



Project title:

Development of a web based REACH Toolkit to support the chemical safety assessment of nanomaterials

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Report Title

A1. Report on Representative Nanomaterials under REACH

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EXECUTIVE SUMMARY

This document describes the selection of the representative nanomaterials and the process applied for their selection. In total, 30 representative nanomaterials were selected from a larger first selection composed of 52 nanomaterials. The report indicates the information that partners are to collect for the 30 representative nanomaterials.



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1. Scope and Objectives of the Deliverable

1.1. Scope

The scope of this deliverable is to select the nanomaterials to be used within the project to develop the web based tool.

1.2. Objectives

The aim to define a set of representative manufactured nanomaterials in the context of REACH, taking into account the scope and exemptions of REACH provisions. To this end a complete review of the nanomaterials placed on the market will be conducted, identifying the main parameters that determine if a substance falls within scope of REACH.



2. Methodology

The partners first identified a number of suitable sources of nanomaterials to be considered in the project. The sources were mainly the 13 representative nanomaterials under the OECD Sponsorship Programme and the representative nanomaterials identified from the European Commission Staff Working Paper (SWD(2012)288 final) that accompanied the 2nd Regulatory review of nanomaterials (COM(2012)572 final).

In addition, the registered nanomaterials in the ECHA database of registered substances were checked as well as other sources based on the experience of the project partners.

3. Selected Nanomaterials

Based on the methodology described, 30 nanomaterials have been selected to be used within the project (Table 1). For the selected nanomaterials, the information outlined in Appendix I will be generated as far as is possible. The responsible partners for generation of the information are indicated in Table 1.

Table 1. Selected nanomaterials and responsible partner for information gathering

GROUP	NANOMATERIAL	PARTNER
INORGANIC NON-METALLIC	SILICON DIOXIDE	NIA
	TITANIUM DIOXIDE	ITENE
	ZINC OXIDE	NIA
	ALUMINIUM OXIDE	LEITAT
	DIIRON TRIOXIDE	LEITAT
	TRIIRON TETRAOXIDE	LEITAT
	ZIRCONIUM DIOXIDE	NIA
	CERIUM DIOXIDE	NIA
	CALCIUM CARBONATE	ITENE
	TITANIUM NITRIDE	NIA
	SILICON CARBIDE	LEITAT
	SILICON NITRIDE	ITENE
METALS AND METAL ALLOYS	GOLD	ITENE
	SILVER	NIA
	PLATINUM	ITENE
	COPPER OXIDE	LEITAT
	COBALT	LEITAT
	FULLERENES	NIA
CARBON-BASED	CARBON NANOTUBES SINGLE-WALLED	LEITAT
	CARBON NANOTUBES MULTI-WALLED	LEITAT
	CARBON BLACK	NIA
	GRAPHENE FLAKES	ITENE
	GRAPHITE	NIA
	NANODIAMONDS	ITENE
	NANOCELLULOSE	ITENE
POLYMERS AND DENDRIMERS	DENDRIMERS	LEITAT
	POLYMER NANOPARTICLES, NANOTUBES, NANOWIRES, NANORODS	ITENE
	NANOCLOCKS	NIA
OTHERS	QUANTUM DOTS	ITENE
	NANOZEOLITES	LEITAT



4. Current status of Nanomaterials under REACH Regulation

Following the CARACAL document 'Nanomaterials in REACH' (CA/59/2008 rev. 1), it is stated that 'REACH addresses substances, on their own, in preparations or in articles. It deals with all substances, in whatever size, shape or physical state. This document was endorsed by the European Member States Competent Authorities and published on the European Commission website. This was the first recognition that nanomaterials are 'substances' following the substance definition in the REACH Regulation (EC) 19047/2006.



5. Nanomaterials on the market

The European Commission published its 2nd Regulatory Review on Nanomaterials (COM(2012)572 final) in October 2012. This communication was accompanied by a Commission Staff Working Paper (SWD(2012)288 final) that provides information on types and uses of nanomaterials. The SWD is recognised as being currently the most accurate compilation of information on nanomaterials on the market.

The information provided below is information from chapter 3 of the SWD:

‘The market is dominated by two very widespread commodity materials, i.e. carbon black (9.6 million t), and synthetic amorphous silica (1.5 million t). Other nanomaterials with significant amounts on the market include aluminium oxide (200 000 t), barium titanate (15 000 t), titanium dioxide (10 000 t), cerium oxide (10 000 t), and zinc oxide (8 000 t). Carbon nanotubes and carbon nanofibres are currently marketed at annual quantities of several hundreds of tonnes (other estimates go up to a few thousands of tonnes). Nanosilver is estimated to be marketed in annual quantities of around 20 tonnes.’

5.1 Forms in which the nanomaterials are placed on the market

Nanomaterials are provided as powders or suspensions. To reduce occupational exposure (e.g. dust form nanomaterials) nanomaterial manufacturers are often working close to the nanomaterial users to optimise the nanomaterial incorporation process into the produce to reduce the chances of occupation exposure. For example, nanomaterial powders can be supplied in plastic bags that are composed of a plastic suitable for incorporation into the final product. The plastic bag is not opened, but directly added to the formulation mixture.

5.1 identified uses and applications

The information provided below is from chapter 3 of the SWD:

‘By far the biggest use is as a reinforcing agent for rubber in tyres and other rubber goods (global market around 15 bn €, mainly carbon black), followed by functional fillers in polymers (around 1.5 bn €, mainly synthetic amorphous silica, in lower quantities also other metal oxides and silver), various uses in electronics (1 bn €), in cosmetics (100 m €) and biomedical applications (60 m €). In electronics, the biggest use are CMP31 slurries, i.e. fine abrasives (mainly colloidal synthetic amorphous silica) used in the preparation of electronic components, followed by multi-layered ceramic capacitors (MLCC, mainly barium titanate). In cosmetics, the main nanomaterials are synthetic amorphous silica, titanium dioxide and zinc oxide. Among biomedical applications, gold nanoparticles in medical diagnostics and silver nanoparticles (e.g. in hospital textiles) seem to be the biggest applications in terms of market value. In addition to those applications, there is use of a wide range of nanomaterials in paints and coatings, catalysts, solar and fuel cells, etc.’



