



CONSIDERATIONS FOR DEVELOPMENT OF RED IMPORTED FIRE ANT INSECTICIDE PRODUCTS

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Much of the information below was prepared by Daniel B. Peacock, Biologist, Insect-Rodenticide Branch Registration Division (H7504C), United States Environmental Protection Agency, Washington, D.C. 20460; 703/305-5407; <http://www.epa.gov>. For more information about effectiveness testing call Paul Schroeder (703/305-6602) or Vern McFarland (703/305-6694).

In the United States, *ANY* chemical-containing product sold that claims on the product label or marketing literature to control any pest(s). Pesticides must be registered by the United States Environmental Protection Agency (EPA) unless the active and inert ingredients are exempt under section 25(b) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). All pesticides sold in Texas must also be registered with the Texas Department of Agriculture (TDA; contact Charlie Thomas, 512/463-7422).

Development and registration of a pesticide may take millions of dollars and years to develop the documentation to satisfy regulatory requirements. Requirements change over time, and it is best to contact EPA and TDA personnel directly to determine the steps to take in developing of an imported fire ant insecticide. Because fire ants sting and are a pest of human medical significance, the EPA requires product performance (efficacy) data to support product claims (see: Product Performance Test Guidelines, OPPTS 810.3100, below). However, the cost in dollars and time to develop these performance data may be small compared to the cost of the rest of the data required (see: Imported Fire Ant Insecticide Product Development Outline, below) .

Companies wanting to develop and market a fire ant control product should consider:

- Cost of registration (federally and within target states where the product will be sold)
- Existing fire ant product market (What products are already registered? Will potential sales recover the developmental costs?)
- Cost of the end product and labor to apply it compared to available products
- Product effectiveness relative to “standard” products
- Usage “sites” - locations in which the product’s use will be supported, e.g., pastures, cropland, electrical boxes, vegetable gardens, lawns, etc.

If you decide to develop the product, and product evaluations are needed, contact the author (979/845-5878, b-drees@tamu.edu) or Dr. Charles L. Barr, Extension Program Specialist at the Texas Cooperative Extension (979/845-6800) and see “Animal and Plan Health Protection Product Evaluation Protocol” (FAPFS003) at <http://fireant.tamu.edu> under “materials” and “fact sheets” (particularly FAPFS036 and FAPFS037).

Imported Fire Ant Insecticide Product Development Outline

I. Requirements for Registration

A. Forms (available from the Environmental Protection Agency; see **“Sources for Pesticide Registration Materials,”** below)

1. Application form (EPA Form 8570-1)
 - a. Packaging/container size
2. Confidential Statement of Formula (CSF, Form 8570-4)
3. Certification Form (July 1998 version)
4. Data Matrix (July 1998 version)

B. Data

1. Product Chemistry (individual components of product)
 - a. Active Ingredient (Submit data consistent with 40 CFR 158 for the active ingredient.)
 - b. Inert Ingredients
If an individual component of the product is "food grade," no information must be submitted other than that indicated above under the CSF. If additional data are needed later, EPA will inform the applicant by letter. (Note: See Pesticide Registration (PR) Notice 98-X, “Notice to manufacturers, formulators, producers and registrants of pesticide products - Minimum Risk Pesticides Exempt from Registration under FIFRA **25(b)**” at <http://www.epa.gov/day-06/pr-577.html>.)
2. Product Chemistry (product as a whole)
Submit data consistent with 40 CFR 158 for the active ingredient.
3. Acute Toxicity (active ingredient)
Submit data consistent with 40 CFR 158 for the active ingredient.
4. Acute Toxicity (product as a whole)
Submit data consistent with 40 CFR 158 for the active ingredient.
5. Effectiveness
 - a. Basic Testing
As See EPA Registration Guidelines, Subpart G, 95-3, “Efficacy of Invertebrate Control Agents, General Soil Treatments,” for information about establishing basic effectiveness (OPPTS 810.3 100). Below are the names of two people in the agency with whom you can discuss testing.
 - b. Mode of Action (any information or data in this regard)
 - c. Claims
Specify claims about the dosage rates, selectivity,

treatment intervals, level or type of control (For example: Does the product kill just individuals, certain stages or all individuals, including queens?). Once the EPA has reviewed the effectiveness data, it will provide additional guidance about acceptable claims.

