



OECD RECOMMENDATION ON THE SAFETY OF NANOMATERIALS

QualityNano Conference, 15-17 July, 2015, Heraklion, Crete



OECD



	Australia		Austria		Belg
	Canada		Czech Republic		Chile
	Denmark		Estonia		France
	Germany		Finland		Hungary
	Iceland		Greece		Israel
	Italy		Ireland		Korea
	Luxembourg		Japan		Norway
	Netherlands		Mexico		Poland
	Portugal		NZ		Slovenia
	Spain		Slovak Republic		Switzerland
	Turkey		Sweden		US
			UK		

- **EC**
- **IGOs**
- **Non-member economies**
- **Industry**
- **Trade Unions**
- **Environmental NGOs**
- **Animal Welfare NGOs**



OECD's Areas of Work on Nano

**Testing and
Assessment**

**Risk
Assessment
and
Regulatory
Framework**

**Env.
Sustainable Use
of MN**

**Exposure
Measurement
and Mitigation**



OECD's Work on Environment, Health and Safety

PROTECT
(man & environment)

**Harmonized policies and
Instruments of high
quality for
regulatory purposes**

EFFICIENCY

**Work sharing
Avoid duplication
Avoid non-tariff trade barriers
shorten time to market**



OECD CHEMICALS

OECD
Council

OECD
Secretariat

Chemicals
Committee

**JOINT
MEETING**

WP
Chemicals,
Pesticides &
Biotechnology

- Good Laboratory Practice
- Test Guidelines
- **Manufactured Nanomaterials**
- Hazard Assessment
- Exposure Assessment
- Pollutant Release and Transfer Registers
- Pesticides
- Biocides
- Chemical Accidents
- Biotechnology
- Novel Foods and Feeds



Mutual Acceptance of Data (MAD)

**Test
Guidelines**

A single quality standard should be applied for testing of all chemical substances

**Good Laboratory
Practice**

A single quality standard for test facilities throughout OECD

Mutual Acceptance of Data
Legally binding on OECD Member countries
and other MAD Adherents

- Avoids duplication of testing: around Euros 150 million saved each year
- Reduces use of animals
- Reduces trade barriers

OECD COUNCIL RECOMMENDATION ON NANO: Endorsed on 19th September 2013

- Existing Legal Frameworks are applicable (**might need to be adapted**)
- Members, in the testing of manufactured nanomaterials, apply the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured nanomaterials;
- the OECD Principles of Good Laboratory Practice;
- It is open to non-members.



TESTING AND ASSESSMENT OF MN

TESTING MN:

International effort to share the testing of an agreed set of MN selected by OECD

- Fullerenes
- SWCNTs
- MWCNTs
- Nano -Silver
- Titanium dioxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide
- Dendrimers
- Nanoclays
- Gold nanoparticles

To review existing OECD TGs for adequacy

- Phys-chem
- biotic systems
- degradation and accumulation
- health effects

Guidance documents:

- Guidance Manual for the Testing Programme
- Sample Preparation and Dosimetry (GNSPD)



List of Endpoints Addressed by the OECD Testing Programme

- ▶ **Nanomaterial Information/Identification** (9 endpoints) substance name, chemical identity, uses, coating
- ▶ **Physical-Chemical Properties and Material Characterization** (17 endpoints) water solubility, particle size, agglomeration/aggregation
- ▶ **Environmental Fate** (15 endpoints) biodegradability, adsorption, accumulation
- ▶ **Environmental Toxicology** (6 endpoints) effects on aquatic and terrestrial organisms
- ▶ **Mammalian Toxicology** (9 endpoints) inhalative toxicity, reproductive toxicity, genotoxicity
- ▶ **Material Safety** (3 endpoints) flammability



TESTING AND ASSESSMENT WORK UNDERWAY

- **Identify TG/GD needs**
- **Communicate the results of the Testing Programme**
- **Assessment of the Data: Lessons Learned/ Read Across**



TG/ GD under revision

- Amendments to the Inhalation TG and GD to Accommodate NM
- GD on Aquatic (and Sediment) Toxicology Testing of NM
- TG for the Dissolution Rate of Nanomaterials in the Aquatic Environment
- GD for Dispersion and Dissolution of NM in Aquatic Media – Decision Tree
- GD on Assessing the Apparent Accumulation Potential of NM
- TG for Dispersibility and Dispersion Behaviour of NM in Aquatic Media
- (new) TG for Nanomaterial Removal from Wastewater
- GD on the Adaptation of *In Vitro* Mammalian Cell Based Genotoxicity TGs for Testing of Manufactured Nanomaterials



RESULTS OF THE TESTING PROGRAMME: DOSSIERS

The Nanomaterials were chosen **to assess the applicability and accuracy of existing test guidelines and to identify where technical adaptation were needed. It was not intended conclude on risks** associated with the use or application of nanomaterials.

