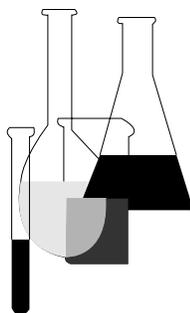




Product Performance Test Guidelines

OPPTS 810.3300 Treatments to Control Pests of Humans and Pets



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

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OPPTS 810.3300 Treatments to control pests of humans and pets.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*)

(2) **Background.** The source materials used in developing this harmonized OPPTS test guideline are OPP guideline 95–9 Treatments to control pests of humans and pets and 95–30 Acceptable methods (Pesticide Assessment Guidelines, Subdivision G: Product Performance, EPA report 540/9–82–026).

(b) **Overview.** This guideline is concerned with efficacy testing of invertebrate control pesticides used on humans and pets. Humans may be infested by three types of lice: The body louse, the head louse, and crab louse. The demonstration of effectiveness against any species should therefore be based on tests against lice of that particular type. Dogs and cats are generally infested by lice, fleas, ticks, and the species used must be fully identified in the report. There are many factors involved in actual use conditions that testing cannot always adequately evaluate. The habits of the host animals, infestation pressures of the parasite, exposure to rain, dew, sunlight, or even pH of water and geographical considerations can result in a change in the degree or duration of efficacy for a particular product. In order to make label claims more meaningful, an accurate description of product performance under a broad spectrum of use conditions should be recorded.

(c) **Definitions.** The following definitions apply to this guideline.

Control animals. Those animals not treated with any pesticide product.

Placebo. A collar formulated from the same carrier matrix as the collar to be tested, but lacking any active pesticide ingredients.

Positive control. A collar registered for the proposed label claims.

Qualified personnel. Individuals who count or apply the reinfestations and are trained in finding and recognizing the parasites on the dog. They should also be familiar with the biology of the parasite and the recording techniques necessary in development of meaningful data.

Test collar animals. Those animals wearing the collar which is under evaluation.

(d) **General considerations**—(1) **Number of trials.** A minimum of 5 large-scale, geographically-prepared trials are generally necessary, but the number of trials can vary somewhat due to the accessibility of infestations, fluctuations in pest population pressures, behavior, and other important considerations in the biology of the target pest.

(2) **Treatment techniques and equipment.** Product treatments to control pests of humans are applied as sprays, dusts, lotions, towels, ointments, creams, sticks, soaps, and shampoos. Product treatments to control pests of pets are applied as sprays, dusts, foams, flea collars, flea tags, soaps, and shampoos.

(3) **Evaluation and reporting considerations.** Reports should distinguish between killing and repelling effects, since repellent insecticides may preclude any lethal effects. Insect repellency test data should demonstrate minimal contact between the insect and the test chemical. Any adverse effects should be reported. Breed, age, size, and hair length influence the effectiveness of invertebrate control agents applied to dogs and cats, and such factors must be evaluated and reported in testing pet treatments.

(4) **Toxicology tests.** Any product intended to be applied directly to humans or pets, or used so as to provide frequent or constant product exposure to humans or pets, must be tested under the full range of toxicology testing required in OPPTS guideline series 870, Health Effects Test Guidelines. After submittal of such toxicology data, consultation with the Agency is required before extensive product performance testing dealing with human pest control products is undertaken.

(e) **Suggested performance standards.** These standards are presented on the basis of pest population counts from treated compared to untreated subjects unless otherwise specified.

(1) **Pests of humans**—(i) **Body louse.** Demonstrate 100% control of the stage(s) claimed to be controlled by the test product. Efficacy is based on numbers of the body louse before treatment and at intervals after treatment, in tests conducted where clothing, activities, and environments are typical of those of louse-infested populations. Ovicidal activity must be demonstrated unless repeat applications are intended.

(ii) **Head louse and crab louse.** Demonstrate 100% control of the stage(s) claimed to be controlled by the test product. Efficacy is based on the numbers of eggs, nymphs and adults of the head louse or crab louse before and after treatment in tests conducted where activities and environments are typical of those of louse-infested populations. Ovicidal activity should be demonstrated unless repeat application are indicated.

(iii) **Ticks, fleas, and mites.** Should provide 100% in pest infestation through a killing or repelling action when tested under simulated or actual conditions. Or, the product should provide the protection time (in hours) which is justified by the supporting data and appears on the label. The minimum acceptable protection time is one hour, when using first confirmed bite methodology, or sock testing.

(iv) **Mosquitoes.** Should generally provide a minimum of 2–3 hours protection time based upon first confirmed bite field tests, depending upon

the biting pressure evidenced in the testing. If the product provides longer protection times, then this may be stated on the label. Performance standards for killing mosquitoes are listed under OPPTS 810.7400, Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments.

(v) **Biting flies.** The data should indicate a minimum protection time of 3 hours based upon first confirmed bite field tests. A product may be registered for repelling biting flies if it provides one to three hours of protection, but the directions should be stated on the label.

