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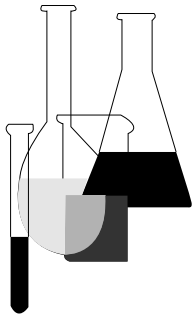
Product Properties Test Guidelines

OPPTS 830.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions



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 830.6313 Stability to normal and elevated temperature, metals, and metal ions.

(a) **Scope**—(1) **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.*).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP guideline 63–13 Stability (Pesticide Assessment Guidelines, Subdivision D: Product Chemistry, EPA Report 540/9–82–018, October 1982) and 40 CFR 158.190 Physical and chemical characteristics.

(b) **Test method**—(1) **Objective.** (i) Data on the physical and chemical characteristics of pesticide active ingredients and products are used to confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process used to produce the pesticide or product.

(ii) The objective of this guideline is to determine how stable the active ingredient is in the presence of normal and elevated temperatures, metals, and metal ions. Data regarding stability to metal and metal ions is required only if there is a likelihood that the technical grade of the active ingredient (TGAI) will come into contact with metals during its storage and use.

(2) **Test details.** (i) In order to fully characterize the stability of the pesticide chemical, standard methods may be used. Subjective judgements by a chemist familiar with the chemical and its intended use are needed in selecting appropriate tests.

(ii) The agency recommends the CIPAC method ‘‘MT 46 Accelerated Storage Tests by Heating’’ to determine stability of a pesticide when subjected to elevated temperature (see paragraph (d)(1) of this guideline).

(A) Test procedure. Dispersible powders: A 20 g sample of the pesticide is placed in a beaker and spread in a smooth even layer of constant thickness. A plastic coated metal disk of the approximate diameter of the beaker is placed on top of the sample and the beaker is placed in an oven. The sample is maintained in the oven at 54 °C for 14 days. Upon removal from the oven, the specimen is allowed to cool in a dessicator without dessicant and samples of the hard cake are submitted for appropriate testing and analysis.

(B) [Reserved]

(iii) To determine stability in the presence of metals and metal ions, the following test method is recommended.

(A) Test method. A fine metal is typically uniformly dispersed in a solid mixture or sunk in liquid formulations and analyzed for active in-

gredient at time 0 and after 14 days of exposure; or by differential scanning calorimetry/differential thermal analysis (DSC/DTA) by comparison to a non-exposed test sample. Two metals in their natural state and in their ionic form are typically tested. Oven testing is usually periodic, typically analyzing after 1, 2, 7 and 14 days of exposure to collect more than single point data for exposure to each material. Typically the metal and salt of a weak acid, such as an acetate or carbonate (e.g., iron filings and ferric acetate, aluminum rods and aluminum acetate, lead shot and lead acetate) are used. Since exposure to metals is usually of short duration, especially if reactive, testing at ambient temperature can be used as a control, as measured against elevated temperature.

(B) [Reserved]

(iv) Consultation with the Agency is recommended if there are questions about appropriate methods for the other determinations.

(v) If an alternative method is used, it is recommended that the registrant consult with the Agency prior to adopting the test method.

(c) **Reporting.** (1) Descriptions and results of all tests should be reported. The information on stability shall include consideration and discussion of the sensitivity of the active ingredient to metals and metal ions it may come in contact with, at normal and elevated temperatures.

(2) Any methods used to characterize the physical properties of a pesticide shall be referenced or described in the application for registration. If the methods used are listed in this guideline, reference to the method will suffice. If other methods are used, copies of such methods must be submitted with the application.

(3) References denoting ''CIPAC'' refer to standardized methods of the Collaborative International Pesticide Analytical Council, Ltd., Hatching Green, Harpenden, Hertfordshire, England.

(4) The applicant shall submit his own statistical evaluation of the precision and accuracy of these measurements (e.g., standard deviations or confidence intervals) when appropriate.

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

(1) *Collaborative International Pesticide Analytical Council Ltd.* (CIPAC) *Handbook,* ''MT 46 Accelerated Storage Tests by Heating,'' CIPAC, Hatching Green, Harpenden, Hertfordshire, England (1970).

(2) [Reserved]