

Prevention, Pesticides and Toxic Substances (7101) EPA 712-F-08-002 November 2008

Product Properties Test Guidelines

OPPTS 830.1900 Submittal of Samples



INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances (OPPTS), United States Environmental Protection Agency (EPA or the Agency) for use in the testing of pesticides and toxic substances, and the development of test data to meet the data requirements of the Agency under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*), and section 408 of the Federal Food, Drug and Cosmetic (FFDCA) (21 U.S.C. 346a).

OPPTS developed this guideline through a process of harmonization of the testing guidance and requirements that existed for the Office of Pollution Prevention and Toxics (OPPT) in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) in publications of the National Technical Information Service (NTIS) and in 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.

For additional information about OPPTS harmonized guidelines and to access this and other guidelines, please go to <u>http://www.epa.gov/oppts</u> and select "Test Methods & Guidelines" on the left side menu.

OPPTS 830.1900: Submittal of samples.

(a) Scope—

- 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.*), the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601), and section 408 of the Federal Food, Drug and Cosmetic (FFDCA) (21 U.S.C. 346a).
- (2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 64–1 Submittal of samples (Pesticide Assessment Guidelines, Subdivision D: Product Chemistry, EPA Report 540/9–82–018, October 1982).

(b) Submittal of samples.

- (1) A sample of the analytical grade of each active ingredient in a product, weighing about 5 gm, and a sample of the technical grade of each active ingredient in a product, weighing about 200 gm, must be submitted (see paragraph (b)(3) of this guideline) to support the registration of each manufacturing-use product and those end-use products produced by an integrated formulation system.
- (2) When specifically requested by the Agency, the applicant for an end-use product or a manufacturing-use product shall submit samples that are representative of:
 - (i) The proposed product (about 200 gm) with a composition conforming to limits certified under OPPTS 830.1750.
 - (ii) Intentionally-added inert ingredients, listed in accordance with OPPTS 830.1550.
 - (iii) A specific product impurity, for which a certified upper composition limit, in accordance with OPPTS 830.1750, may be required.
 - (iv) A specific degradation product or metabolite of either the active ingredient or an intentionally-added inert.
- (3) Samples should be sent to:

US EPA National Pesticide Standard Repository 701 Mapes Road Fort Meade, MD 20755-5350.

Samples of any new or changed test substances (e.g., if the manufacturing process or source of ingredients changes) should be sent to the same address on a case-by-case basis.