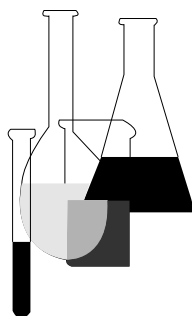




# Biochemicals Test Guidelines

## OPPTS 880.1100 Product Identity and Composition



## 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](http://gopher.epa.gov)) under the heading "Environmental Test Methods and Guidelines."

**OPPTS 880.1100 Product identity and composition.**

(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 OPP guideline 151-10.

(b) **Product identity.** As required by 40 CFR 158.165, each application for the registration of a biochemical pest control agent that is a pesticide product shall contain the product name and trade names (if different). The company code numbers may be given.

(c) **Confidential statement of formula.** As required by 40 CFR 158.165, an application for registration of a product shall contain a confidential statement of formula. The appropriate EPA form shall be used (i.e., form 8570-4). The name of each ingredient in the product for which OPPTS 830.1670 and 830.1750 specifies certified limits to be established should be listed. A separate confidential statement of formula is required for each alternate formula of a product. See FIFRA sec. 10 for requirements related to protection of trade secrets.

(d) **Information on ingredients.** As required by 40 CFR 158.165, an application for registration should contain the following information (if available) on each ingredient which is listed in the confidential statement of formula required by paragraph (c) of this guideline:

(1) Each biochemical, including microbial toxins, should be identified by:

(i) The chemical name from the Chemical Abstracts Index or other well-defined name.

(ii) The Chemical Abstracts Service (CAS) Registry Number.

(iii) The structural formula and empirical formula.

(iv) The amount of biochemical present in the product in recognized units of potency or other appropriate expression of biological activity or percentage of weight.

(v) The genus and species names of organisms from which the biochemical was separated or with which it is commonly associated.

(vi) The specificity or host range of the biochemical activity and mode of action. With respect to mode of action of the biochemical, the applicant should discuss any potential hazard to humans, the environment, or nontarget species.

(2) Ingredients, other than biochemicals, shall be identified by:

- (i) Percentage composition (by weight) of each ingredient.
  - (ii) Whether the ingredient is an active ingredient, an intentionally added ingredient, or an impurity.
  - (iii) The chemical name from the Chemical Abstracts Index or other well-defined name.
  - (iv) The Chemical Abstracts Service (CAS) Registry Number.
  - (v) The product name, the trade name, and the common name (if established).
  - (vi) The experimental or internal code number.
  - (vii) For each active ingredient other than the biochemical, the empirical formula and the molecular weight or the molecular weight range.
  - (viii) The structural formula, if it can be determined.
- (3) The composition limits shall be given for each ingredient for which 40 CFR 158.110 requires limits to be certified. If space permits, this information can be listed in the confidential statement of formula; otherwise, a separate statement on certification of limits must be submitted.