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Nanotehnologije - Navodilo za določanje agregacijskega in aglomeracijskega stanja nanoobjektov

Nanotechnologies - Guidance on the determination of the aggregation and agglomeration state of nano-objects

Nanotechnologien - Leitfaden zur Bestimmung des Aggregations- und Agglomerationszustands von Nanoobjekten

Nanotechnologies - Guide pour la détermination de l'état d'agrégation et d'agglomération des nano-objets

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Nanotechnologies - Guidance on the determination of the aggregation and agglomeration state of nano-objects

Nanotechnologies - Recommandations sur la détermination de l'état d'agrégation et d'agglomération de nano-objets

Nanotechnologien - Leitfaden zur Bestimmung des Aggregations- und Agglomerationszustands von Nanoobjekten

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European foreword

This document (CEN/TS 18269:2026) has been prepared by Technical Committee CEN/TC 352 “Nanotechnologies”, the secretariat of which is held by AFNOR.

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This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

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Introduction

This document guides users in the appropriate selection and use of commercially available techniques for determination of the measurands associated with the agglomeration state and aggregation state of nano-objects in powders, in aerosols and in suspensions (liquid dispersions). Many materials consist of agglomerates and aggregates composed of constituent particles (CP) and also isolated, individual (IIP) (not bound) particles. The agglomeration state and aggregation state can explain macroscopic properties of particulate systems, for example stability, transport in air and liquids, dustiness and inhalability for aerosols. The situation is further complicated by a variety of synthesis and dispersing mechanisms used.

Guidance is provided on key terminology, for example what is meant by agglomerate, aggregate, agglomeration state and aggregation state. Additionally, the differences between terminology used by standardization organizations and some regulatory bodies are noted.

The document describes measurands that can be used to determine the agglomeration state and aggregation state (AgAg state) of nano-objects and connects them with corresponding measurement techniques. They are briefly explained along with their advantages and limitations. The document also describes methods for the determination of the AgAg state, which generally includes both a well-specified preparation and the measurement of samples. Sample preparation can majorly affect the AgAg state and therefore constitutes a crucial part within methodology. This document advises on the proper use of measurement techniques and provides general rules on sample preparation including sonication in liquids and shear flow in aerosols for AgAg state determination. However, specific protocols on sample preparation are not described. This document also discusses aspects of stability, i.e. the time dependency of AgAg state which depends on factors such as the chemistry of particles, solvent and additives.

This document will be a useful tool for nanotechnology scientists, companies, risk assessors and regulators to identify relevant information for measuring measurands of aggregates and agglomerates and the state of agglomeration and aggregation.

1 Scope

This document provides guidance for users in the correct selection and usage of routinely available techniques for the determination of the aggregation and agglomeration state of nano-objects in powders, aerosols and suspensions. It provides guidance on measurands and measurement methods to use along with guidance on sample preparation.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp/
- IEC Electropedia: available at https://www.electropedia.org/

3.1
nanoscale
length range approximately from 1 nm to 100 nm

[SOURCE: EN ISO 80004-1:2023, 3.1.1]

3.2
nano-object
discrete piece of material with one, two or three external dimensions in the nanoscale

[SOURCE: EN ISO 80004-1:2023, 3.1.5]

3.3
particle
minute piece of matter with defined physical boundaries

Note 1 to entry: A physical boundary can also be described as an interface.

Note 2 to entry: This general particle definition applies to nano-objects (3.2).

[SOURCE: EN ISO 80004-1:2023, 3.2.1]

3.4
agglomerate
collection of weakly or medium strongly bound particles where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: EN ISO 80004-1:2023, 3.2.4]

3.5
aggregate
particle comprising strongly bonded or fused particles where the resulting external surface area is significantly smaller than the sum of surface areas of the individual components

Note 1 to entry: The forces holding an aggregate together are strong forces, for example covalent or ionic bonds, or those resulting from sintering or complex physical entanglement.

Note 2 to entry: Aggregates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: EN ISO 80004-1:2023, 3.2.5]

3.6
constituent particle
identifiable, integral component of a larger particle

Note 1 to entry: The constituent particle structures can be primary particles or aggregates.

