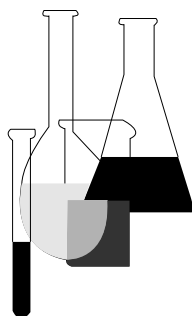




Product Properties Test Guidelines

OPPTS 830.1620

Description of Production 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.*).

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OPPTS 830.1620 Description of production process.

(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 Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is 40 CFR 158.162 Description of production process.

(b) **Information required.** (1) If the product consists solely of the technical grade active ingredient or is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information on the formulation process, in accordance with § 158.165.

(2) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product (e.g., salts of 2,4-D, diazonium salts). If the production process is accomplished in stages or by different producers, the information must be provided for each such production process.

(3) The following information must be provided for each process resulting in a separately isolated substance:

(i) The name and address of the producer who uses the process, if not the same as the applicant.

(ii) A general characterization of the process (e.g., whether it is batch or continuous) and quantity of product produced (lbs or kg) per theoretical batch size (or per unit time, if continuous).

(iii) A flow chart of the chemical reactions at each step of the process, and of the major unit operations, including separation steps.

(iv) The identities of the reactants, solvents, and catalysts used to produce the product, their quantities in pounds or kilograms, and the order in which they are added.

(v) A description of the equipment used that may influence the composition of the substance produced.

(vi) A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(vii) A description of the purification steps (including those used to recover or recycle starting materials, intermediates or the substance produced).

(viii) A description of the procedures used to assure consistent composition of the substance produced, e.g. calibration of equipment, sampling regimens, analytical methods, and other quality control measures.