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Prevention, Pesticides
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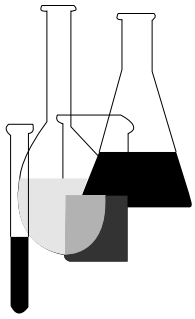
Microbial Pesticide Test Guidelines

OPPTS 885.1100
Product Identity



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 885.1100 Product identity.

(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 OECD guidelines 151A–1 and 151A–10.

(b) **Product identity.** 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. As required by 40 CFR 158.740, each application for registration of an MPCA shall contain the following information: The product name; the trade names (if different). The company code numbers may be given.

(c) **Confidential statement of formula.** As required by 40 CFR 158.740, an application for registration of a product shall contain a confidential statement of formula (CSF). The appropriate EPA form (EPA Form 8570-4) shall be used. This statement shall include the nature and quantity of the active ingredients and diluents and the identity and purpose of inert ingredients such as ultraviolet screens, stickers, spreaders, and other such material. The name of each ingredient in the product for which OPPTS 830.1550 requires certified limits to be established shall be listed. A separate CSF is required for each alternate formula of a product. See section 10 of the Act for requirements related to the protection of trade secrets.

(d) **Information on ingredients.** Information on ingredients is required by 40 CFR 158.740 to support each application for registration.

(1) The identification of the MPCAs in the product shall (to the extent possible) include the following:

(i) The taxonomic position, serotype, strain, or any other appropriate designation. The precise test procedures and criteria used for identification (i.e., the morphological, biochemical, analytical (physical, chemical), serological, or other identification means) and the results of such tests should be provided. If the MPCA contains plasmids or other extrachromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity,

etc., these must be identified as well as any known phenotypic characters coded by such elements and their stability. Whether or not a wild type or genetically altered strain is considered to be a new active ingredient will be determined on a case-by-case basis upon comparison with existing related strains.

(ii) The common, alternative, and superseded names.

(iii) The natural occurrence of the organism, its relationship to other species (particularly those that are pathogenic), and its history.

(iv) A description of the morphological types of the MPCA and any unusual morphological, biochemical, or resistance characteristics of the organism if such characteristics are different from the classic description of the organism.

(v) The amount of MPCA present in the product in recognized units of potency, percentage of weight, units of MPCA per unit weight or volume of product, or other appropriate expression of biological activity.

(vi) The biological properties of the active agent with respect to target species, pest host range, life cycle, and mode of action. With respect to the properties of the microbial agent, any known or potential hazard (such as infectivity) to mammals (including humans), the environment, and nontarget species should be discussed.

(vii) If the MPCA in question has been altered genetically, in addition to paragraph (d)(1)(i through vi) of this guideline, the methods used to alter the microbe genetically should be provided. In the case of genetically altered products, the identity of the inserted or deleted genetic material (source, nature, size, base sequence data and/or restriction endonuclease map), information on the gene control region, descriptions of the phenotypic traits to be gained or lost, and information as to the genetic stability (reversion tendency or rate of exchange/transfer with other organisms) of the genetically altered chromosomal region or extrachromosomal entity are to be discussed. Genetic material adjacent to the intentionally inserted genes which may have been engineered into the recipient are to be fully characterized and the likelihood of expression must be provided.

(2) An application for registration shall contain the following information on each ingredient, other than the MPCAs, listed in the CSF rquired in paragraph (c) of this guideline which is known to be present or which might reasonably be identified in the pesticide product.

(i) Percentage composition (by weight) of each ingredient; the number of units per unit volume or weight is needed for microbial impurities; viability data in terms of PFU, CFU, etc., per unit weight or volume of product.

(ii) Whether the ingredient is an active ingredient, an intentionally added ingredient, or an impurity.

(iii) The chemical name from the Chemical Abstracts Index of Nomenclature, or other well-defined name. (If one or more impurities are microbial agents, the agents are to be classified/identified according to acceptable nomenclatural systems.)

(iv) The Chemical Abstracts (CAS) Registry Number.

(v) The product name, the trade name, and the common name.

(vi) The experimental or internal code number.

(vii) For each active ingredient other than the MPCA, the empirical formula, and the molecular weight or the molecular weight range.

(viii) The structural formula (when known).

(ix) The composition limits for each ingredient for which OPPTS 830.1550 requires limits to be certified. This information is to be listed on the CSF, EPA Form 8570-4 revised 2/85 (or superseding revisions).