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BSI Standards Publication

Workplace exposure – Assessment of dermal exposure to nano-objects and their aggregates and agglomerates (NOAA) (ISO/TS 21623:2017)

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National foreword

This Published Document is the UK implementation of CEN ISO/TS 21623:2018. It is identical to ISO/TS 21623:2017.

The UK participation in its preparation was entrusted to Technical Committee EH/2/2, Work place atmospheres.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Workplace exposure - Assessment of dermal exposure to nano-objects and their aggregates and agglomerates (NOAA) (ISO/TS 21623:2017)

Exposition sur les lieux de travail - Évaluation de l'exposition cutanée aux nano-objets et à leurs agrégats et agglomérats (NOAA) (ISO/TS 21623:2017)

Exposition am Arbeitsplatz - Leitfaden zur Beurteilung der dermalen Exposition an Nano-Objekten sowie deren Aggregaten und Agglomeraten (NOAA) (ISO/TS 21623:2017)

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European Foreword

This document (CEN ISO/TS 21623:2018) has been prepared by Technical Committee ISO/TC 146 " Air quality " in collaboration with Technical Committee CEN/TC 137 “Assessment of workplace exposure to chemical and biological agents” the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of ISO 21623:2018 has been approved by CEN as CEN ISO/TS 21623:2018 without any modification.

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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 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

ISO/TS 21623 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 137, *Assessment of workplace exposure to chemical and biological agents*, in collaboration with ISO Technical Committee ISO/TC 146, *Air quality*, Subcommittee SC 2, *Workplaces atmospheres*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

Dermal exposure assessment explores the dynamic interaction between environmental contaminants and the skin. In contrast to inhalation exposure assessment, the assessment of dermal exposure requires a different set of exposure considerations. During the last decades, the body of knowledge with regard to dermal exposure has expanded for many types of substances, which amongst others resulted in publications for the evaluation of dermal exposure to chemical substances that can be found, for example, in CEN/TR 15278, CEN/TS 15279, and ISO/TR 14294.

Currently, engineered/manufactured nanomaterials and nano-enabled products are produced and used on a wide scale. Occupational skin exposure to these substances can have biological relevance to human health. Potential adverse effects include local skin effects, systemic toxicity following skin absorption/uptake and inadvertent ingestion through the hand-to-mouth pathway. This document provides guidance for the evaluation of potential dermal exposure to manufactured nano-objects, their agglomerates and aggregates (NOAA).

This document is a compilation of the results of a pre-normative research project, executed under Mandate M/461 for standardization activities regarding nanotechnologies and nanomaterials as issued by the European Commission. This pre-normative research gives an overview of the mechanisms of occupational dermal exposure to nanoparticles or nano-enabled products. This includes potential concomitant for intake or uptake. It is based on relevant evidence of exposure for identified job titles. Part of the pre-normative research comprised experimental work on the skin penetration of nanoparticles, transfer of nanoparticles from a surface to the skin, and exploratory work on the feasibility to quantify dermal exposure to NOAA[4]-[6].

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TECHNICAL SPECIFICATION **ISO/TS 21623:2017**

Workplace exposure – Assessment of dermal exposure to nano-objects and their aggregates and agglomerates (NOAA) (ISO/TS 21623:2017)

1 Scope

This document describes a systematic approach to assess potential occupational risks related to nano-objects and their agglomerates and aggregates (NOAA) arising from the production and use of nanomaterials and/or nano-enabled products. This approach provides guidance to identify exposure routes, exposed body parts and potential consequences of exposure with respect to skin uptake, local effects and inadvertent ingestion.

This document also considers occupational use of products containing NOAA by professionals, e.g. beauticians applying personal care products, cosmetics or pharmaceuticals, but does not apply to deliberate or prescribed exposure to these products by consumers.

This document is aimed at occupational hygienists, researchers and other safety professionals to assist recognition of potential dermal exposure and its potential consequences.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1540, *Workplace exposure — Terminology*

ISO 18158, *Workplace air — Terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 1540, ISO 18158 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
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: ISO/TS 80004-2:2015, 3.4]

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