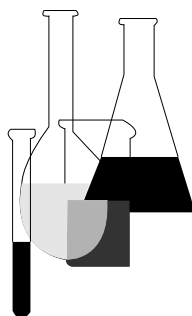




Product Properties Test Guidelines

OPPTS 830.1750 Certified Limits



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 document 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 available 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 830.1750 Certified limits.

(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 158.175 Certified limits.

(b) **Information required.** The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date.

(c) **Ingredients for which certified limits are required.** Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product consists solely of the technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(d) **Determination of standard certified limits for active and inert ingredients.** Unless the applicant proposes different limits as provided in paragraph (e) of this guideline, the upper and lower certified limits for active and inert ingredients will be determined on the basis of the nominal concentration of the ingredient in the product, according to the following table 1:

Table 1.—Standard Certified Limits

If the nominal concentration (N) for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper Limit	Lower Limit
N < 1.0%	N + 10% N	N – 10% N
1.0% < N ≤ 20.0%	N + 5% N	N – 5% N
20.0% < N ≤ 100.0%	N + 3% N	N – 3% N

(e) **Applicant proposed limits.** (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (d) of this guideline.

(2) If certified limits are required for impurities, the applicant must propose upper certified limits. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the product when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale or distribution.

(4) The applicant must include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g. sample analysis, quantitative estimate based on production process), and its accuracy and precision.

(f) **Special cases.** If the Agency finds unacceptable any certified limit (either standard or applicant-proposed), the Agency will inform the applicant of its determination and will provide supporting reasons. The Agency may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(g) **Certification statement.** The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable.

I hereby certify that for purposes of FIFRA section 12(a)(1)(C), the description of the composition of [product name], EPA Reg. No. [insert registration number], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: No ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified

for that ingredient in a currently-approved Statement of Formula (or as calculated by the Agency); and if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

(h) **References.** The following references should be consulted for additional background material on this test guideline.

(1) Official Methods of Analysis of AOAC-International, Association of Official Analytical Chemists (AOAC)-International, Arlington, VA, latest edition.

(2) *EPA Manual of Chemical Methods for Pesticides and Devices*, published by Association of Official Analytical Chemists (AOAC), Arlington, VA (1992).