

Communicating business-to-business product information

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EVONIK
INDUSTRIES

Manufactured nanomaterials according to OECD

Elemental nanomaterials

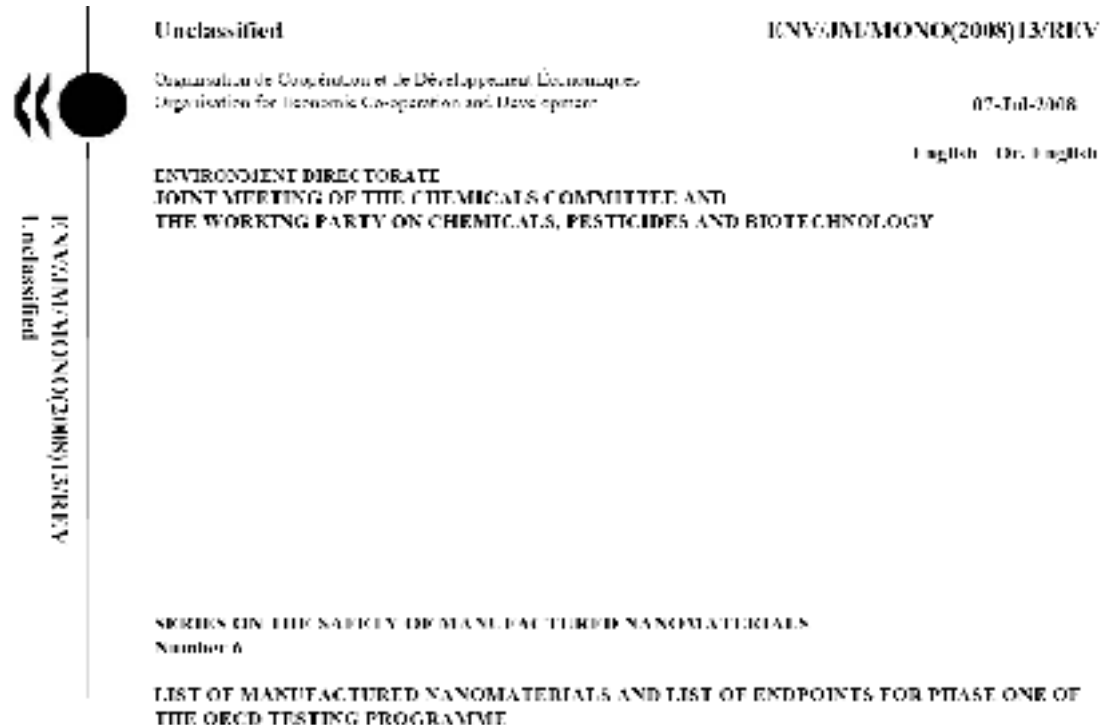
- Fullerenes (C₆₀)
- Multi-walled carbon nanotubes
- Single-walled carbon nanotubes
- Carbon black
- Silver nanoparticles
- Iron nanoparticles

Oxides

- Nanoclays
- Titanium dioxide
- Aluminium oxide
- Cerium oxide
- Zinc oxide
- Silicon dioxide

Organic compounds

- Polystyrene
- Dendrimers



OECD Manufactured Nanomaterials
[http://appl1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono\(2008\)13-rev](http://appl1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)13-rev)

Responsible Care® applies to all products of the chemical industry

The global Responsible Care® principles require to:

- **continuously improve HSE-knowledge and performance** of technologies, processes and products over their life cycles
- **report openly on performance, achievements and shortcomings**
- **listen, engage and work with people** to understand and address their concerns and expectations
- **cooperate with governments and organisations** for effective regulations and standards, and meet or go beyond them
- **provide help and advice to foster the responsible management of chemicals along product chain**

Good product stewardship of nanomaterials

German Chemical Industry Association VCI



Principles document

- Implementing Responsible Care® on Nanomaterials

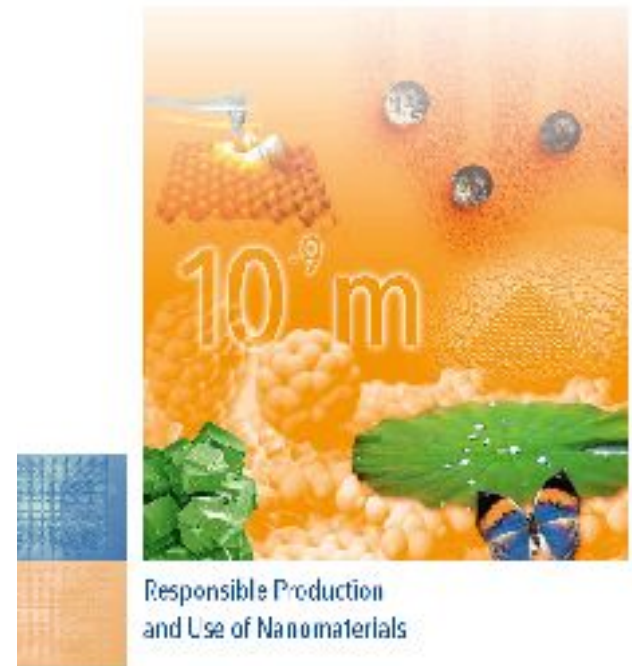
Regulatory documents

- Nanomaterials and REACH
- Data for Risk Assessment
- Occupational Safety and Health
- **Safety Data Sheet and Supply Chain**
 - Guidance to fill in MSDSs for nanomaterials
 - checklist and recommendations for downstream users and SMEs
- Standardization

