

Regulatory activities in the area of environmental risk assessment of nanomaterials

Scientific Stakeholder Meeting on
Nanomaterials in the Environment

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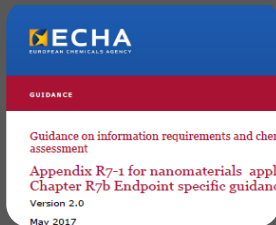


Tools to implement and support regulations under REACH, BPR and CLP



REGULATE

- REACH, BPR, CLP
- Formal regulatory processes



SUPPORT

- Nanomaterials Expert Group (NMEG)
- ECHA Guidance documents and Practical guides
- Contribution for standardisation activities: OECD
- Helpdesk

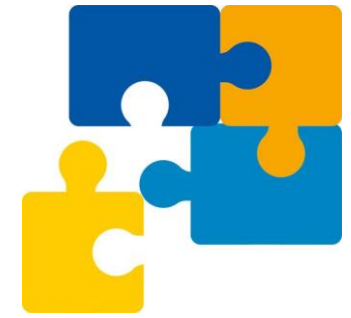


COMMUNICATE

- ECHA Nanomaterials web-site
- Conferences, workshops, communication throughout the supply chain
- EUON: broad audience

REGULATE





REACH and nanomaterials

- Currently no explicit reference to nanomaterials (NMs) in REACH, but:
 - NMs considered as covered by the substance definition under REACH
 - REACH annexes are currently under revision to include specific provisions for nanomaterials/nanoforms
- NMs can be registered as:
 - Substances on their own → registered as such (e.g. CNT)
 - Nanoforms of a substance → included in the dossier of the corresponding bulk form of the substance* (e.g. CaCO_3)
[*this also applies to any other form, e.g crystalline form]
- Registrant needs to demonstrate the safe use of its substance, whatever the form
- Absence of explicit provisions in REACH on nanomaterials gives rise to legal, scientific and technical challenges

INFORMATION ON NANOFORMS

Registration

- Produced/imported in volume higher than 1 ton/year
- Registered as a substance on its own or as a nanoform of a substance included in the dossier of the corresponding bulk or other forms of the substance
- IUCLID "tick boxes" 2.1 and 4.1

Information in the dossier - depend on the volume per year produced/manufactured

- Substance identity (including forms and surface treatment)
- Manufacture and uses
- Hazard characterisation; phys-chem properties, toxicity to environment, toxicity to human health
- Fate and exposure
- Classification

Exposure and risk characterisation

- Volume higher than 10 ton/year if classified or PBT

NANOFORMS in REACH Database 2010 – 2017

21 substances

- Carbon black,
- Cerium dioxide,
- Calcium carbonate,
- Zinc oxide,
- Silver,
- MWNT, MWNT as a form of graphite,
- Titanium dioxide,
- Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate,
-

REGULATORY PROCESSES

Evaluation

- Dossier evaluation
- Substance evaluation

Authorisation

Substances of Very High Concern (SVHCs); CMRs, PBTs or "equivalent concern"

Restriction

Community wide risk management measures, Risk assessment and socio-economic analysis (e.g. Tattoo inks, process ongoing)

Classification

RAC: TiO₂ Carcinogen cat 1B (via the inhalation route)

CORAP substances containing nanoforms (1)

1. Silicon dioxide (synthetic amorphous silica)(2012 NL)
 - Characterisation, Human health
2. Silver (2014 NL)
 - **Ecotoxicity, environmental fate**, exposure, wide dispersive uses, aggregated tonnage
 - Decision; characterisation, aquatic toxicity, toxicity to soil microorganisms
3. Zinc oxide (2017 Germany)
 - Suspected Carcinogenic and Mutagenic, Other hazard based concern, Cumulative exposure, **Exposure of environment**, Wide dispersive use
4. Potassium titanium oxide (K₂Ti₆O₁₃) (2017 France)
 - (Suspected) CMR, exposure of workers
5. Titanium dioxide (2018 France)
 - Suspected Carcinogenic and Mutagenic, Other hazard based concern, Cumulative exposure, **Exposure of environment**, Wide dispersive use