**Cerium oxide
Dendrimers
Fullerenes (C60)
Multi-walled carbon
nanotubes (MWCNTs)
Single-walled carbon
nanotubes (SWCNTs)**

**Nanoclays
Silicon dioxide
Silver nanoparticles
Titanium dioxide
Zinc oxide
Gold nanoparticles**



Dossiers in a IUCLID style printed form

ENV/CHEM/NANO(2015)17/PART1

SUBSTANCE: SILVER NANOPARTICLES

A. CAS NUMBER: 7440-22-4 (silver)
 B. NAME: Citrate capped silver nanoparticles (cAgNPs)
 C. MOLECULAR FORMULA/STRUCTURAL FORMULA: Ag
 D. Manufacturer: ABC Nanotech Co. Ltd (Korea)

A. CAS NUMBER: 7440-22-4 (silver)
 B. NAME: Silver powder (AgNPs)
 C. MOLECULAR FORMULA/STRUCTURAL FORMULA: Ag
 D. Manufacturer: NAMATECH Co. Ltd (Korea)

1.02. OECD INFORMATION
 A. CO-SPONSORS (COUNTRY): Republic of Korea & United States
 B. LEAD ORGANISATION: National Institute of Environmental Research, Korea
 C. NAME OF RESPONDER (COMPANY):

1. GENERAL INFORMATION

1.1 Identification

Substance identification

Chemical name Silver Nanoparticles

Reference substance

Silver

Type of substance

Composition other: Existing Chemical
 Origin element

Other names

Flag	Name Type	Name	Country	Remarks
	other: 7440-22-4 (silver)	Silver Powder	Korea, Republic Of	Reference substance: silver / silver(1+) / 7440-22-4, EC number: 231-131-3, EC name: silver, CAS number: 7440-22-4, IUPAC name: silver(1+)

11

ENV/CHEM/NANO(2015)17/PART1

other: 7440-22-4 (Silver)	Citrate-stabilized AgNPs		
other:	H2-AgNPs (13 nm, -22 mV; Citrate-AgNPs (10 nm, -39 mV); PVP-AgNPs (12 nm, -10 mV) BPEI-AgNPs (10 nm, +40 mV) [US EPA]		
	NanoComposix uncapped nano-scale silver, 10, 20, 30, 50 nm sizes		
	NM-300K silver < 20 nm		
	SARPU 200KW		
	Silver nanoparticle (Korea)	Korea, Republic Of	

1.2 Composition

Substance composition

Name	
Constituents	
Reference substance	silver

1.3 Identifiers

1.4 Analytical information

1.5 Joint submission

1.6 Sponsors

1.7 Suppliers

1.8 Recipients

1.9 Product and process orientated research and development

12

ENV/CHEM/NANO(2015)17/PART1

2. CLASSIFICATION & LABELLING AND PBT ASSESSMENT

2.1 GHS

2.2 DSD - DPD

3. MANUFACTURE, USE AND EXPOSURE

3.1 Technological process

Technological process

3.2 Estimated quantities

Estimated quantities

Remarks	
Quantity	10000 ... 50000 tonnes

3.3 Sites

3.4 Information on mixtures

3.5 Life Cycle description

Identified uses

Uses at industrial sites

Identified Use number	
Environmental Release Category	ERC 7: Industrial use of substances in closed systems ERC 5: Industrial use resulting in inclusion into or onto a matrix
Subsequent service life relevant for that use?	yes

Uses by professional workers

Identified Use number	
Environmental Release Category	ERC 9b: Wide dispersive outdoor use of substances in closed systems ERC 9a: Wide dispersive indoor use of substances in closed systems ERC 8c: Wide dispersive indoor use resulting in inclusion

