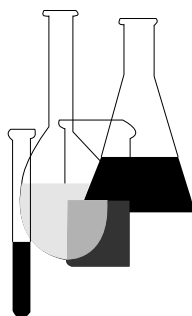




Microbial Pesticide Test Guidelines

OPPTS 885.3400 Hypersensitivity Incidents



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 885.3400 Hypersensitivity incidents.

(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 the OPP guideline 152A–15.

(b) **Reporting.** (1) The reporting requirements for these incidents should be the same as those for conventional chemical pesticide incident reports as specified in the Pesticide Incident Report form (EPA Form Number 8550–5, OMB Form number 158–R0008). The following information should be provided, if available:

(i) A description of the ingredients (including the microbial pest control agent (MPCA)) to which affected individuals were exposed.

(ii) The frequency and duration of exposure to the material, and routes of exposure.

(iii) The time, date, and location of exposure to the material.

(iv) The situation or circumstances under which exposure to the material occurred.

(v) Any clinical observations.

(2) The data should be submitted to one of the following addresses:

(i) Via the U.S. Postal Service: Document Processing Desk, Office of Pesticide Programs (7504C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(ii) Via personal or courier delivery: Office of Pesticide Programs, Document Processing Desk, Rm. 266A, Crystal Mall 2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

(c) **Tier progression.** If any incidents of hypersensitivity of humans or domestic animals are observed during the production or testing of the technical grade of the active ingredient, the manufacturing-use product, or the end-use product, additional testing may be required. The specific requirements will depend on the nature of the observations and will be determined after consultation with the Agency.