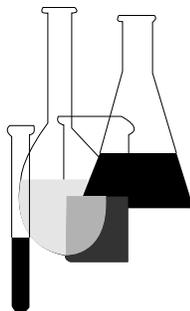




Microbial Pesticide Test Guidelines

OPPTS 885.1200 Manufacturing Process



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."

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(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 are OPP guidelines 151A-1 and 151A-11.

(b) **Information needed.** The product analysis data requirements for microbial pest control agents (MPCAs) parallel those for conventional chemical pesticides in OPPTS Series 830. However, due to the unique nature, composition, and mode of action of the MPCAs, there are some important differences. For example, protozoa, bacteria, fungi, and viruses should be identified to the extent possible by taxonomic position, serotype, composition, and strain, or by any other appropriate specific means. This information would take the place of chemical name and structure information for conventional chemical pesticides. In addition, the Agency must be reasonably assured that the methods used and the data submitted are capable of demonstrating that the microbial pesticide used in the field is the same as that which was tested for safety. Each application for registration of a manufacturing-use product or end-use product shall contain a description of the basic manufacturing process. The starting and intermediate materials should be listed (including EPA Registration No. and/or source and purity) together with the steps taken to ensure the integrity of these materials, and the steps taken to limit the extraneous contamination, both chemical and biological, in preparations of the unformulated MPCA. This description shall include the procedures used by the manufacturer to establish the identity and purity of the culture from which the unformulated MPCA is produced, the method of manufacture, and techniques used to ensure a uniform or standardized product. The integrity of the product as determined by specific and sensitive chemical, serological or biological tests is to be demonstrated. If the test is not a recognized standard test, a detailed description of the test together with information regarding precision, specificity, interfering substances, accuracy, and sensitivity must be provided.

(c) **Maintenance of samples.** A sample of registered MPCAs is to be maintained on deposit in a nationally recognized culture collection. A large initial batch could be preserved in small aliquots to serve as seed stock for subsequent batches. This would minimize contamination and variation (chromosomal and extrachromosomal) caused by serial passage. If the MPCA produces a toxin, this may need to be monitored as a form of quality control.