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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

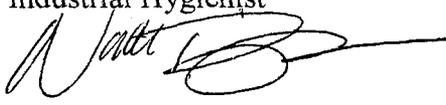
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 21, 2006

MEMORANDUM

SUBJECT: Cyphenothrin: Review of Sergeant's Pet Products, Inc. Draft Protocol, "Dislodgeability of Gokilaht from the Haircoat of Dogs Treated with a Spot-On Formulation." DP Barcode: 330741, PC Code: 129013

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This document serves as a response to Sergeant's Pet Care Products, Inc. request that the draft protocol titled, "Dislodgeability of Gokilaht from the Haircoat of Dogs Treated with a Spot-On Formulation," submitted as a part of, "Information to Upgrade MRID 46082302, MIRD 45869402, and MRID 45869401 (MRID 46874501); Appendix V, Specific Information to Address MRID 45869402," be reviewed by the Health Effects Division (HED). Upon review, the submitted draft protocol required some changes which are addressed in this memorandum. These changes are presented as a revised draft protocol, with a description of determined changes preceding, for use by Sergeant's Pet Care Products, Inc. to move forward with plans to fulfill HED's request for a dog spot-on study.

Changes Made for Part A. General

Upon consideration of the submitted draft pet spot-on study, "Dislodgeability of Gokilaht from the Haircoat of Dogs Treated with a Spot-On Formulation," HED determined several changes which were deemed necessary for the protocol. Major changes, as reflected in Part A. General, are the addition of a pilot study to precede the experimental study and the division of the experimental study into two separate portions (pet hug and hand-to-mouth exposure scenarios).

As detailed in the revised protocol (A. General, #8. Experimental Summary), a pilot study (changed to A. General, # 8. Pilot Study Summary) was determined necessary to decide upon the loading capacity of the sampling media as it pertains to the number (replicates) of petting simulations required for each time interval tested. This will reduce the number of replicates required for each time interval, while producing results representative of exposure to residues on the pet for the pet hug exposure scenario. The study director will determine at what number of simulations that loading occurs and the increase of replicate number becomes moot.

The pilot study (for use with the pet hug portion of the study only) will be conducted in the following manner. 5 beagle dogs will be treated with Gokilaht between the shoulder blades on Day 0. Each treated dog will then be sampled using a different number of petting simulations at 24 hours post-application (HED has considered how each petting simulation will be performed, this is addressed in Changes to Parts B and C). The number of petting simulations (replicates) for each treated dog will be performed for either 1 simulation, 5 simulations, 10 simulations, 15 simulations, and 20 simulations (i.e., Dog #1 will have 1 simulations performed, Dog #2 will have 5 simulations performed, etc.). 2 pre-washed cotton gloves will be worn over a 5-mil Nitrile glove. All gloves will be analyzed separately and combined for each simulation to determine the appropriate number of replicates for the experimental study. Samples will be stored and shipped in glass containers. In addition, the study director will determine if breakthrough is occurring to the Nitrile glove. The Nitrile glove will only be required to be analyzed in the experimental study if breakthrough is occurring; however, whether occurring or not, it is necessary for test participants to continue to wear the Nitrile glove under the cotton layers.

HED is requiring some changes to the experimental study, as well as the addition of the pilot study, as addressed in Part A. General, 8. Experimental Summary. It was determined that the experimental study will be divided into two portions to better analyze the exposures representative of the pet hug and the hand-to-mouth scenarios. In addition, HED determined that the sampling of multiple time periods would be beneficial for analysis of Gokilaht activity on the treated pet for the pet hug portion of the experimental study. The updated sampling time periods are as follows: prior to application, 1, 6, and 24 hours after dosing, and on Days 2, 4, 7, 14, and 28 after dosing. The pet hug experimental study will be performed using the number of simulations (replicates) which

were determined appropriate from the pilot study for the updated sampling time periods. Sampling may be discontinued if and when 2 non-detect samples are identified from the results of glove analysis. All other variables of the test system will remain the same.

The hand-to-mouth portion of the experimental study will be conducted as follows. HED determined that a 1 simulation set repeated for 10 dogs, prior to and 24 hours after application, will be acceptable for representation of this exposure scenario. The 10 dogs required for this sample set will be a separate group from those used in the pilot study, or the other portion of the experimental study. All other variables of the test system will remain the same.

Changes to Parts B. and C.

Most of the changes in Parts B. Experimental Design and C. Analysis of Sergeant's Pet Care, Inc. draft protocol are reflective of the alterations deemed necessary by HED and explained previously in Part. A. General. The following changes will be found in HED's reviewed protocol (only the sections that have changed are outlined below):

B. Experimental Design

1. Test System – Gloves

The draft protocol recommended cotton gloves only. HED recommends two pairs of cotton gloves with a 5 mil Nitrile glove underneath be worn for all study replicates.

2. Test System – Animals

d. Quantity

The draft protocol recommends the use of 10 beagle dogs for the proposed study. After review, HED recommends the use of 25 beagle dogs total for the entire study. This total includes 5 dogs for the pilot study, 10 dogs for the pet hug portion of the experimental study, and 10 dogs for the hand-to-mouth portion of the experimental study.

6. Post-Treatment Test Sampling

Changes recommended by HED for this section have been described in detail under Changes Made for Part A. General, # 9. Experimental Study (below). A description of how the petting simulation will be performed is included in HED's revised protocol. The petting simulation will be performed in the same manner for all parts (pilot, and experimental (pet hug, hand-to-mouth) studies) of the protocol. The description, as written in the revised protocol, is as follows:

The petting simulation or stroke will be performed in a manner which has been determined to mimic normal petting actions as well as actions that may occur during a child hugging the dog. Each stroke action will involve petting in a back-and-forth motion (2 pre-washed cotton gloves over 5 mil Nitrile glove) with splayed hands. The initial motion will be the back stroke, against the grain of the fur. This will be immediately followed by a forward motion, with the grain of the fur. These motions will be repeated starting with both sides (along the ribcage) of the dog, followed by the same motion along the back (dorsally). The two sides and back, in this order, with back-and-forth motion, will account for one stroke. This sequence of motions will be required for the pilot test and the experimental studies.

C. Analysis

2. Method of Analysis

The draft protocol describes cotton and latex glove collection for analysis. HED's revised protocol is changed to reflect analysis for two pairs of pre-washed cotton gloves and the 5 mil Nitrile glove (if breakthrough is determined from the pilot study).

Draft Protocol as Revised by HED for the Proposed Pet Spot-on Study

A. General

1. Study Title: Dislodgeability of Gokilaht from the Haircoat of Dogs Treated with a Spot-on Formulation
2. Purpose: To measure the dislodgeability of the test article from the haircoats of dogs treated with a spot-on formulation containing Gokilaht
3. Regulatory Compliance: This study will be conducted in compliance with US EPA Good Laboratory Practice Standards 40 CFR 160.

All procedures must be in compliance with Animal Welfare Act Regulations. All methods can be found in STILLMEADOW, Inc. Standard Operating Procedures (SOPs).

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