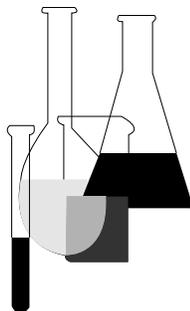




# Product Properties Test Guidelines

## OPPTS 830.6319 Miscibility



## 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 830.6319 Miscibility.**

(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 63–19 Miscibility (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.** Data on the physical and chemical characteristics of pesticide products are used to confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process to produce the pesticide or product. This test is intended to determine whether a pesticide solution is suitable for application after dilution with oil or other nonpolar solvents, where applicable, instead of water. Data on miscibility also provide necessary information to support acceptable labeling for tank mix and spray applications (if the tank mix of the pesticide product is oil based or diluted with oil).

(2) **Test details.** (i) For miscibility, the Agency recommends the method described in “MT 23 Miscibility with Hydrocarbon Oil,” of the CIPAC Handbook (see paragraph (d) of this guideline), with the exception that the test be conducted at 20 °C or 25 °C and observations be made after 30 minutes rather than 30 °C and 1 hour as specified in the CIPAC method. If an alternative method is used, it is recommended that the registrant consult with the Agency prior to adopting the test method.

(ii) The evaluation of miscibility of emulsifiable liquid products bearing directions for dilution with nonpolar solvents shall be made at 20 °C or 25 °C.

(iii) The product shall be mixed with nonpolar solvents whose composition reflects those of the label and at the rate specified on the label. After the mixture has stood for 30 minutes, it shall be examined for separation.

(c) **Reporting.** (1) At the end of 30 minutes, report whether the solution is homogeneous, there has been any separation of solid matter, or any separation into layers.

(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 paragraph (d) of this guideline, reference to the methods 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 evaluations of the precision 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 23 Miscibility with Hydrocarbon Oil,” CIPAC, Hatching Green, Harpenden, Hertfordshire, England (1970).

(2) [Reserved]