13



Table of Contents Example: Silver part 1

ENV/CHEM/NANO(2015)17/PART1

TABLE OF CONTENTS

PART 1

PREAMBLE	3
FOREWORD	5
ACKNOWLEDGMENTS	6
Substance: Silver Nanoparticles	11
1. General information	11
1.1 Identification	11
1.2 Composition	12
1.3 Identifiers	12
1.4 Analytical information	12
1.5 Joint submission	12
1.6 Sponsors	12
1.7 Suppliers	12
1.8 Recipients	12
1.9 Product and process orientated research and development	12
2. Classification & Labelling and PBT assessment	13
2.1 GHS	13
2.2 DSD - DPD	13
3. Manufacture, use and exposure	13
3.1 Technological process	13
3.2 Estimated quantities	13
3.3 Sites	13
3.4 Information on mixtures	13
3.5 Life Cycle description	13
3.6 Uses advised against	14
3.7 Exposure Scenarios, exposure and risk assessment	15
3.7.1 Exposure scenarios and local assessment	15
3.7.2 Environmental assessment for aggregated sources	15
3.7.3 Generic exposure potential	15
3.8 Biocidal information	15
3.9 Emissions Information	15
3.10 Application for authorisation of uses	15
4. Physical and chemical properties	16
4.1 Appearance/physical state/colour	16
4.2 Melting point/freezing point	20

ENV/CHEM/NANO(2015)17/PART1

4.3 Boiling point	21
4.4 Density	23
4.5 Particle size distribution (Granulometry)	24
4.6 Vapour pressure	36
4.7 Partition coefficient	37
4.8 Water solubility	38
4.9 Solubility in organic solvents / fat solubility	48
4.11 Flash point	51
4.12 Auto flammability	52
4.13 Flammability	53
4.14 Explosiveness	53
4.15 Oxidising properties	54
4.16 Oxidation reduction potential	55
4.17 Stability in organic solvents and identity of relevant degradation products	55
4.18 Storage stability and reactivity towards container material	55
4.19 Stability: thermal, sunlight, metals	55
4.20 pH	55
4.21 Dissociation constant	55
4.22 Viscosity	55
4.23 Additional physico-chemical information	55
4.24 Agglomeration/aggregation	71
4.25 Crystalline phase	86
4.26 Crystallite and grain size	98
4.29 Zeta potential	106
5. Environmental fate and pathways	113
5.1 Stability	113
5.1.1 Phototransformation in air	113
5.1.2 Hydrolysis	113
5.1.3 Phototransformation in water	113
5.1.4 Phototransformation in soil	113
5.1.5 Preliminary: Dispersion stability in water	115
5.2 Biodegradation	121
5.2.1 Biodegradation in water: screening tests	121
5.2.2 Biodegradation in water and sediment: simulation tests	123
5.2.3 Biodegradation in soil	123
5.2.4 Mode of degradation in actual use	124
5.3 Bioaccumulation	125

ENV/CHEM/NANO(2015)17/PART1

5.3.1 Bioaccumulation: aquatic / sediment	125
5.3.2 Bioaccumulation: terrestrial	126
5.4 Transport and distribution	126
5.4.1 Adsorption / desorption	126
5.4.4 Other distribution data	156
5.6 Additional information on environmental fate and behaviour	163
6. ECOTOXICOLOGICAL INFORMATION	178
6.1 Aquatic toxicity	178
6.1.1 Short-term toxicity to fish	178

PART 2

6.1.2 Long-term toxicity to fish	ENV/CHEM/NANO(2015)17/PART2
6.1.3 Short-term toxicity to aquatic invertebrates	ENV/CHEM/NANO(2015)17/PART2
6.1.4 Long-term toxicity to aquatic invertebrates	ENV/CHEM/NANO(2015)17/PART2

PART 3

6.1.5 Toxicity to aquatic algae and cyanobacteria	ENV/CHEM/NANO(2015)17/PART3
---	-----------------------------

PART 4

6.1.6 Toxicity to aquatic plants other than algae	ENV/CHEM/NANO(2015)17/PART4
Endpoint study record: Toxicity to aquatic plants other than algae - Lemna 002	ENV/CHEM/NANO(2015)17/PART4

PART 5

Endpoint study record: Toxicity to aquatic plants other than algae - Lemna 001	ENV/CHEM/NANO(2015)17/PART5
Endpoint study record: Toxicity to aquatic plants other than algae - Myriophyllum 001	ENV/CHEM/NANO(2015)17/PART5