[SOURCE: EN ISO 80004-1:2023, 3.2.3]

3.7
primary particle
original source particle of agglomerates or aggregates or mixtures of the two

Note 1 to entry: Constituent particles of agglomerates or aggregates at a certain actual state can be primary particles, but often the constituents are aggregates.

Note 2 to entry: Agglomerates and aggregates are also termed secondary particles.

[SOURCE: ISO 26824:2022, 3.1.4]

3.8
dispersion
multi-phase system in which discontinuities of any state (solid, liquid or gas: discontinuous phase) are distributed in a continuous phase of a different composition or state

Note 1 to entry: This term also refers to the act or process of producing a dispersion; in this context the term “dispersion process” should be used.

Note 2 to entry: If solid particles are distributed in a liquid, the dispersion is referred to as a suspension. If the dispersion consists of two or more immiscible liquid phases, it is termed an “emulsion”. A suspoemulsion consists of both solid and liquid phases distributed in a continuous liquid phase.

[SOURCE: CEN ISO/TS 80004-6:2021, 3.14]

3.9
aerosol
system of solid and/or liquid particles suspended in gas

[SOURCE: CEN ISO/TS 80004-6:2021, 3.12]

3.10
suspension
heterogeneous mixture of materials comprising a liquid and finely dispersed solid material

[SOURCE: CEN ISO/TS 80004-6:2021, 3.13]

3.11
dispersibility

qualitative or quantitative characteristic or property of a particulate source material assessing the ease with which said material can be dispersed within a continuous phase

Note 1 to entry: Spatially uniform distribution (homogeneity) of the dispersed phase is considered an integral part of the desired end point.

Note 2 to entry: Particle size or particle size distribution is often used as an end point relative to defined criteria specific to the application.

Note 3 to entry: Dispersibility refers to a specific dispersion process and specific process time.

Note 4 to entry: Dispersion stability, though a related phenomenon, should not be confused with dispersibility.

[SOURCE: ISO/TS 22107:2021, 3.6]

3.12
measurand

quantity intended to be measured

[SOURCE: ISO/IEC Guide 99:2007, 2.3]

3.13
agglomeration state

degree to which constituent particles are bound together as agglomerates (3.4) and are spatially arranged

Note 1 to entry: Agglomeration state is time dependent and is likely to depend on the environmental and thermodynamic conditions such as chemistry, concentration, pH, turbulence and temperature and the hydrodynamic forces acting on the agglomerates. Sonication and other energy sources inputted in the system can change the agglomeration state.

Note 2 to entry: Agglomeration state is difficult to measure in practice, as it is difficult to separate agglomeration state and aggregation state. An indication of the combined agglomeration and aggregation state can be determined by measuring the ratio by number/volume/mass of agglomerated particles to constituent particles.

Note 3 to entry: The constituent particles can be bound as dimers, trimers or higher numbers. The number of constituent particles per agglomerate affects the agglomeration state as does the shape and structure of each agglomerate.

Note 4 to entry: Over a period of time, the binding forces between agglomerates can change to stronger forces and hence agglomerates can change to aggregates. A system can have both an agglomeration state and an aggregation state.

3.14
aggregation state

degree to which constituent particles are bound together as aggregates (3.5) and are spatially arranged

Note 1 to entry: Aggregation state is likely to be less time dependent than the agglomeration state and is only likely to change on extreme changes in environmental conditions especially the chemistry, pH and temperature.

Note 2 to entry: Aggregation state is difficult to quantitatively measure in practice as it is difficult to separate agglomeration state and aggregation state. An indication of the combined agglomeration and aggregation state can be determined by measuring the ratio by number/volume/mass of aggregated particles to constituent particles.

Note 3 to entry: The constituent particles can be bound as dimers, trimers or higher numbers. The number of constituent particles per aggregate effects the aggregation state as does the size and shape of each aggregate.

3.15
agglomeration
action leading to the formation of agglomerates (3.4)

[SOURCE: EN ISO 29464:2024, 3.2.12]

3.16
aggregation
action leading to the formation of aggregates (3.5)

3.17
dispersion stability
ability to resist change or variation in the initial properties (state) of a dispersion over time, in other words, the quality of a dispersion in being free from alterations over a given time scale

Note 1 to entry: In this context, for instance agglomeration or segregation represents a loss of dispersion stability.