(2) **Pests of pets (dogs, cats, birds)—(i) Fleas and ticks.** Provide 90% reduction in pest infestation through a killing action when tested under simulated or actual field conditions.

(A) **Guidance for the testing of flea and tick collars for control of ticks on dogs and cats—(1) Scope.** There are many commercially produced pesticidal matrices (as collars and tags) which may now or in the future bear label claims for the control of fleas or ticks. Such claims are acceptable only upon a demonstration of the efficacy of the product, as claimed, when used according to label directions. The strength and kind of acceptable label claims are generally determined by four factors which will be discussed later in greater detail. These factors are:

- (i) The degree of control against fleas and ticks.
- (ii) The anatomical coverage of the product.
- (iii) The species of parasites controlled.
- (iv) The duration of the control afforded.

This protocol is designed to aid the investigator or registrant in the development of data as it applies to the registration of various claims for impregnated products, in such a manner as to include all of the above mentioned considerations.

(2) **Size of the test.** The test should be large enough to permit good statistical evaluation. The exact number of animals to be evaluated cannot be specifically stated. However, the investigator is reminded that the validity of the results of the testing program is directly related to the degree of variability within the test. Increasing the number of test animals increases the reliability of the test results. In general, a minimum of six animals per group is required, with 10 preferred in any single test.

(3) **Selection of test arthropods—(i) Ticks.** Limited or single species testing may be utilized to support restricted claims. For general tick control claims, however, testing should be designed to show sufficient biological activity to control those species of ticks common to dogs. Therefore, a minimum amount of testing should be conducted to ascertain sufficient activity against representative tick species. In order to support a general

tick claim, data must be derived on the brown dog tick (*Rhipicephalus sanguineus*) and at least one other species of tick common to dogs. In addition to the brown dog tick, other tick species common to dogs include the lone star tick (*Amblyoma americana*), American dog tick (*Dermacentor variabilis*) and the Rocky Mountain wood tick (*Dermacentor andersoni*). *D. variabilis* is preferred.

(ii) **Fleas.** The only species required to be tested is the cat flea, *Ctenocephalides felis*. This flea is the predominant species on both dogs and cats. Mixed flea populations may be used providing that an adequate infestation of *C. felis* is established on the test animals and the fleas of different species are counted and recorded separately.

(4) **Characteristics of control.** The magnitude of the infestation on the control animals should be representative of the population as established by the screening procedures. Test collar dogs will then be compared to the controls by parasite count and body areas infested. The acceptance of a collar for registration and ultimate control claims allowed will be dependent on a number of factors. These may include the overall number of fleas or ticks, the number of live attached ticks and live fleas on the test collar dogs in comparison to the control animals; and the positive control animals.

(5) **Testing specifications.** (i) All testing shall be conducted on male and female adult dogs of various sizes and hair lengths.

(ii) Placebo collars shall be used on the control animals.

(iii) The animals should have a clean bill of health substantiated by a veterinarian and should undergo a preconditioning period of at least seven days before use. All animals should be washed with a non-residual insecticidal shampoo before initiation of the testing.

(iv) All control and test collar dogs shall be prescreened for tick attachment before initiation of the test. Only animals showing acceptable tick attachment shall be used in the study.

(v) Any other insecticides used on or near the animals during the course of any testing period must be fully justified, including any effects of such application on tick populations

(vi) While not required, a positive control test using a collar registered for tick control would serve as a standard reference and aid in the final evaluation of the test collars.

(vii) A minimum of 5 large dogs (40 lbs.) must be represented in the sum of the entire series of tests submitted for registration. It is recommended, that at least 3 large dogs be included in each group in each test.

(6) **Exposure.** (i) Adult parasites are recommended for infestation of the control and test collar animals. All ticks should be of uniform age and feeding status (unfed) since the last moult.

(ii) There are several basic methods for infesting dogs with fleas and ticks. Any of these may be acceptable in developing data for registration. Regardless of the infestation procedure, the primary consideration is to achieve adequate numbers of attached parasites with sufficient anatomical distribution to allow evaluation of collar effectiveness. The infestation procedure should be refined to the extent that equal infestation pressures are applied to both control and test collar dogs. In general, a minimum of 3 ticks and/or 5 fleas per dog (controls) are necessary for a valid test.

(iii) All animals should be housed individually in holding enclosures. The holding environment should provide both indoor and outdoor exposure.

(iv) If the proposed label claims refer to the ability of the collar such that performance is unaffected by washing, then the test collared animals should be bathed biweekly with a non-insecticidal shampoo.