6. Conclusion

This report describes the selection of the 30 nanomaterials for which the information outlined in Annex 1 will be provided. The selection of the nanomaterials is based on the collected expertise of the project partners combined and assessment of nanomaterials that are placed, or foreseen to be placed on the market.



Appendix 1.

Titanium Dioxide [Replace nanomaterial name as appropriate]

1. Tonnage Level in which the Nanomaterial is manufactured or imported

Tonnage bands under REACH					
NMs Form	1 – 10 tonnes	10-100 tonnes	100-1000 tonnes	> 1000 tonnes	References

Tonnage band on the basis of the information collected:

2. Forms in supply chain

NMS Form	Structural Data		Physical States		Form in Supply chain under REACH			References
	Size range	Shape	Solid (Primary Particle)	Liquid Phase (Suspension, emulsion of foam)	Substance	Mixture	Article	

3. Preliminary hazard classification

CLP Bulk-Form	
CLP Data	Reference



Hazard information from peer reviewed publications (relevant for CLP)

Hazard Information	NMs Forms						
Relevant REACH Annex:							
Physicochemical Properties :							
Particle size							
Aspect ratio, shape							
Toxicological Information:							
Skin irritation/corrosion and eye irritation							
Skin sensitisation							
Mutagenicity							
Acute toxicity							
Repeated dose and reproductive toxicity							
Toxicokinetics							
Carcinogenicity							
Ecotoxicological Information:							
Ecotoxicity Short term aquatic							
Degradation							
Effects on terrestrial organisms							
Long-term toxicity to sediment organisms							

Evaluation by Partner

NMS Form	Nano-specific Information					Preliminary Evaluation by Partners			
	Relevant Health hazards	Relevant Environmental Hazards	Related Physical Hazards	CMR effects	Bioaccumulation Potential	Significant toxicity in humans (Danger)	Potential to be harmful (Warning)	Potential Hazards Pictograms	Classification not possible

4. Sector of Use and Main Commercial Applications

Main Commercial applications



Use Sectors [Mark with X]

DESCRIPTOR	SECTORS OF USE (SU):	NMS Form			
SU 1	Agriculture, forestry, fishery				
SU2a	Mining, (without offshore industries)				
SU2b	Offshore industries				
SU4	Manufacture of food products				
SU5	Manufacture of textiles, leather, fur				
SU6a	Manufacture of wood and wood products				
SU6b	Manufacture of pulp, paper and paper products				
SU7	Printing and reproduction of recorded media				
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)				
SU9	Manufacture of fine chemicals				
SU10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)				
SU11	Manufacture of rubber products				
SU12	Manufacture of plastics products, including compounding and conversion				
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement				
SU14	Manufacture of basic metals, including alloys				
SU15	Manufacture of fabricated metal products, except machinery and equipment				
SU16	Manufacture of computer, electronic and optical products, electrical equipment				
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment				
SU18	Manufacture of furniture				
SU19	Building and construction work				
SU20	Health services				
SU21	Consumer uses: Private households (= general public = consumers)				
SU22	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)				
SU23	Electricity, steam, gas water supply and sewage treatment				
SU24	Scientific research and development				
SU0	Other				

Product Categories [Mark with X]

DESCRIPTOR	CHEMICAL PRODUCT CATEGORY (PC): describes in which types of chemical products (= sub-stances as such or in mixtures) the NM is finally contained	NMS Form			
PC1	Adhesives, sealants				
PC2	Adsorbents				
PC3	Air care products				
PC4	Anti-Freeze and de-icing products				



PC5	Non Defined by ECHA				
PC6	Non Defined by ECHA				
PC7	Base metals and alloys				
PC8	Biocidal products (e.g. Disinfectants, pest control)				
PC9a	Coatings and paints, thinners, paint removers				
PC9b	Fillers, putties, plasters, modelling clay				
PC9c	Finger paints				
PC10	Non Defined by ECHA				
PC11	Explosives				
PC12	Fertilizers				
PC13	Fuels				
PC14	Metal surface treatment products,				
PC15	Non-metal-surface treatment products				
PC16	Heat transfer fluids				
PC17	Hydraulic fluids				
PC18	Ink and toners				
PC19	Intermediate				
PC20	Products such as ph-regulators, flocculants, precipitants, neutralization agents				
PC21	Laboratory chemicals				
PC22	Non Defined by ECHA				
PC23	Leather tanning, dye, finishing, impregnation and care products				
PC24	Lubricants, greases, release products				
PC25	Metal working fluids				
PC26	Paper and board dye, finishing and impregnation products				
PC27	Plant protection products				
PC28	Perfumes, fragrances				
PC29	Pharmaceuticals				
PC30	Photo-chemicals				
PC31	Polishes and wax blends				
PC32	Polymer preparations and compounds				
PC33	Semiconductors				
PC34	Textile dyes, finishing and impregnating products;				
PC35	Washing and cleaning products				
PC36	Water softeners				
PC37	Water treatment chemicals				
PC38	Welding and soldering products (with flux coatings or flux cores.), flux products				
PC39	Cosmetics, personal care products				
PC40	Extraction agents				
PC0	Other				

5. Summary

Tonnage bands under REACH				
NMs Form	Tonnage level	Forms in supply chain	Qualitative Hazard Evaluation	Applications