- d. Requirements for scientific data. The best way to proceed is to contact the effectiveness reviewer and discuss the basis of an acceptable study design. When completed, submit a copy of the protocol for EPA review. After you incorporate any needed changes in the study design, begin testing.

6. Environmental Effects and Fate (See 40 CFR 158)

C. Labeling Requirements

These documents contain general information about labeling requirements:

1. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
2. 40 Code of Federal Regulations 156.10
3. Label Review Manual

Study existing labeling in the marketplace. Once you have submitted all the required data in the correct format (See PR Notice 86-5 or the Label Review Manual.) and the EPA has reviewed those data, it will give you with more guidance before registration.

D. Formatting Data

Submit any data in the format outlined in PR Notice 86-5. Among other things, properly formatted submissions will include:

Three (3) copies of each study, each of which will include:

1. Title Page
2. Confidentiality Page
3. Good Laboratory Practices (GLP) Statement
4. Copy of Study

Pagination should begin with Title Page (I of 10, 2 of IO, etc.)

If you have formatting questions, please contact the EPA.

II. Information about the Registration Process

1. General Information

The EPA's "General Information on Applying for Registration of Pesticides in the United States," 2nd Edition is available from the National Technical Information Service (NTIS) in Springfield, Virginia. The telephone number for NTIS is 703/487-4640, and the Order No. is "PB92-22181 I."

2. Sources for Pesticide Registration Material (See below).

3. Labeling Information

Another NTIS publication (PB95-159818), "Label Review Manual," explains the finer parts of developing a pesticide label and provides additional guidance to 40 CFR 156.10.

4. Forms and Other Key Registration Documents

For copies of registration forms and other key registration documents, such as copies of the Act or Regulations, call 703/308-8341.

5. Testing Information

The NTIS distributes the EPA Registration Testing Guidelines, which should be studied before commissioning tests to support the product's registration.

6. Questions about Effectiveness Testing

If you have questions about effectiveness testing after you review the guidelines, call Paul Schroeder (703/305-6602) or Vern McFarland (703/305-6694). They review effectiveness data and are familiar with the protocols.

Product Performance Test Guidelines

OPPTS 810.3100

Soil Treatments for Imported Fire Ants

INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) of the United States Environmental Protection Agency (EPA) 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 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 and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs which appeared in publications of the National Technical Information Service and the guidelines published by the Organization for Economic Cooperation and Development.

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 EPA 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.*).

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, D.C. 20402 on *The Federal Bulletin Board*. By modem dial 202/512-1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call 202/512-0132 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from EPA's World Wide Web site (<http://www.epa.gov/epahome/research.htm>) under the heading "Researchers and Scientists/Test Methods and Guidelines/OPPTS Harmonized Test Guidelines."

OPPTS 810.3100 Soil treatments for imported fire ants

(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 material used in developing this harmonized

OPPTS test guideline is OPP guideline 95–3 General Soil Treatments (Pesticide Assessment Guidelines, Subdivision G: Product Performance, EPA report 540/9–82–026, October 1982).

(b) **Overview.** This guideline is concerned with efficacy testing of invertebrate control pesticides used for control of imported fire ants.

(c) **General considerations.** The testing of pesticide products for use in home gardens should follow the same procedures as are appropriate for evaluating their commercial use.

(d) **Evaluation and reporting procedures.** The procedures used to evaluate product performance should be specified. Reports should include insect counts, percent damage, or other measures for determining the effectiveness of the test product. Results should include the average infestation reduction throughout the sampled post-treatment period compared with that in control plots or in pre- and post-treatment periods. Raw data on pest counts, injury counts, or other measures of control should be summarized. Any adverse effects such as phytotoxicity should be reported.

(e) **Site selection.** Sites should be selected from several states within the range of the imported fire ant. Usually, three such sites are necessary to provide information in the data derived.

(f) **Plot size—(1) Mound application.** In general, use a minimum of 10 mounds per plot. Usually, 3 to 4 plots are treated with the candidate compound and 1 plot is used as a control.

(2) **Broadcast treatments.** Plots should be of sufficient size to permit the use of the application equipment specified on the label. Replication may be difficult when very large plots are necessary, but is encouraged to develop statistically valid data.