(7) **Reinfestation.** (i) Since fleas and ticks will leave a dog in certain situations regardless of the presence of a collar, a reinfestation of unfed parasites must be made at specific intervals during the testing. All animals should be reinfested periodically following the initial infestation for the entire period of control proposed for the product. Frequent observations as described below for the initial infestation should be recorded for each subsequent reinfestation. The same period of observation (1–7 days) should be utilized for these reinfestations, and all remaining parasites should be removed at the end of each counting period. The duration of testing must be consistent with label claims; therefore, infestation pressure must be maintained throughout the entire period of control. It is suggested that the actual testing be continued in excess of the label claim being sought to provide more confidence in the data derived.

(ii) The reinfestation pressure should be of sufficient degree to induce an acceptable quantity of parasites to attach to the control animals.

(iii) The same collar shall be used on an animal for the duration of a study, and control and test collar animals shall not be interchanged prior to a reinfestation challenge.

(8) **Observations.** (i) All observations should be made and records maintained by qualified personnel.

(ii) A pretreatment inspection of all animals should be made to ascertain the number of parasites on the dogs prior to the installation of the collars.

(iii) The initial observations should be made soon after inoculation to ascertain the knockdown potential of the collar. This observation (usually at 2 hours, once again at 8 hours) is essential for a “fast acting” claim if so desired by the registrant. It is realized that observations made this soon after inoculation may affect the degree of attachment for the first counting period.

(iv) Frequent counts of parasites are then recorded (e.g., every 2–3 days) after infestation for a period of 5–7 days or until substantial detachment occurs after engorgement. These inspections should indicate the number, sex, attachment and viability (living or dead) of the ticks along with the specific locations on the animals (head, neck, torso, rump, legs, feet). This information should be recorded in conjunction with the age of the collar for the particular day on which a dog was inspected. For fleas; only the number of parasites need be recorded.

(v) Records should be kept for each individual animal, and the data combined into tables which compare the various test groups (test collars, controls, positive control animals).

(vi) All parasites remaining on animal (both test collar and control) at the end of the counting period should be removed as well as possible.

(vii) All abnormal signs and symptoms during the course of the study shall be noted and recorded for both control and test collar animals.

(9) Evaluation and interpretation of data derived from testing. The strength and kind of acceptable level claims are generally determined by four factors:

- (i) The degree of control.
- (ii) Anatomical sites of tick attachment.
- (iii) The species of parasites tested.
- (iv) The duration of effectiveness.

(v) **Ticks.** (a) First is the degree of control afforded by the collar. Such claims as “control ticks” must be supported by data which indicate that the collar will effectively reduce substantial populations of ticks to a level significantly below that of the control. For all practical purposes, this would be control to the extent that the user would not usually be required to rely on other pesticides or methods of control during the time period specified on the labeling. It is realized that 100% tick control will rarely be achieved in tests where the outdoor exposure may provide for a source of additional reinfestation. In general, 90% control is a desirable level of reduction, but even 80% control may support label claim under certain circumstances.

(b) It is also realized that some benefit is derived from collars which do not give control of ticks, yet induce a consistent recognizable reduction in the number of ticks on the test animals as compared to the control animals. Label claims for “aids in the control of ticks” are appropriate for such products. A recognizable reduction is a level of protection which is evident not only upon statistical analysis but which would be apparent to the purchaser of the product in actual use situations. A minimum of 50% reduction must be apparent for an “aids in control” claim.

(c) The second area of consideration is the use of anatomical restriction in those cases where the concentrations of pesticide generated from the collar matrix do not control ticks over the entire body of the dog. If anatomical restrictions are necessary, they will be added to the tick claim. A familiar example could be to specify control “in the head and neck area only.”

(d) As stated in paragraph (e)(2)(i)(A)(3)(i) of this guideline, the species of ticks tested will determine the label claims to be supported.

(e) The final factor involved in the interpretation of the data is the duration of testing as compared with efficacy. Label claims must be justified by data which are derived from testing the collar for that period of time which is to appear on product labeling. Such data must at least show the collar to be efficacious over the control period proposed for the product.

(f) **Fleas.** For fleas, a minimum of 90% control, as compared to the counts on the placebo animals, is required for the duration of testing. There are no “aids in control” claims or anatomical restrictions in regard to claims for the control of fleas.

(10) **Other data.** (i) Note that other kinds of data are also considered when evaluating the efficacy of a product. Such information as pesticide release rates, when accurately measured and correlated with the effective dosage of the active ingredient to ticks, may also be used. Such data should be derived from in vivo tests and reported as mg active ingredient released per day. Additionally, consumer or veterinary testing is often utilized to further indicate the performance of a collar.

(ii) This provisional protocol is not designed to be the only acceptable test methodology for the generation of applicable data. It is merely one acceptable method which attempts to resolve many of those items which have resulted in data which were unacceptable to support registration in the past.

(ii) **Lice.** Demonstrate 100% reduction in pest infestation through killing or repelling action when tested under simulated or actual field conditions.

(iii) **Mites.** Provide 100% reduction in pest infestation through killing or repelling action when tested under simulated or actual field conditions.