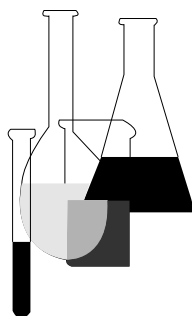




# Biochemicals Test Guidelines

## OPPTS 880.1200 Description of Starting Materials, Production, and Formulation 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](http://gopher.epa.gov)) under the heading "Environmental Test Methods and Guidelines."

**OPPTS 880.1200 Description of starting materials, production, and formulation process.**

(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 151-11.

(b) **Manufacturing process.** As required by 40 CFR 158.165, each product's registration must be supported by an accurate and current description of the process used to manufacture or formulate the product.

(1) **Description.** The description shall contain the basic manufacturing process.

(i) For each biochemical derived from biological sources:

(A) The starting material shall be listed.

(B) The steps taken, both chemical and biological, to ensure the integrity of the starting material and to limit the extraneous contamination in the unformulated biochemical shall be given.

(C) The procedures by which the manufacturer established the identity and purity of the seed stock from which the unformulated biochemical is produced shall be described.

(D) The quality control methods and the techniques used to ensure a uniform or standardized product shall be reported. Unless the quality control methods are well established and recognized, they shall be submitted in detail with information regarding their accuracy, sensitivity, and interfering substances.

(ii) For other ingredients, active and inert, follow the guidelines in OPPTS 830.1600, 830.1620, and 830.1650.

(2) **Toxic or sensitizing substances.** If the presence of ingredients toxic or sensitizing to humans or other nontarget mammalian species is suspected at any stage of the manufacturing process, then data must be submitted to show that the substances do not exist in the final biochemical product or exist only in quantities too small to pose any hazard.