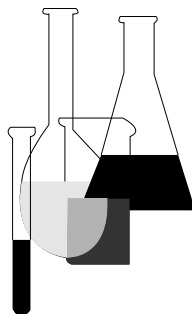




Biochemicals Test Guidelines

OPPTS 880.1400

Discussion of Formation of Impurities



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) under the heading "Environmental Test Methods and Guidelines."

OPPTS 880.1400 Discussion of formation of impurities.

(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 151-12.

(b) **Unintentional ingredients.** As required by 40 CFR 158.167, a registration application shall include a discussion concerning potential formation and presence of unintentional ingredients in the product in quantities which may produce adverse human or environmental effects.

(1) As described under OPPTS 830.1670, such unintentional ingredients may be introduced during the following manufacturing process:

(i) With the starting material, process solvents, equipment, packaging, and other sources.

(ii) From side reactions in the manufacturing process.

(iii) From interactions between ingredients.

(iv) From the degradation of ingredients.

(2) The applicant should base his discussion on established chemical theory.

(3) For biochemicals, the unintentional ingredients can include but are not limited to extraneous host residues and residues of contaminants that remain following the extraction or purification process.