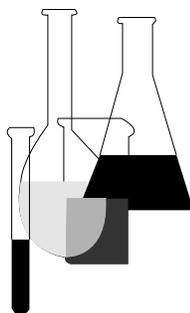




Occupational and Residential Exposure Test Guidelines

OPPTS 875.1600

Application exposure monitoring data reporting



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.*).

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202-512-1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), internet: <http://fedbbs.access.gpo.gov>, or call 202-512-0132 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading "Environmental Test Methods and Guidelines."

OPPTS 875.1600 Application exposure monitoring data reporting.

(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.*) and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 236. This guideline should be used with OPPTS 875.1000.

(b) **Report format.** If, in the registrant's opinion, a better format would result in a more efficient review by the Agency, it may be used. However, the information described herein must be included.

(1) *Title page.* The title page should conform with existing Agency requirements.

(2) *Table of contents.* The table of contents should indicate the overall organization of the report and list the page numbers for the different sections. Tables, figures, and appendices should be listed separately. (Section tabs would be of help to the Agency in its review.)

(3) *Introduction and summary.* (i) This section should open with a description of the purpose of the study and what requirement(s) it is intended to satisfy. Background and historical information relative to the study should be placed in this section.

(ii) The introduction and summary section should also contain an overall summary of the study and mention, at a minimum, the following points:

(A) The chemical (use the name used throughout the report and indicate the formulation) was applied according to actual practice to the primary crop.

(B) The application rate in units of active ingredient per unit of area, volume of spray per unit of area, and total units of active ingredient handled during each work activity.

(C) The number of individuals involved in the study, indicating duties and clothing worn during each work activity monitored.

(D) Indicate unusual problems (such as spills, unusual weather, or equipment failure) resulting in necessary deviations from the intended test protocol. Describe the effects of these deviations in the results of the study.

(E) Provide a name and phone number of a contact person in the event the reviewer has technical questions about the study.

(4) *Materials and methods.* (i) This section should be in narrative form, and should contain (in the following order) all details with regard

to the materials, equipment, experimental design, site description, and procedures used in conducting the study. The registrant is encouraged to include drawings (or preferably photographs) of the test site equipment, and the workers that show the placement of monitoring devices.

(ii) In this section, the following should be included:

(A) *Chemical*. The name of the active ingredient, CAS number, formulation and percent or concentration of active ingredient and impurities, EPA registration number, lot number, type of container, and chemical trade name.

(B) *Site*. A description of the test site indicating the location, crop, row spacing, and acres treated for outdoor applications and location, room size, size of surface treated, ventilation during and after application, and the air exchange for indoor applications.

(C) *Test method*. For all applications, a description of the application rate, spray tank capacity, type of carrier and other additives, final mix concentration, total pounds of active ingredient applied or mixed, and the mixing procedures.

(1) For outdoor applications a detailed description of the application and mixing/loading equipment including nozzle type, height from the ground and the top of the crop, nozzle pressure, ground speed, boom length, and cab description shall also be provided when applicable.

(2) For indoor applications a detailed description of the application equipment, including type of spray nozzle shall be provided.

(3) A description of the subjects used in the study. This shall include work function, clothing worn (including protective clothing), placement of all monitoring devices on the subjects, and the duration of the monitored work function.

(4) A detailed description of the monitoring devices. The description shall specify the material and brand of the devices used for passive dosimetry including total area and the area of the surface exposed to the test chemical. The description of any air sampling devices shall include brand, air flow rate, and the type of trapping device used, including the composition of the material in the collection media.

(5) A description of the laboratory studies conducted prior to initiating the field studies. This shall include a description of the methodology used to determine test chemical, stability on the collection media, the efficiency of extraction, and stability of the extracts.

(6) A description of the handling of samples from the time they were taken in the field through analysis with special attention to the conditions under which the samples were stored. In addition, the handling of storage

stability samples to be used in determining if the pesticide residues are stable under storage conditions shall be described.

(7) A description of the required field stability, field fortification, environmental conditions to which the fortified media was exposed, and a description of the handling of the samples from field collection to laboratory analysis.

(8) Elaboration on the difficulties or special problems that arose during the study that necessitated deviation from the intended test protocol and on the effects the deviations had on the results. This is intended to include such circumstances as equipment failure and repair with may affect the exposure monitoring.

(5) *Analytical method.* (i) The methods used in the study for each test (i.e. efficiency of extraction, field fortification) are to be described fully and include method validation data, recovery and method sensitivity data, stability date, sample chromatograms, and sample calculations. Preparation and handling of the samples throughout the method should be described in detail.

(ii) Identify the instrumentation, equipment, reagents used, and the operating conditions of the instruments. If the extraction/clean-up procedure is complex, a flow diagram should be submitted. Extraction efficiencies, recoveries, precision, and limit of detection need to be reported along with the technique used to determine these parameters for each method.

(6) *Results.* This section should contain the scientific results of the study and must be interpretive. Narrative and tables describing all calculations should be presented. The results shall be reported as described in OPPTS 875.1000, under paragraphs (h)(6) and (i)(6). A sample calculation for each separate mathematical manipulation must be provided.

(7) *Discussion and conclusions.* Because the ultimate determination of the exposure produced by the use of a pesticide rests with the Agency, these sections are optional.

(8) *Quality assurance.* Name (including signature and date) of the person(s) responsible for the major quality control (QC) duties, should be included. Also included should be the procedures undertaken by the registrant/laboratory to validate the report. This may be a list of all audits and reviews performed that includes the study activity, the date activities were performed, and the individual(s) involved. Any deficiencies and subsequent corrective action taken should be described.

(9) *Location of raw data and final report.* The name and address of the facility in which the raw data and final report are reposed must be reported.

(10) *Signature page.* This page shall contain the dated signatures of all professionals and scientists involved with or responsible for the study.

(11) *Tables and figures.* Tables and figures are to be numbered using Arabic numerals rather than Roman numerals or letters.

(12) *References.* References must be presented in a standard and consistent format.

(13) *Appendix(es).* The Appendix(es) should contain:

(i) Copies of all relevant communications.

(ii) A copy of the Agency-approved study protocol and all subsequent amendments to the protocol.

(iii) To facilitate exposure data reporting and entry into the computerized data base, as well as to facilitate data entry for the registrants, data entry diskettes and a Data Entry Diskette User's Guide are available at no charge by calling the Agency contractor for Pesticide Handler Exposure Database (PHED), Versar, Inc., at 1-800-2-VERSAR.

(iv) Sample chromatograms, diagrams, photographs, or other pictorial material.