

Environmental endpoints

Webinar: updated REACH
Guidance for nanomaterials:
what you need to know

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Endpoint specific Guidance updates - May 2017

Appendix R7-1 for Chapter R.7.a

- Sample preparation: specific extension and information for environment
- Water solubility
- Partitioning coefficient n-octanol/water (log Kow)
- Adsorption/desorption (log Koc)
- Column 2 adaptations on physical-chemical properties and alternative measurements

Appendix R7-1 for Chapter R.7.b

- How to perform eco-toxicity and fate testing
- Aquatic pelagic toxicity
- Toxicity to sediment organisms
- Degradation/biodegradation
- Transformation

Appendix R7-2 for Chapter R7c

- Specific advice for endpoints
- Aquatic bioaccumulation
- Soil and sediment bioaccumulation
- Effects on terrestrial organisms



Appendix R7-1 for nanomaterials

Applicable to Chapter R7a

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Chapter R7a: sample preparation

Nano-specific considerations in sample preparation

- Choice of testing material
 - Representative of registered substance and/or relevant nanoform
 - Chemical composition
 - Characterisation: particle-size (distribution), shape, aspect ratio and surface chemistry
- Characterisation of physicochemical properties and state present in test medium (degree of agglomeration/sedimentation)



OECD Guidance/Test Guideline documents

Referred in R7-1 and R7-2

- Limited applicability of OECD GD 23, targeted for poorly soluble substances
- Guidance on sample preparation and dosimetry for safety testing of manufactured nanomaterials
OECD No. 36 ENV/JM/MONO(2012)40
- Ecotoxicology and environmental fate of manufactured nanomaterials from OECD reports
 - 40 ENV/JM/MONO(2014)1
 - ENV/JM/MONO(2014)1/ADD1



OECD Guidance/Test Guideline documents

Referred in R7-1 and R7-2

- OECD Test Guideline 318: dispersion stability of nanomaterials in simulated environmental media
- Under development or finalisation:
 - Test guideline: dissolution rate of nanomaterials in the aquatic environment
 - Guidance: agglomeration and dissolution behaviour of nanomaterials in aquatic media
 - Guidance: apparent accumulation of nanomaterials in fish
 - Guidance: aquatic and sediment toxicity testing of nanomaterials



General considerations for ecotoxicological testing

Chapter R7a

- Physico-chemical properties and potential (eco)toxicological effects influenced by interactions with test media
- Test item preparation and dispersion (including stability) should take into account the characteristics of the test media
- Testing carried out with accompanying analytics to monitor exposure concentration. Use of chemical analysis alone is not sufficient



General considerations for ecotoxicological testing

Chapter R7a

- Most appropriate dose metrics may not be known: other dose metrics than mass-based, such as surface area and particle counts, may be considered
- Selected sample preparation procedure and controls, if applied justified and sufficiently reported in robust study summary



Water solubility

Chapter R7a

- Water solubility covered in Section R.7.1.7 of parent guidance
- OECD Test Guideline 105 (water solubility) not appropriate for testing nanomaterials
- Dissolution rate and degree of dispersion important information on substance



Water solubility

Chapter R7a

- Measurement of water solubility may be of value for nanomaterials with a high and fast dissolution rate- if so then water solubility will suffice
- Solubility and dispersibility different and distinct phenomena with different implications on testing and characterisation



Water solubility

Chapter R7a

Other guidelines and protocols when available
(used also for partition coefficients)

- OECD Test Guideline: dissolution rate of nanomaterials in aquatic environment
- OECD Guidance: agglomeration and dissolution behaviour of nanomaterials in aquatic media

Insolubility as a waiver

- Cannot be used as a waiver on its own
- Robust technical and scientific justification including e.g. considerations on agglomeration behaviour and dissolution needed



Partition coefficient n-octanol/water and adsorption/desorption

Chapter R7a

- LogKow or logKoc not applicable in most cases
- Conditions when applicable, substance has high and fast dissolution rate- water soluble
- Alternative parameters under development for weight of evidence, agglomeration behaviour, dissolution rate, attachment, sedimentation



Partition coefficient n-octanol/water and adsorption/desorption

Chapter R7a

- Examples of available models (Appendix 1); SimpleBox4nano, NanoDUFLOW, Steady-state distribution model
- Weight of evidence for alternative testing strategy in the environment



Appendix R7-1 for nanomaterials

Applicable to Chapter R7b

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General advice to perform ecotoxicity and fate testing