[SOURCE: ISO/TS 22107:2021, 3.8]

3.18
isolated, individual particle
IIP
single, individual piece of matter that is physically separate, with identifiable boundary and independent from other particles

Note 1 to entry: IIP can vary in size in a given system but should not be composed of other such particles.

Note 2 to entry: The independent behaviour refers to no significant interaction force with other particles.

Note 3 to entry: IIP cannot be part of a larger structure such as an agglomerate or an aggregate.

4 Symbols and abbreviations

AC	analytical centrifugation
AFM	atomic force microscope or atomic force microscopy
AF4	asymmetric-flow field-flow fractionation
AgAg state	agglomeration state and aggregation state
ALS	angular light scattering
BET	Brunauer, Emmett and Teller
CLS	centrifugal liquid sedimentation
CNT	carbon nanotubes
CP	constituent particle
CPC	condensation particle counter
CR	counting rule
DCS	differential centrifugal sedimentation
DEMA	differential electric mobility analysis

DEMC	differential electrical mobility classifier
DLS	dynamic light scattering
DMAS	differential mobility analysing system
ELPI	electrical low-pressure impactor
FCAE	Faraday cup aerosol electrometer
HR	high resolution
IIP	isolated, individual particle
LDS	laser diffraction spectroscopy
MD-AF4	multi-detector asymmetric-flow field-flow fractionation
NP	nanoparticle
OPC	optical particle counter
PDWS	photon density wave spectroscopy
PSD	particle size distribution
mPSD	mass-based particle size distribution
nPSD	number-weighted particle size distribution
vPSD	volume-based particle size distribution
PTA	particle tracking analysis
RPS	resistive pulse sensing
SAXS	small-angle X-ray scattering
SEM	scanning electron microscope or scanning electron microscopy
SMLS	static multiple light scattering
spICP-MS	single particle inductively coupled plasma mass spectrometry
TEM	transmission electron microscope or transmission electron microscopy
UV-Vis	ultra-violet-visible

5 Structure of this document

This document provides guidance for users in the selection and usage of routinely available techniques for the determination of the agglomeration state and aggregation state (AgAg state) of nano-objects in powders, aerosols and suspensions. These characteristics are complex to assess, as no single measurand or measurement can fully define the agglomeration and aggregation state. The AgAg state determination can for example comprise: the quantity of non-agglomerated/non-aggregated particles, the size and mass (distributions) of agglomerates and aggregates, the morphology of the agglomerates and aggregates or the quantity ratio between aggregates and agglomerates. It depends on the purpose of the analysis as to which of these aspects should be addressed by the characterization method. Hence, it is up to the user, depending on the type of material to be analysed, to choose which measurands and techniques to use to determine AgAg state based on the guidance given in this document. Follow the flow chart given in Figure 1 and Clauses 6 to 9 in order to help determine AgAg state.

Clause 6 provides general information on what is meant by agglomerate, aggregate, agglomeration state and aggregation state. It also highlights differences in terminology used by ISO, CEN and in the regulatory framework addressing nanomaterials in the European Union.

Clause 7 details the measurands to use to determine AgAg state.

Clause 8 details guidance on the measurement methods that are used to determine AgAg state.

Clause 9 provides information on the temporal nature and stability of AgAg state.

Annex A provides examples of AgAg states.

Annex B gives examples of measuring the agglomeration state in nano-object suspensions.

Annex C briefly lists the factors influencing the agglomeration and aggregation state.

