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Nanotechnologies - Use and application of acellular in vitro tests and methodologies to assess nanomaterial biodurability

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National foreword

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Nanotechnologies — Use and application of acellular in vitro tests and methodologies to assess nanomaterial biodurability

Nanotechnologies — Utilisation et application des tests in vitro sur cellules et méthodes pour évaluer la biodurabilité des nanomatériaux

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Foreword

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This document was prepared by Technical Committee ISO/TC 229, *Nanotechnologies*.

TECHNICAL REPORT ISO/TR 19057:2017(E)

Nanotechnologies — Use and application of acellular in vitro tests and methodologies to assess nanomaterial biodurability

1 Scope

This document reviews the use and application of acellular *in vitro* tests and methodologies implemented in the assessment of the biodurability of nanomaterials and their ligands in simulated biological and environmental media.

This document is intended to focus more on acellular *in vitro* methodologies implemented to assess biodurability and, therefore, excludes the general review of relevant literature on *in vitro* cellular or animal biodurability tests.

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 terminological databases for use in standardization at the following addresses:

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

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

3.1
bioaccumulation
process of accumulation of a substance in organisms or parts

[SOURCE: ISO/TR 13329:2012, 3.3]

3.2
biodegradation
degradation due to the biological environment

Note 1 to entry: Biodegradation might be modelled by *in vitro* tests.

[SOURCE: ISO/TR 13329:2012, 3.4]

3.3
biodurability
ability of a material to resist *dissolution* (3.6) and mechanical disintegration from chemical and physical clearance mechanisms

[SOURCE: ISO/TR 13329:2012, 3.5, modified]

3.4
biopersistence
ability of a material to persist in a tissue in spite of the tissue's physiological clearance mechanisms and environmental conditions

[SOURCE: EN 18748:1999]