

ISO/TR 19057:2017-10 (E)

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

Contents		Page
Foreword		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Symbols and abbreviated terms	2
5	Background including need for assessing the biodurability of particles	4
6	Aims and objectives	6
7	Approaches for assessment of micrometre mineral particle and fibre biodurability	6
7.1	General	6
7.2	Dissolution of nanomaterials versus their dispersion and biodegradation	7
8	Need for the assessment of nanomaterial biodurability	7
9	Influence of different types of ligands and coatings on nanomaterial biodurability	8
10	Review of methodologies to assess micrometre mineral particle and fibre biodurability	8
10.1	General	8
10.2	In vitro acellular methods	8
10.3	Description of different simulated physiological media	9
10.3.1	General	9
10.3.2	Simulated lung airway lining fluids	9
10.3.3	Simulated lung macrophage phagolysosomal fluid	10
10.3.4	Digestive system (saliva, gastric and intestinal fluids)	10
10.3.5	Simulated sweat (SSW)	11
10.4	Description of different simulated environmental media	11
10.4.1	General	11
10.4.2	Simulated natural freshwaters	11
10.4.3	Simulated seawater	11
10.4.4	Simulated estuarine waters	11
10.5	Description of different test systems to assess dissolution of particles and fibres	11
10.5.1	General	11
10.5.2	Static dissolution system	12
10.5.3	Continuous flow system (CFS)	12
10.5.4	Batch and batch filter systems	12
10.5.5	Tangential flow filtration system	12
10.6	Assessment of dissolved mass concentration post dissolution experiment	13
10.6.1	General	13
10.6.2	Techniques based on physical principles	13
10.6.3	Techniques based on mechanical concepts	14
10.6.4	Techniques based on chemical principles	15
10.6.5	Ultraviolet-visible (UV-Vis) spectroscopy	16
10.6.6	One-dimensional mathematical models	16
10.6.7	Single particle inductively coupled plasma-mass spectrometry (spICP-MS)	16

11	Calculation of micrometre mineral particle biodurability	17
11.1	General	17
11.2	Dissolution kinetics, dissolution rates, and dissolution rate constants	18
11.3	Dissolution kinetics and dissolution rate of larger particles and fibres	18
11.4	Dissolution kinetics and dissolution rate of nanoparticles	20
11.5	Assessment of halftime estimates of particles and fibres	20
11.6	Assessment of lifetime estimates for particles and fibres	21
11.6.1	General	21
11.6.2	Shrinking sphere theory	21
11.6.3	Shrinking fibre theory	22
11.7	Assessment of halftime and lifetime estimates	23
12	Examples of micrometre mineral particles and fibres where biodurability was assessed using in vitro acellular systems	24
12.1	Glass and asbestos fibres	24
12.2	Silicon dioxide (SiO ₂)	24
12.3	Talc	25
12.4	Tungsten oxide	25
12.5	Beryllium	25
13	Examples of nanomaterials where biodurability was assessed using in vitro acellular systems	25
13.1	SWCNTs and MWCNTs	25
13.2	Silver nanoparticles (AgNPs)	26
13.3	Titanium dioxide (TiO ₂)	26
13.4	Zinc oxide (ZnO)	26
14	Biodurability of ligands	27
14.1	General	27
14.2	Examples of ligands attached to particles where biodurability has been assessed	27
14.3	Methodologies to assess the biodurability of the attached ligands	27
14.3.1	General	27
14.3.2	Gel permeation chromatography (GPC)	27
14.3.3	Matrix-assisted laser desorption ionization mass spectrometer (MALDI-MS)	28
14.3.4	Attenuated total reflectance-Fourier transform infrared spectroscopy (ATR-FTIR)	28
14.3.5	Liquid chromatography coupled with mass spectrometry (LC-MS/MS)	28
15	Relationship with relevant international documents	28
15.1	Simulated sweat	28
15.2	Simulated sebum	29
15.3	Simulated lung fluids	29
15.4	Simulated digestive system fluids	29
16	Assessing the validity of assay/test systems	29
17	Biological relevance of the dissolution assay	30
18	Use of biodurability tests in risk assessment and its limitations	31
	Annex A (informative) Tables of relevant information	32
	Bibliography	36