CORAP substances containing nanoforms (2)

6. MWCNTs (2018 Germany)
 - Suspected Carcinogenic, Other hazard based concern, Consumer use, Cumulative exposure, **Exposure of environment**, Wide dispersive use
7. Carbon black (2019 France)
 - Carcinogenic, Suspected Reprotoxic, Consumer use, Cumulative exposure, Exposure of sensitive populations, Exposure of workers, High (aggregated) tonnage, Wide dispersive use
8. Cerium dioxide (2019 Germany)
 - Suspected Carcinogenic and Mutagenic, Other hazard based concern, Cumulative exposure, **Exposure of environment**, wide dispersive use
9. Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate] (Germany 2019)
 - suspected Carcinogen, wide dispersive use, exposure of workers

Biocidal Products Regulation (BPR)



- Biocides are chemicals used to control pests, to disinfect or to preserve materials
- Scope; active substances, biocidal products and treated articles
- Principle; centralised approval of an active substance followed by authorisation of a biocidal product on national (including mutual recognition) or Union level
- Review Programme: systematic examination of all existing active substances on the EU market
- States that approval does not cover nanomaterials except where explicitly mentioned (Article 4(4))

Nanomaterials under the BPR

- BPR partly implements the Commission recommendation of 18 October 2011 on the definition of nanomaterials (Article 3(1)(z))
- The nanomaterial provisions apply both for active and non-active substances with the following characteristics:
 - 50% or more of the particles have a size of 1-100 nanometres in at least one dimension
 - Particles are in an unbound state, as an aggregate or as an agglomerate
- If a nanomaterial is supported the risks need to be evaluated separately

BPR: Nanomaterials in the Review Programme

- Synthetic amorphous silicon dioxide
 - CAS No: 112926-00-8; EC No: 231-545-4
- Pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated
 - CAS No: 68909-20-6; EC No: 272-697-1
- Silver as nanomaterial
 - CAS No: 7440-22-4; EC No: 231-131-3
- Silver adsorbed on silicon dioxide (as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale)

GHS and CLP: General issues on classification of nanoforms

- C&L is based on intrinsic hazardous properties of the substance (or mixture)
- The impact of form (including nanoforms) on the hazardous properties needs to be considered for C&L
- There are currently no specific entries for nanoforms in the Annex VI to (EU) CLP but these are likely to be added in the future
- Discussion is currently ongoing at UN level on the applicability of GHS for the classification of NMs

Issues to be addressed by the GHS Informal Correspondence Group on nanomaterials

Scope of work in the current biennium

- monitoring work concerning classification related issues regarding nanoform materials by other bodies, including the OECD Working party on Manufactured Nanomaterials and other relevant research projects on nanomaterials (worldwide);
- discuss which findings are relevant from the viewpoint of classification;
- develop a plan how to continue this work after the coming biennium.

GHS Classification exercise

- GHS working group on NMs decided to conduct a classification exercise on physical, health environmental hazards
- A classification exercise on the ENV classification of selected NMs was conducted by FI
 - carbon nanotubes (CNTs)
 - titanium dioxide (TiO₂)
- Preliminary conclusions have been reported to the 32nd meeting of the UN/SCEGHS at the end of 2016 (available from <http://www.unece.org/fileadmin/DAM/trans/doc/2014/dgac10c4/UN-SCEGHS-28-INF28e.pdf>)
 - Hazards to the aquatic environment; Aquatic toxicity, rapid degradation and bioaccumulation

SUPPORT



Nanomaterials Expert Group

- Meets twice a year
- Seeks consensus at EU level on scientific and technical challenges relating to the implementation of REACH, CLP and BPR for nanomaterials
- A forum for ECHA, member states, and stakeholders to address key scientific questions
- Aims to share existing knowledge and provide the best scientific and technical advice possible
- Link to the NMEG webpage:
<https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group>



Nanomaterials Expert Group – issues discussed

Guidance development

Nanoform

ENV and HH hazard assessment

Read across and grouping

Exposure and fate

Risk assessment

Regulations & processes implemented

REACH, BPR, CLP

REACH Registration

REACH Annexes

Dossier/substance evaluation

BoA

Other (EFSA, EMA)

