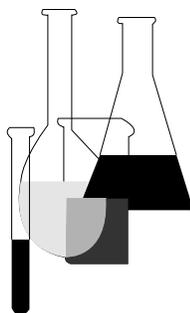




# Product Properties Test Guidelines

## OPPTS 830.1550 Product Identity and Composition



## 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 830.1550 Product identity and composition.**

(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 158.155 Product composition.

(b) **Information required.** Information on the composition of the pesticide product must be furnished. This normally includes completion of a Confidential Statement of Formula (EPA Form 8570–4) provided by the Agency. The information required by paragraphs (c), (d), and (h) of this guideline must be provided for each product. In addition, if the product contains solely the technical grade active ingredient or is produced by an integrated system, the information on impurities required by paragraphs (e) and (f) must also be provided.

(c) **Active ingredient.** The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product.

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with OPPTS 830.1750.

(2) If the source of any active ingredient in the product is not an EPA-registered product or if the product contains solely technical grade active ingredient:

(i) The chemical name according to Chemical Abstracts Service (CAS) nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular formulae and structures and the molecular weight or weight range.

(iii) The nominal concentration in weight percent.

(iv) Upper and lower certified limits of the active ingredient in accordance with OPPTS 830.1750.

(v) The purpose of the ingredient in the formulation.

(d) **Inert ingredients.** The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts Service nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration in the product.

(3) Upper and lower certified limits in accordance with OPPTS 830.1750.

(4) The purpose of the ingredient in the formulation.

(e) **Impurities of toxicological significance associated with the active ingredient.** For each impurity associated with the active ingredient that is determined to be toxicologically significant, as determined by EPA toxicologists, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with OPPTS 830.1750.

(f) **Other impurities associated with the active ingredient.** For each other impurity associated with an active ingredient that was found to be present in any sample at a level  $\geq 0.1$  percent by weight of the technical grade active ingredient, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) Chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(g) [Reserved]

(h) **Ingredients that cannot be characterized.** If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as certain mixtures, e.g. polymers, natural products, complexes, etc.),

the applicant must provide sufficient information to enable EPA to identify its source and composition, to the extent necessary for its review.