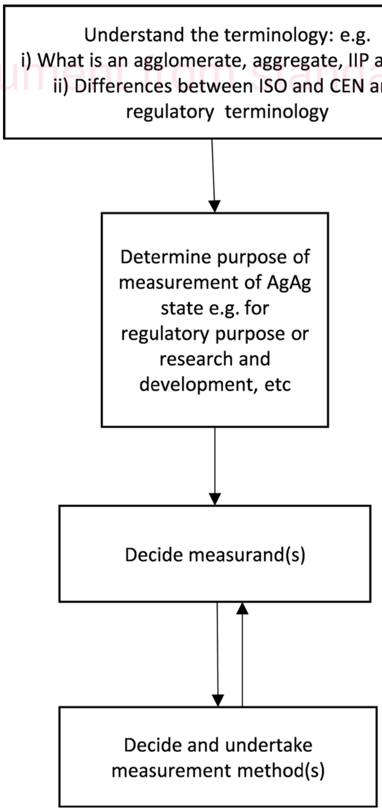


Figure 1 — Chart summarizing the step-wise approach to help determine AgAg state

6 Agglomerates, aggregates, agglomeration state and aggregation state

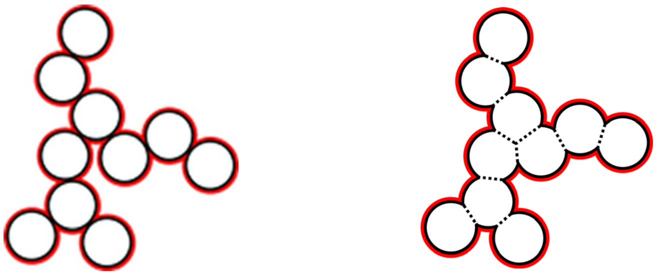
6.1 Introduction to terminology

This section provides descriptive information on the terms used to describe agglomerates, aggregates, agglomeration state and aggregation state and other key terms. These are discussed in 6.2. The European Commission uses different terminology and these differences are discussed in 6.3.

6.2 Agglomerates and aggregates

Agglomerates and aggregates are collections of bound particles that themselves can be considered as individual particles in many aspects. They are frequently observed in *dispersed material* like powders, aerosols and suspensions (liquid dispersions). In such materials, agglomerates and aggregates can be the dominating form of dispersed matter or they can comprise only a minor fraction of all the particles present. In general, they constitute only one part of the dispersed matter and are accompanied by non-agglomerated and non-aggregated particles, called here isolated, individual particles (IIP). The state of disperse material is characterized by a) the degree to which the particles are bound in aggregates and agglomerates (or reversely: the fraction of IIPs), the size and size distribution of the particles including aggregates and agglomerates, b) their shape and internal structure, and c) also the spatial distribution of the particles within the material.

The distinction between agglomerates and aggregates relies on the notion of the strength of the binding energies between the constituent particles (CPs) which is also dependent on the particles contact surface areas. However, the definitions across different ISO Technical Committees, European Union [1] regulatory frameworks and scientific peer-reviewed publications provide a much less harmonized landscape. Some definitions only refer to both agglomerates and aggregates being made of particles adhering to each other. Some mention relative stability of the resulting physical structure. Here, the definitions of agglomerate and aggregate from ISO 80004-1 from ISO/TC 229 (Nanotechnologies) are used [2]. These are based on the strength of the constituent particle binding. Both agglomerates and aggregates are termed secondary particles comprised of loosely or tightly bound constituent particles based on their binding strength and typically having relatively small or large common adhesion surface areas respectively, as shown in Figure 2.



a) b)

Red contour indicates the external surface area of the secondary particles; dashed lines indicate the (apparent) boundaries between constituent particles.

Figure 2 — Simplified 2D illustration demonstrating the difference between a) agglomerates and b) aggregates

Aggregates are formed when constituent particles’ binding energy is high, and much work has to be done to break down such a structure into smaller objects. Agglomerates are formed by weaker bonds between constituent particles and have in general smaller contact surface areas, giving more porous structures of lower density and higher surface area. Binding energy distinction is covered in Annex C. The red surrounding trace in Figure 2 indicates schematically the external surface area for each agglomerate and aggregate. It should be noted that Figure 2 is merely a very simple 2D schematic of very complex 3D structures and other structures are possible.

A material is likely to contain both agglomerates and/or aggregates as well as isolated, individual particles. These IIPs, as shown in Figure 3 a) and Figure 4, are particles that do not adhere to other particles and that are neither agglomerates nor aggregates. They are so termed as they are isolated from other particles, i.e. separated from other particles. They are also individual, i.e. they are the smallest possible single entity that still fulfils the definition of particle.

In addition to this, some smaller aggregates can form hierarchically bound agglomerates as shown in Figure 3 d).

