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Environmental Protection
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Prevention, Pesticides
and Toxic Substances
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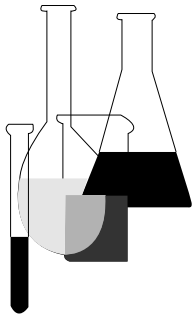
Microbial Pesticide Test Guidelines

OPPTS 885.3550
Acute Toxicity, Tier II



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 885.3550 Acute toxicity, Tier II.

(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–20.

(b) **Purpose.** Acute toxicity data provide information on health hazards likely to arise from a single exposure to toxins or toxic components derived from or associated with the test substance. The toxic components are to be isolated and identified. The purpose of an acute toxicity study is to determine the median lethal dose, its statistical limits, and slope using a single exposure and a 14–day postexposure observation period.

(c) **Definitions.** The following definitions apply to this guideline.

Acute toxicity is the adverse effects occurring from administration of a single dose of a component, or components, of the test substance.

Median lethal dose is a statistically derived single dose of a substance that can be expected to cause death in 50 percent of animals. It is expressed in terms of weight of test substance per unit weight of test animal, and also in terms of the proportion, by weight, of toxic components in the test substance per unit weight of test animal.

(d) **Principle of the test method.** The test substance, including toxic components, is administered in graduated doses to several groups of experimental animals, one dose being used per group. Subsequent observations of effects and deaths are made. Animals which die during the test are necropsied, and at the conclusion of the test, the surviving animals are sacrificed and necropsied as indicated by the nature of the toxic effects observed.

(e) **Substance be tested.** Toxic components of the MPCA preparation are to be isolated and identified. The test substance will comprise an appropriately purified preparation of the toxic components. The proportion by weight of toxic components in the test substance is to be determined and reported.

(f) **Test procedures**—(1) **Animal selection.** The species and strains of test animal to be used are those in which toxic effects were observed in the acute toxicity/pathogenicity studies from Tier I.

(2) **Route of exposure.** The route or routes of exposure should correspond to each and all routes (i.e. oral, dermal, and pulmonary) where toxicity was observed in the acute toxicity/pathogenicity studies from Tier I. A separate acute toxicity test is required for each route of exposure.

(3) **Other test standards.** (i) The applicable test standards set forth in OPPTS 885.2500, 885.2550, and 885.2600, and in OPPTS 870.1100, 870.1200, and 870.1300 should be followed.

(ii) If acute pulmonary toxicity tests are required, the applicable standards set forth in OPPTS 885.3150 usually will take precedence over the standards set forth in OPPTS 870.1300.

(g) **Tier progression.** The Agency will make recommendations on appropriate further test requirements. In general, further test requirements comprise appropriate tests as described for biochemical pest control agents in this series of guidelines (OPPTS 885) or for chemical pesticides as described in OPPTS series 870.