### PROTOCOL REVIEW

PRODUCT:

Novel Commensal Rodent Pellet #2

FILE SYMBOL:

72500-RG

DATE:

June 5, 2007

GLP:

Yes

BARCODE:

D338362

**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:** 

47065205. Borchert, J. (2007) Norway Rat (Rattus

norvegicus) and Fleas 15-Day Laboratory Test of Novel Commensal Rodent Pellet #2. Project Number: 06026. Unpublished study prepared by Genesis Laboratories, Inc.

221 p.

TEAM REVIEWER:

Dan Peacock

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

SECONDARY

EFFICACY REVIEWER: Joanne Edwards, M.S., Entomologist

## 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 a table with reformatted data.

47065205. Borchert, J. (2007) Norway Rat (Rattus norvegicus) and Fleas 15-Day Laboratory Test of Novel Commensal Rodent Pellet #2. Project Number: 06026. Unpublished study prepared by Genesis Laboratories, Inc. 221 p.

The primary objective of this study was to determine the laboratory efficacy of Novel Commensal Rodent Bait #2 to control both rats (*Rattus norvegicus*) and their infesting fleas (*Xenopsylla cheopis*).

The experimental design consisted of offering test bait and challenge diet to 40 rats in a 10-day choice test. Two days following initial bait exposure, rats were restrained and approximately 10-15 unfed fleas were placed within an apparatus attached to the rats. All fleas were allowed to feed for a minimum of four hours, before apparatuses were removed. Observations on mortality were recorded the following day.

In addition to Novel Commensal Rodent Pellet #2 and a control, rodent bait containing only warfarin was tested. Observations on mortality of fleas infesting rats that consumed both 1 gram or more and less than 1 gram of test bait were recorded.

#### Results:

Table 1. Percent Flea (Xenopsylla cheopis) Mortality

(40) S 4(1)	Percent Flea Mortality				
	Day 2	Day 3	Day 4	Day 5	Total
Control	20.5%	8.3%	15.4%	19.0%	15.8%
Warfarin	25.2%	10.7%	13.2%	8.5%	14.4%
Rep 1 Imidacloprid warfarlu	68.3%	71.5%	56.4%	43.5%	59.9%
Rep 2 Imidacloprid warfarin	82.4%	68.4%	70.4%	50.0%	67.8%
STATE OF THE			DANSON PROPERTY.	Total:	63.9%
Rep 1 <sup>a</sup> Imidacloprid warfarin	69.3%	81.4%	90.5%	51.2%	73.1%
Rep 2ª Imidacloprid warfarin	84.4%	88.3%	74.6%	90.2%	84.4%
4. 41. 10. 0				Total:	78.8%

adjusted; removal of rats that consumed <1 g bait

Although the data lack adequate level of control to support registration (90% or more), they do show some degree of kill for fleas. It should be noted that the percent mortality for fleas infesting rats that consumed at least a gram of bait is greater than the percent mortality for fleas infesting rats that consumed less than a gram of bait. In addition, it should be noted that the data contained an unacceptable level of control percent mortality (greater than 10%).

## **RECOMMENDATIONS:**

The submitted data are inadequate to support the registration of Novel Commensal Rodent Pellet #2. MRID # 47065205 has been determined to be

supplemental data and will be used to help support future efficacy data submitted to the Agency. It should be noted that the requirement for laboratory studies to determine bait efficacy against fleas after a single feeding are still deficient. A submitted protocol was determined acceptable in an Agency review dated May 16, 2007. This data is required to fulfill the insecticide efficacy portion necessary for product registration.