Chapter R7b

Ecotoxicity and environmental fate testing for nanomaterials with link to sample preparation and conditions for monitoring and use of metrics

- Define representative controls
- Consider dissolution rate and potential ion release
- Consider agglomeration behavior, degradation and transformation
- Provide justification for selected exposure regimes
- Confirm level of exposure during study

Aquatic toxicity modifications

Chapter R7b

- High insolubility cannot be used as waiver. Additional justification needed
- Consider dispersion, dissolution and agglomeration behavior
- Confirm applicability of test guideline used
- Preference for long-term testing
- Recommendations for additional endpoint specific parameters:
 - Fish: mechanical effects, histopathology
 - Algae: shading effects, fluorescence measurements, oxidative stress and membrane damage
 - Daphnia: nutrient depletion and sex-ratio or adherence to organisms
 - Potential toxicity due to photocatalytic effects



Sediment endpoints modifications

Chapter R7b

- Limited applicability of equilibrium partitioning method (EPM)
- Consider potential interactions with sediment and related transformations products
- Select appropriate spiking method; direct or indirect
- OECD test guidelines generally applicable;
 - OECD TG 225 (Sediment Lumbriculus Assay)
 - OECD TG 218 and 219 (Sediment - Water Chironomid Toxicity Test)
 - OECD TG 233 (Sediment - Water Chironomid Life - Cycle Toxicity Test)



Degradation/transformation

Chapter R7b

Degradation

- Biodegradability applied to organic substances
- Limited or no meaning for inorganic substances, including inorganic nanomaterials
- Carbon-based nanomaterials
 - Recommended to consider biodegradation study or provide justification



Degradation/transformation

Chapter R7b

Degradation

- Abiotic degradation in some cases relevant for nanomaterials and coatings
 - Hydrolysis
 - Oxidation
 - Photocatalytic degradation
- Degradation/transformation assessment
 - Organic nanomaterial
 - Coated/functionalised nanomaterial
 - Coating agent
 - Functionalisation agent



Degradation/transformation

Chapter R7b

Transformation

- Methods still scarce
- Qualitative assessment may be used
- Relevant to consider surface chemistry in degradation/transformation assessment



Degradation/transformation

Chapter R7b

Transformation

- Some relevant transformation processes influencing environmental fate and behaviour
 - Oxidation-reduction
 - Photochemical degradation
 - Biotransformation
 - Speciation-complexation
 - Loss of coating
 - Adsorption/desorption of (other) substances
 - Corona formation



Appendix R7-2 for nanomaterials

Applicable to Chapter R7c

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Bioaccumulation

Chapter R7c

Non-testing data

- In general not possible to make bioaccumulation estimations based on log Kow or solubility since nanomaterials are dispersed and not in solution (see also R.7.a)
- Waiving information requirement for bioaccumulation in aquatic species based on log Kow, log Koc or other screening methods in most cases inappropriate
- Alternative approaches and models under development to be used as weight of evidence (R7-1 to R.7.a Appendix 1)

Bioaccumulation

Chapter R7c

In vivo tests

- BCF cannot be calculated as no thermodynamic equilibrium will be reached between the organism and the water phase and a stable aqueous concentration cannot be maintained
- OECD TG 305 via aquatic exposure not applicable if the nanomaterial remains as particles - except for high and fast dissolution nanomaterial

Bioaccumulation

Chapter R7c

In vivo tests

- OECD TG 305 via dietary exposure is partially applicable
- OECD GD for assessing apparent accumulation potential under development
- Alternative methods
 - OECD TG 315 Bioaccumulation in sediment dwelling benthic oligochaetes
 - OECD TG 317 bioaccumulation in terrestrial oligochaetes
- Monitoring of exposure during tests important



Terrestrial toxicity

Chapter R7c

Non-testing data

- Limited applicability of equilibrium partitioning method (EPM)
- No established other estimation methods available
 - QSARs validated not available
- Separate guidance for grouping (Appendix R.6-1)
- Case-by-case assessment (WoE)



Terrestrial toxicity

Chapter R7c

Testing data

- Methods described in parent guidance Section R.7.11 in principle applicable for testing nanomaterials
- Sample preparation and spiking method: well justified and reported in detail
- Spiking methods
 - As aquatic dispersion into soil (wet spiking) or directly into test media (dry spiking), or put onto a carrier e.g. silica sand or spiked food



Terrestrial toxicity

Chapter R7c

Testing data

- Follow recommendations set out in OECD 36 (sample preparation) and OECD 40 (ecotoxicity testing)
- Monitoring of exposure during tests important

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