PART 6

6.1.7 Toxicity to microorganisms	ENV/CHEM/NANO(2015)17/PART6
6.1.8 Toxicity to other aquatic organisms	ENV/CHEM/NANO(2015)17/PART6
6.2 Sediment toxicity	ENV/CHEM/NANO(2015)17/PART6
6.3 Terrestrial toxicity	ENV/CHEM/NANO(2015)17/PART6
6.3.1 Toxicity to soil macroorganisms except arthropods	ENV/CHEM/NANO(2015)17/PART6



Assessment of submitted physchem data from the testing programme

- test method used?
- adaptations
- dispersion method was used?
- Is the test method suitable and sufficient (this/ other nanos)
- Is the test method suitable and sufficient for other (group(s) of) nanomaterials?
- recommendations for adaptations of the test method included in the dossier?
- Expert opinion on the validity of the method



Results of method evaluation

- For most evaluated parameters, one or more methods were found suitable for testing nanomaterials:
- Methods suitable for (almost) all NMs, available to measure **Aggregation/Agglomeration, Crystalline phase, Dustiness, Chemical composition, Radical formation potential**
- Methods limited to specific types of NM / specific conditions, available to measure **Specific surface area, Zeta potential, Photocatalytic activity, Porosity**
- No suitable methods available (in this evaluation) for **Particle size distribution, Redox potential**



WORK UNDERWAY

1. Assessment of the quality and relevance of **data** in the context of hazard characterization.



2. Based on this exercise evaluate if it is possible to continue with integrated approaches to testing strategies, broader risk assessment for MN which may including grouping/category and read-across approaches



OECD's Areas of Work on Nano

**Testing and
Assessment**

**Risk
Assessment
and
Regulatory
Framework**

**Env.
Sustainable Use
of MN**

**Exposure
Measurement
and Mitigation**



Risk Assessment and Regulatory Framework

- To identified uncertainties in risk assessment when extrapolating from conventional chemical frameworks to manufactured nanomaterials [see ***ENV/JM/MONO(2012)8***]
- Prioritize gaps in risk assessment [***ENV/JM/MONO/2013(2013)18***]
- Regulated Nanomaterials [published as ***ENV/JM/MONO(2014)28***]



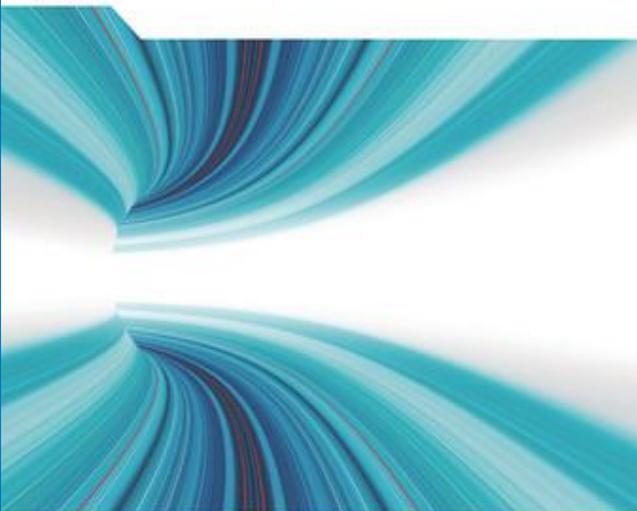
ENV. SUSTAINABLE USE OF MN

NANOTECHNOLOGY AND TYRES:

GREENING INDUSTRY AND TRANSPORT



Nanotechnology and Tyres
GREENING INDUSTRY AND TRANSPORT



 OECD

The report emphasizes the importance of:

- The *policies* to support research in the environmental, health and safety risks, as well as those to support the commercialisation of nanotechnology research results, for fostering responsible innovation in the tyre sector;
- Using available tools (e.g. cost/benefit analysis, LCA) to gain better insight into the socio-economic and environmental impacts of nanotechnology applications;
- Collaboration between governments and industry to address the specific challenges raised by the introduction of new nanomaterials in different industry sectors.



Contact / Information/ Publications

THANK YOU! OECD Secretariat

peter.kearns@oecd.org

mar.gonzalez@oecd.org

terumi.munekane@oecd.org

hoseok.song@oecd.org

jihane.elgaouzi@oecd.org

nanosafety@oecd.org

Publications free to download

www.oecd.org/env/nanosafety

Results from the testing programme

<http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm>