

EFFICACY REVIEW

PRODUCT: Novel Commensal Rodent Pellet #2

FILE SYMBOL: 72500-RG

DATE: October 25, 2007

GLP: Yes

BARCODE: D345277

DECISION: 375342

CHEMICAL: Warfarin (0.025%)
Imidacloprid (0.020%)

CHEMICAL NUMBER: Warfarin.....086002
Imidacloprid.....129099

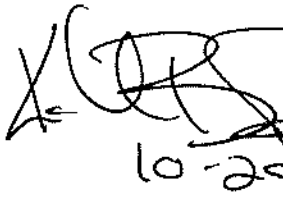
PURPOSE: Review data to determine if it supports product registration.

MRIDS: 47218101. Borchert, J. (2007) Determining the Blood Titer Levels and the Effectiveness of Genesis Formulations Against *Xenopsylla cheopis* Fleas on Laboratory Rats (*Rattus norvegicus*): Novel Commensal Rodent Pellet #2. Project Number: 07007. Unpublished study prepared by Genesis Laboratories, Inc. 121p.

TEAM REVIEWER: Dan Peacock

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

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BACKGROUND:

Novel Commensal Rodent Pellet #2 is a ready-to-use pesticide intended for the control of wild rats, mice and voles 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.

47218101. Borchert, J. (2007) Determining the Blood Titer Levels and the Effectiveness of Genesis Formulations Against *Xenopsylla cheopis* Fleas on

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The experimental design was constructed as to “mimic the ‘one-feeding’ consumption of 1g and 2 g of rodent bait containing 200 mg/kg imidacloprid and rodent bait containing 200 mg/kg imidacloprid and 250 mg/kg warfarin by rats.” Twenty-five rats were divided evenly into four treatment groups and one control group (see table 1). All rats were healthy male and female adults roughly 6-8 weeks of age.

Table 1. Treatment Group Designations

Group	Quantity Orally Gaviged (equivalent of orally ingesting)
Treatment 1	1 g of bait containing 200 mg/kg imidacloprid (~0.2 mg imidacloprid)
Treatment 2	2 g of bait containing 200 mg/kg imidacloprid (~0.4 mg imidacloprid)
Treatment 3	1 g of bait containing 200 mg/kg imidacloprid and 250 mg/kg warfarin (~0.2 mg imidacloprid; 0.25 mg warfarin)
Treatment 4	2 g of bait containing 200 mg/kg imidacloprid and 250 mg/kg warfarin (~0.4 mg imidacloprid; 0.5 mg warfarin)
Control	No Active Ingredient

Three hours after oral gavage, all rats were infested with 10-15 unfed *X. cheopis* fleas via an on-rodent flea feeding apparatus secured to the rats 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. 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:

Table 2. Percent Mortality of Fleas Exposed to Rats Within Four Treatment Groups and One Control

	Percent Flea Mortality	
	24-Hours	48-Hours
Treatment 1	78.0%	80.5%
Treatment 2	75.0%	80.8%
Treatment 3	60.5%	74.4%
Treatment 4	82.1%	83.6%
Control	12.3% ¹	12.3% ¹

¹ *unacceptable level of control percent mortality*

The percent flea control after 24 hours ranged from 60.5% (Treatment 3) to 82.1% (Treatment 4), while the percent flea control after 48 hours ranged from 74.4% (Treatment 3) to 83.6% (Treatment 4). It should be noted that there was an unacceptable level of control mortality (>10%) observed at both 24 and 48 hours. The registrant explained that they feel this was due to “flea stress”.

Table 3. Concentration of Imidacloprid in Blood Taken From Rats

	Concentration of A.I. in Blood
Treatment 1	0.47 ug/ml
Treatment 2	0.89 ug/ml
Treatment 3	0.48 ug/ml
Treatment 4	0.78 ug/ml
Control	0.04 ug/ml

¹ due to contamination in two blood samples

The concentration of imidacloprid within the blood of rats within each of the treatment groups ranged from 0.47 ug/ml (treatment group 1) to 0.89 ug/ml (treatment group 2).

RECOMMENDATIONS

The submitted data support the registration of Novel Commensale Rodent Pellet #2 (EPA File Symbol 72500-RG). The following recommendations apply:

1. Revise the label "*Kills the Fleas of Wild Rodents while Simultaneously Killing the Rodent Host.*" to read "*Aids in the Reduction of Flea Populations while Simultaneously Killing the Rodent Host.*"
2. Within the **Rats and Mice** portion of the **USE RESTRICTIONS** section of the label, revise the sentence "*Use this product to control Norway Rats, Roof Rats and House Mice and to kill their fleas.*" to read "*Use this product to control Norway Rats, Roof Rats and House Mice and to aid in the reduction of their infesting flea populations.*"
3. Within the **Rats and Mice** portion of the **USE RESTRICTIONS** section of the label, revise the sentence "*Use this product to control pine, meadow or mountain voles (Microtus spp.) around buildings and to kill the voles' fleas.*" to read "*Use this product to control pine, meadow or mountain voles (Microtus spp.) around buildings and to aid the reduction of their infesting flea populations.*"