addition of claims regarding the kill of fleas infesting prairie dogs. ✓

All references to *Oropsylla hirsute* fleas must be deleted from the label. ✓

2. Revise the label claim "*Kills the Fleas of Wild Rodents and Rabbits while Simultaneously Killing the Rodent or Rabbit Host.*" to read "*Aids in the Reduction of Flea Populations while Simultaneously Killing the Squirrel Host.*" ✓
3. Statements within the **USE RESTRICTIONS** section of the label should be revised to specify that this product aids in the reduction of fleas infesting squirrels. ✓
4. The submitted data do not support the addition of *Oropsylla montana* fleas to the label. All references to *Oropsylla montana* must be revised to read *Oropsylla idahoensis*. To have these fleas added on in the future, acceptable data must be submitted on at least 100 fleas. In addition, please provide an explanation as to why, in MRID 47256401, 100% of fleas died when exposed to squirrels that consumed 1 gram ai in contrast to a mortality of only 75% in fleas exposed to squirrels that consumed 2 grams ai after 24 hours.