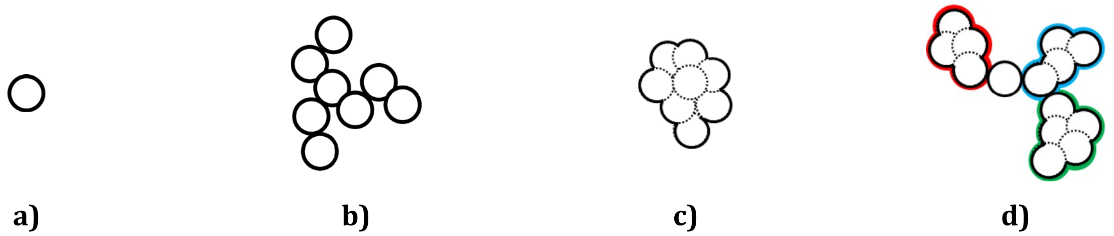
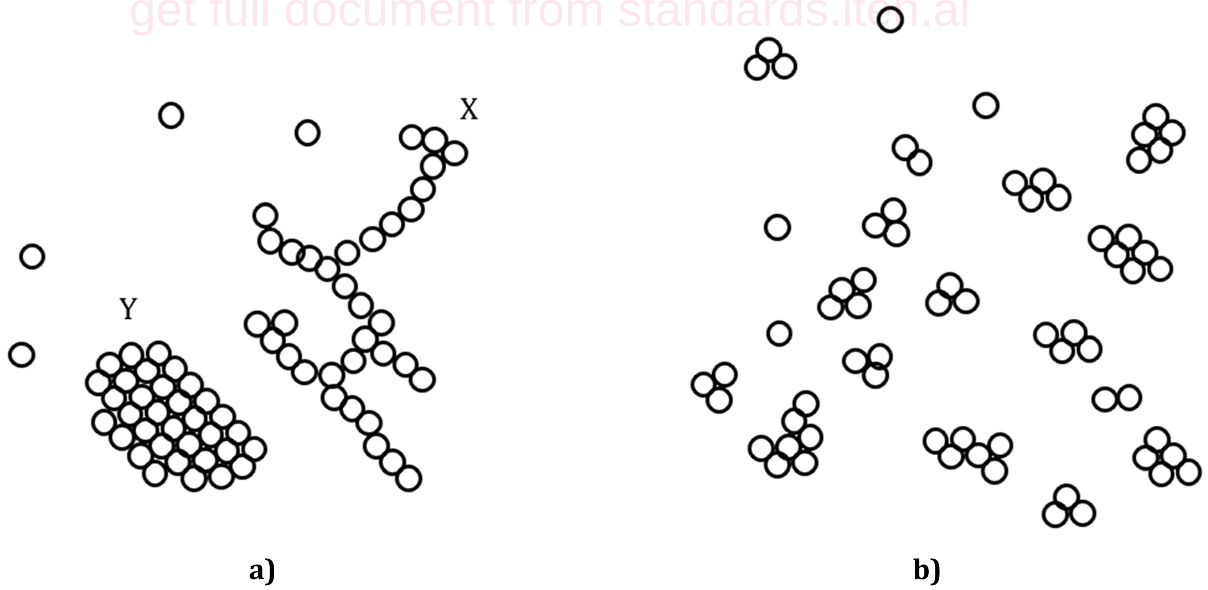


Figure 3 — Various species in a simplified 2D diagram: a) isolated, individual particle, b) agglomerate, c) aggregate, d) agglomerate of three aggregates shown with different colours

The complexity is increased further when both agglomerates and aggregates can have virtually any number of those constituent particles arranged in many possible ways. An example is shown in Figure 4, which consists of two samples both with the same number of constituent particles. In Figure 4 a), the sample consists of 4 IIPs and 2 large agglomerates whereas Figure 4 b) consists of 4 IIPs but with 16 smaller agglomerates or aggregates each consisting of between 2 and 7 constituent particles. These two samples are likely to have very different properties. In addition, Figure 4 a) shows two different agglomerates both with the same number of constituent particles but of very different size, shape and structure.



Each of a) and b) contain the same number of constituent particles (including IIPs) as do the structures labelled X, Y in a).

Figure 4 — Simplified diagram showing that aggregation state and agglomeration state depends on the structure of the agglomerates and aggregates