(g) **Suggested performance standards.** Unless otherwise specified, these standards are presented on the basis of pre- and post-treatment pest population counts from the treated as well as the untreated lots and standard comparative treatments. All percentages of control refer to the performance of the test substance (as determined by insect counts and other measures correlated to insect population pressures) against the vulnerable stage(s) of the target pest, when evaluated according to a recognized treatment program under actual field conditions.

(1) **Control claims.** A minimum of 90 percent control based on counts made for a minimum of 30 days for mound applications and 60 days for broadcast treatments is required. Percent control is based on the percent reduction in both old and new active mounds in the treatment area as compared to precounts and untreated controls.

(2) **Suppression claims.** For broadcast treatments only, a minimum of 80 percent control based on counts made for a minimum of 60 days and based upon the adjusted percentage of reduction of the total number of old and new active mounds in the treatment area and untreated controls is required. A lower percentage of control may be acceptable if testing was done under adverse conditions, but in no case would less than 70 percent control be acceptable.

Sources for Pesticide Registration Materials (10/1998)

http://www.epa.gov/pesticides	Pesticide information
http://www.epa.gov/oppmsd1	“
http://www.access.gpo.gov	“
http://www.epa.gov/pesticides/registrationkit/	registration kit
http://www.epa.gov/oppd001/forms/	registration forms
http://www.epa.gov/oppmsd1/PR_notices	PR notices
http://www.epa.gov/oppfead1/labeling/lrm	label review manual
http://www.pestlaw.com/label_unit/index.htm	“
http://www.epa.gov/oppfead1/fqpa/fqpaiffr.htm	FIFRA (w/ FQPA)
http://www.law.cornell.edu/uscode/7/ch6.html	“
http://www.epa.gov/pesticides/cfr.htm	code of federal regulations (CFR title 40, parts 150-189)
http://www.access.gpo.gov/nara/cfr/index.html	“
http://www.epa.gov/fedrgstr	Federal Register (FR)
http://www.gpo.gov/su_docs/aces/aces140.html	“
http://www.epa.gov/oppmsd1/PR_notices/pr98-5pdf	data compensation forms (7/98)
http://www.epa.gov/oppmsd1/DataSubmittersList	data submitters list
http://www.epa.gov/oppmsd1/RestProd/index.html	restricted use pesticide list
http://www.epa.gov/opped001/inerts/	inert lists
http://www.epa.gov/oppd001/tolerance/tolind.htm	pesticide tolerances
http://fedbbs.access.gpo.gov/lib/epa_ti.htm	“
http://www.epa.gov/OPPTS_Harmonized	data test guidelines
http://www.cdpr.ca.gov/docs/epa/epamenu.htm	pesticide product data & labels
(online queries)	
http://www.epa.gov/oppmsd1/PPISdata	“
(data download)	
http://www.epa.gov/REDS	re-registration eligibility documents
http://www.epa.gov/opprrd1/REDS	“
http://www.epa.gov/pesticides/contacts.htm	EPA contacts - Office of Pesticide Programs
http://www.epa.gov/oppd001/contacts_rd.htm	EPA contacts - OPP/Registrations Division
http://siri.uvm.edu/msds/	MSDS forms
http://www.enviro-net.com/technical/msds/	“
http://www.gpo.gov/su_docs/index.html	government printing office

EPA's Office of Pesticide Programs Communications Branch: 703/305-5017

EPA fax-back (call from fax to get list of doc #s): 202/401-0527

EPA - All registration actions, U.S. mail:

Document Processing Desk (insert code word - see PR89-1)

Office of Pesticide Programs (7504C)

U.S. Environmental Protection Agency

401 M. St., SW, Washington, DC 20460-0001

For more information regarding fire ant management, see Extension publications [B-6043](#), *Managing Red Imported Fire Ants in Urban Areas*; [B-6076](#), *Managing Red Imported Fire Ants in Agriculture*; [B-6099](#), *Broadcast Baits for Fire Ant Control*; or [L-5070](#) *The Texas Two-Step Method Do-It-Yourself Fire Ant Control for Homes and Neighborhoods*. Also visit our web site at <http://fireant.tamu.edu>.

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