BSI Standards Publication

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

bsi.

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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2018

ISBN 978 0 580 95729 1

ICS 13.040.30

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 March 2018.

Amendments/corrigenda issued since publication

Date	Text affected

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN ISO/TS 21623

February 2018

ICS 13.040.30

English Version

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)

This Technical Specification (CEN/TS) was approved by CEN on 6 October 2017 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. CEN ISO/TS 21623:2018: E

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.

Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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).

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].

This page deliberately left blank

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]

