



TESTING AND ASSESSMENT OF MANUFACTURED NANOMATERIALS

Manufactured Nanomaterials/ Nanotechnology
UNITAR-OECD Workshop for the Latin America region
Bogotá, Colombia – 22-24 June 2015



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+)

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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 nanoparticles (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

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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

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PART 2

6.1.2 Long-term toxicity to fish	ENV/CHEM/NANO(2015)17/PART2
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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
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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 TESTING PROGRAMME

OECD Secretariat

nanosafety@oecd.org

mar.gonzalez@oecd.org

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