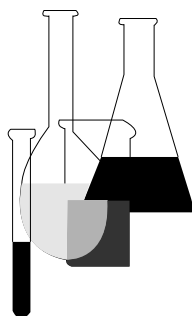




# Residue Chemistry Test Guidelines

## OPPTS 860.1100 Chemical 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.*).

**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 860.1100 Chemical Identity.**

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, *et seq.*).

(2) **Background.** The source material used in developing this harmonized OPPTS guideline is OPP 171–2 Chemical Identity (Pesticide Assessment Guidelines, Subdivision O: Residue Chemistry, EPA Report 540/9–82–023, October 1982). This OPPTS guideline should be used in conjunction with OPPTS 860.1000, Background.

(b) **Purpose.** The Agency needs information on chemical identity to identify components in the technical mixture accurately, to compare compositions of the test substances (i.e. active ingredients) in all chemistry and toxicology required testing, and to identify compounds, other than the active ingredient, that may need to be regulated (i.e. that would require a tolerance or an exemption from a tolerance).

(c) **Active ingredients.** Data requirements for chemical identity are essentially the same as discussed in OPPTS 830.1550, Product Identity and Composition, concerning product identity and disclosure of ingredients. In addition to those data required in the 830 series of guidelines (Product Properties), Section A of a petition for a tolerance or exemption should include an assessment of whether any of the impurities will present a residue problem. If an impurity is likely to occur as a significant residue in food/feed, residue data for the impurity as described in guidelines OPPTS 860.1300 through 860.1520 (Section D of a petition) will be required. The determination of whether residue data for an impurity is needed will be based on the impurity stability, toxicity, and detectability.

(d) **Information required for inert ingredients.** Inert ingredients of the formulation should be fully described, including the chemical as well as any trade names. Chemical Abstract Service (CAS) numbers should be included if available. The chemical names should be in the same form as those for inert ingredients cleared under 40 CFR 180.1001, paragraphs (c), (d), and (e). If only the trade name is known, the petitioner should request that the supplier of the inert ingredient furnish the descriptive information on the nature of the inert ingredient directly to the EPA. Any inert ingredient that has not yet been cleared should be indicated, and a request for clearance initiated as described in OPPTS 860.1550.