Documents on Safety Research

- Human Health
- Environment

VERBAND DER CHEMISCHEN INDUSTRIE e.V.
German Chemical Industry Association



<http://www.vci.de>

Legal requirements without volume thresholds



Legal requirements without volume thresholds and independent of registration timelines

- **Risk Assessment for all uses**
 - See VCI recommendation on gathering HSE-information
- **Classification and labelling**
 - Different products with the same chemical identity can have different classification / labelling (e. g. pyrophorous metal powders)
- **Information in the supply chain according to Title IV of REACH**
 - See VCI guidance document on how to fill in the SDS for Nanomaterials
- **Occupational health and safety** (also other laws)

Voluntary measures in the VCI guide

Recommendations beyond legal requirements

- **Stakeholder dialogues**
- **Intensifying safety research in specific projects**
- **In special cases** (specific toxicity and/or widespread use and repeated exposure) **gathering of HSE information beyond REACH Annex VII** (i.e. from Annex VIII, IX, X)

Recommendations particular relevant for B2B communication and MSDS

- **Minimise exposure at the workplace**, until specific limit values are laid down for nanoparticles or certain nanomaterials
- **Publication of MSDSs** by companies on a regular basis
- **Safety Data Sheets for all substances/preparations**, also for those not classified as dangerous
- **Additional physicochemical information** on top of REACH requirements for risk assessment

SAFETY DATA SHEET (EC 1907/2006)

AEROSIL[®] 200

Material no.	Version	1.17 / REG_EU
Specification	Revision date	14.08.2007
VA-Nr	Print Date	20.06.2008
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safety data sheet
publicly available

2. HAZARDS IDENTIFICATION

Additional safety information for humans and the environment

On the basis of our data the product is not a hazardous substance as defined by the Chemicals Act or

safety data sheets for non
hazardous material issued

7. HANDLING AND STORAGE

Handling

Safe handling advice

If necessary: Local ventilation.

Minimise exposure

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Components with workplace control parameters

Personal protective equipment

Respiratory protection

No special protective equipment required.

If dust occurs: Dust mask with P2 particle filter

<http://www.evonik.com> → products → chemicals

Materials Safety Data Sheet publicly available

MSDS AEROSIL® 200



11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	LD50 Rat: > 10000 mg/kg Method: literature
Acute inhalation toxicity	LC0 Rat: 0,139 mg/l / 4 h Method: literature (maximum concentration attainable in experiments) No deaths occurred.
Acute dermal toxicity	LD50 Rabbit: > 5000 mg/kg Method: literature
Skin irritation	Rabbit / literature not irritating
Eye irritation	Rabbit / literature not irritating
Repeated dose toxicity	Oral no negative effects
	inhalative No irreversible changes and no indication of silicosis.
Mutagenicity assessment	In vitro and in vivo experiments, no evidence of mutagenic effects, literature.
Carcinogenicity	no negative effects
Toxicity to reproduction	no negative effects
Human experience	Silicosis or other product specific illnesses of the respiratory tract were not observed in association with the product.

12. ECOLOGICAL INFORMATION

Elimination information (persistence and degradability)

Behaviour in environmental compartments

Ecotoxicity effects

Toxicity to fish	LC50 (brachydanio rerio): > 10000 mg/l / 96 h Method: OECD 203
Toxicity to daphnia	EC50 Daphnia magna: > 10000 mg/l / 24 h Method: OECD 202

<http://www.evonik.com> → products → chemicals

Comprehensive test data

**Silica passed OECD
High Production Volume Program
→ Low priority for further work**

REACH registration procedure effectively addresses all relevant nanomaterials



Nanomaterials are chemical substances and therefore covered by REACH

REACH Registration

- Mandatory for substances >1 t/a per registrant
- Precautionary Principle already implemented in REACH (Article 1)
- Substances, not uses, must be registered
- All uses must be identified in the registration dossier (also of a substance in its nanomaterial state, even < 1 t/a!)

Allmost all relevant manufactured nanomaterials from OECD list have to be registered under REACH

Due to

- Due to changes of Annex IV: Multi-walled and single-walled carbon nanotubes, fullerenes
- OECD HPV-materials (> 1000 t): Nanoclays*, carbon black, Ag, Fe, TiO₂, Al₂O₃, ZnO, SiO₂
- Volume estimated >> 10 t: CeO₂

* assuming that nanoclays can be assigned to OECD HPV substance hectorite

- **Responsible Care essential tool also for nanomaterials**
- **Specific guidelines on implementing good product stewardship of nanomaterials available**
- **Nanomaterials are not new, but there are new nanomaterials. The extent of available safety information varies accordingly**
- **MSDS effective and central tool for communicating safety information in the value chain**
- **Allmost all relevant manufactured nanomaterials from OECD list have to be registered under REACH**

This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.