

First edition  
2013-06-15

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## Guidelines for the characterization of dispersion stability

*Lignes directrices pour la caractérisation de la stabilité des dispersions*



Reference number  
ISO/TR 13097:2013(E)

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Published in Switzerland

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. [www.iso.org/directives](http://www.iso.org/directives)

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The committee responsible for this document is ISO/TC 24, *Particle characterization including sieving*, Subcommittee SC 4, *Particle characterization*.

## Introduction

Stability with respect to changes in relevant product specifications and product performance is important in industry and for end users.

Various terminologies are used to reflect different phenomena as well as different user perspectives. In the literature and in practice, one frequently finds terms such as dispersion, suspension or emulsion stability, demixing or separation stability, sedimentation or creaming stability, physical stability, colloidal stability, and kinetic stability.

This Technical Report focuses on instability driven by thermodynamics and does not include phenomena that are due to, e.g., radiation, chemical or enzymatic reactions<sup>1)</sup> or are related to the growth/metabolism of biological organisms like bacteria. These phenomena are often described as photo, UV or irradiation stability, thermal or chemical stability of one or the other constituent, enzymatic or microbial stability, etc.

The Technical Report concerns general aspects of stability test methods, acceleration procedures and data evaluation. In addition, recommendations of instrument manufacturer, information from the scientific or user community as well as from regulatory bodies are intended to be taken into account.

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1) Chemical and physical properties are often interrelated.



# Guidelines for the characterization of dispersion stability

## 1 Scope

This Technical Report addresses the stability characterization of liquid dispersions (suspensions, emulsions, foams and mixtures thereof) for applications, such as new product design, optimization of existing products, quality control during processing and during usage of the product. The stability of a dispersion in the sense of this Technical Report is defined in terms of the change in one or more physical properties over a given time period. Stability can be either monitored (determined) in real time or predicted on the basis of physical quantities related to stability. In the case of very stable dispersions, procedures that accelerate the changes under consideration or accelerated aging tests administered over a shorter time scale can be appropriate. Shelf life can be estimated based on the observed rate of the change in the physical property and the user-required specifications for the product. Guidelines are given for choosing relevant measurements that can be used for the ranking, identification and quantification of instability.

## 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

### 2.1

#### **agglomeration**

assembly of particles in a dispersed system into loosely coherent structures that are held together by weak physical interactions

Note 1 to entry: Agglomeration is a reversible process.

Note 2 to entry: Synonymous with coagulation and flocculation.

[SOURCE: ISO 14887:2000,<sup>1</sup> 3.1, modified — text altered; IUPAC Gold Book,<sup>2</sup> modified]

### 2.2

#### **aggregation**

assembly of particles into rigidly joined structures

Note 1 to entry: Aggregation is an irreversible process.

Note 2 to entry: The forces holding an aggregate together are strong, for example covalent bonds or those resulting from sintering or complex physical entanglement.

Note 3 to entry: In common use, the terms aggregation and agglomeration are often applied interchangeably.

[SOURCE: ISO 14887:2000,<sup>1</sup> 3.2, modified — text has been altered; ISO 26824<sup>3</sup>]

### 2.3

#### **coalescence**

disappearance of the boundary between two particles (usually droplets or bubbles) in contact, or between one of these and a bulk phase followed by changes of shape leading to a reduction of the total surface area

Note 1 to entry: The flocculation of an emulsion, namely the formation of aggregates, may be followed by coalescence.

[SOURCE: IUPAC Gold Book<sup>2</sup>]