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Prevention, Pesticides
and Toxic Substances
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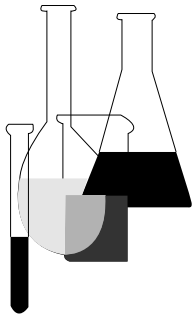
Microbialst Pesticide Test Guidelines

OPPTS 885.1500
Certification of Limits



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 885.1500 Certification of limits.

(a) **Scope—** (1) **Applicability.** This guideline is intended to meet testing requirments of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 163, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline are OPP guidelines 151A–1 and 151A–15.

(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.

(c) **Certification of ingredient limits.** (1) As required by 40 CFR 158.740, each registration must be supported by a certification of ingredient limits. Refer to OPPTS 830.1750 and 830.1800 regarding certification of limits and analytical methods to verify certified limits. The limits for MPCAs and contaminants should be expressed as:

(i) MPCA units per unit weight or volume which may determined using biological, genetic, biochemical, serological or other appropriate tests.

(ii) International units of potency per unit weight which may determined using biological, genetic, biochemical, serological or other appropriate tests.

(iii) Weight percent of product.

(2) Note that two or more methods may be required to verify the certified limits of the MPCAs and any microbial impurities. Plate counts (colony- or plaque-forming units per unit weight or volume) or infectivity assays may be necessary for quantitation and to allow preliminary identification. Antibiotic resistance bioassays may eliminate some contamination as well as provide additional identification support. In some cases, especially in the case of genetically altered MPCAs, absolute identification can be achieved only through the use of one or more of the various immunological methods (such as enzyme-linked immunosorbent assay) or molecular probe methods (such as the Southern hybridization procedure

or restriction endonuclease mapping). Methods must be specific enough to determine the MPCA in the presence of revertants/mutants and contaminants that may have formed or been introduced during the replication/manufacturing process.