Case studies/projects

Characterisation

HH and ENV Toxicity

EnvNano, ProSafe, NanoValid

Substance evaluation cases
e.g. silver, SAS

Scientific & technical issues

IUCLID

Grouping and Read across

Nano definition and nanoform

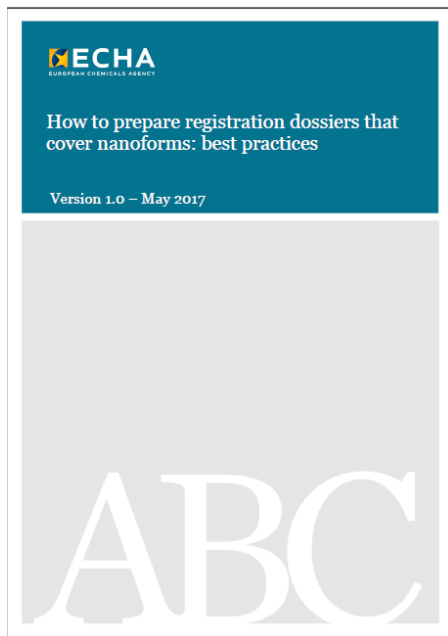
OECD TGs -priorities

Alternative methods

Role of surface treatment

Appendices to existing ECHA Guidance and Practical guide

Includes the issues that are different for nanomaterials (compared to non-nanomaterials)

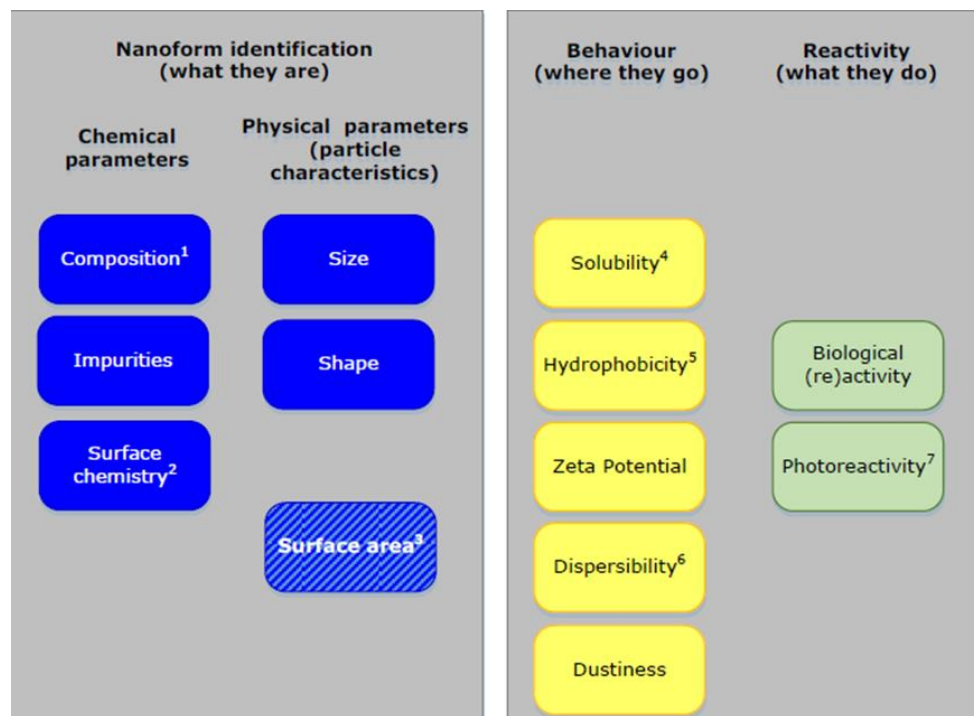


How to prepare registration dossiers that cover nanoforms: best practices (Version 1, May 2017)

- Nanoform considerations (size, shape and surface chemistry)
- Elements to be reported; size, shape and surface chemistry
- Technical reporting; IUCLID

ECHA Guidance for Read across and grouping

- Appendix R.6-1 for nanomaterials applicable to the Guidance on QSARs and Grouping of Chemicals, May 2017
- Introduces a step -wise approach
- Read-Across Assessment Framework ([RAAF](#)) (2017)
 - Main document: human health (HH) & ENV
 - 6 HH and ENV appendices that contain scenarios with assessment elements



Overview of the Endpoint specific ECHA Guidance update (May 2017)

Appendix R7-1 for Chapter R.7.a Endpoint specific guidance

- Sample preparation
- Water solubility
- Partitioning coefficient n-octanol/water (log Kow)
- Granulometry
- Adsorption/desorption
- Human health endpoints

Appendix R7-1 for Chapter R.7.b Endpoint specific guidance

- General advice on how to perform ecotoxicity and fate testing
- Aquatic pelagic toxicity
- Toxicity to sediment organisms
- Degradation/ biodegradation
- Transformation

Appendix R7-2 for Chapter R7c Endpoint specific guidance

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

“Non particulate substances” – data which have most influence in triggering further information needs:

- logKow
- logKoc
- Water solubility
- Volatility
- Ready biodegradation -test results



Regulatory standardisation priorities for ENV

Work underway in OECD:

1. Dispersion stability (on the way)
2. Dissolution rate in aquatic environment
3. Bio-accumulation potential
 - Direct link to need under REACH to clarify the use of log Kow and OECD TG 305

New topics:

1. Distribution of nanomaterials in the environment e.g. attachment affinity
 - absorption/desorption phenomena
 - an alternative to log Kow (TG107, TG117, TG123)
2. Transformation
 - Link to fate descriptors under REACH to determine need for further testing

OECD work on nanomaterials is important to ECHA

- Underpinning the implementation of REACH (TG and guidance)
- ECHAs activities in supporting the progress e.g.
 - Offering a platform for discussion of the priorities
 - Chair of the Steering Group on Testing and Assessment at OECD WPMN
 - Commenting the draft TGs and GDs
 - ECHA in collaboration with OECD prepared a report and datamatrix, "Assessment of the methods applied to generate the data in the Sponsorship Program - Human health in vivo, ecotoxicological and environmental fate endpoints"

COMMUNICATE



COMMUNICATE

- REACH Registration Dossiers [Link](#)
- Infocards
- Nanomaterials in ECHA [Link](#)
 - REACH, CLP and BPR
- Nanomaterials Expert Group (NMEG) [Link](#)
- European Union Observatory for Nanomaterials (EUON) [Link](#)
- Topical Scientific Workshop – Regulatory Challenges in Risk Assessment of Nanomaterials [Link](#)
- Webinars [Link](#)

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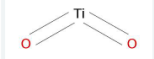
Titanium dioxide

EC number: 236-675-5 | CAS number: 13463-67-7

General information

Identification | Compositions | Registration data | Administrative data | Contact Persons responsible for the SDS

Identification



Display Name:	Titanium dioxide
EC Number:	236-675-5
EC Name:	Titanium dioxide
CAS Number:	13463-67-7
Molecular formula:	O2Ti

Type of substance

Composition: mono-constituent substance

Origin: inorganic

Total tonnage band

Total range: 10 000 - 100 000 tonnes per annum

REACH

Registered as: FULL

Submitted: Joint Submission

EUON - Build up in three phases

Provide objective and reliable information on the market and safety of nanomaterials in the EU

1st Phase -2017- launch

- New web-content for professionals and consumers
 - General information
 - Uses
 - Safety
 - Regulation
 - International activities
 - Research & Innovation

2nd Phase - 2018 - expansion of content

3rd Phase - 2019 - full operation

Summary and future aspects

- Multiple actions have been taken by ECHA to address NM under REACH, CLP and BPR:
 - Dossier and substance evaluation
 - NMEG
 - EUON
 - ECHA's involvement at OECD level
- To decrease the uncertainties in the regulatory processes, there is an urgent need to update the REACH Annexes.
- There is a need for good coverage of standard methods applicable to NM to produce adequate information for regulatory risk assessment.

Thank you!

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