# Communicating business-to-business product information

Dr. Markus Pridöhl

Brussels, Oct 2<sup>nd</sup> 2008



# Manufactured nanomaterials according to OECD



#### Elemental nanomaterials

- Fullerenes (C<sub>60</sub>)
- 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

#### Unclassified

ENV/JNEMONO(2008)13/REV

Organisation de Coopération et de Développement Économiques. Organisation for Regnomic Co-operation and Development

07-Jul-2008

English Or. English

ENVIRONMENT DIRECTORATE
JOINT MERLING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PRETICIDES AND BIOLECHNOLOGY

ENEGRETATIONO(2008)15/REV Unclassified

SERBES ON THE SAFRLY OF MANUFACTURED NANOWATERIALS.
Number 6

LIST OF MANUFACTURED NANOMATERIALS AND LIST OF ENDPOINTS FOR PHASE ONE OF THE OECD TESTING PROGRAMME

OECD Manufactured Nanomaterials http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)13-rev

### Responsible Care®



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**

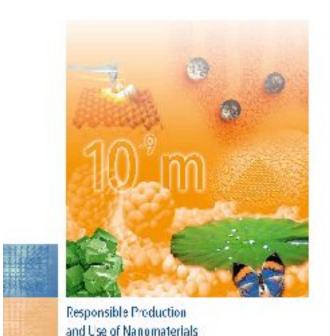
- Nanomaterials and REACH
- Data for Risk Assessment
- Occupational Safety and Health
- Safety Data Sheet and Supply Chain
  - Guidance to fill in MSDSs for nanomaterials
  - checklist and recommendations for downstream users and SMEs
- Standardization

#### **Documents on Safety Research**

- Human Health
- Environment

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





http://www.vci.de

Oct 2<sup>nd</sup> 2008 - Markus Pridöhl

Seite 4

# 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 <u>same</u> chemical identity <u>can</u> have <u>different</u> 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

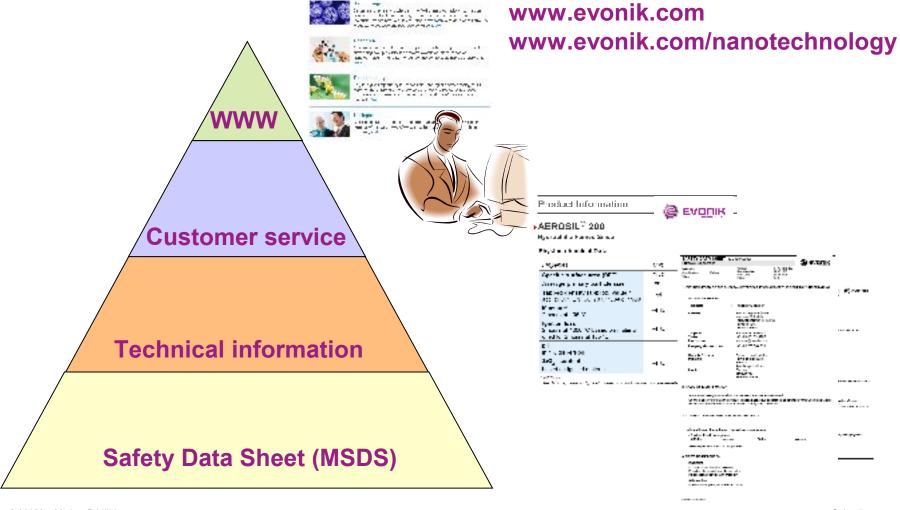
- Stakeholder dialogues
- Intensifying safety research in specific projects
- In special cases (specific toxicity and/or widespread use and repeated exposure)
   gathering of HSE information beyond REACH Annex VII (i.e. from Annex VIII, IX, X)

#### 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 <u>all</u> substances/preparations, also for those not classified as dangerous
- Additional physicochemical information on top of REACH requirements for risk assessment

# Tools to provide safety information along the value chain





## Publicly available product information



#### Product Information

#### AEROSIL® 200

Hydrophilic Fumed Silica

#### Physico-chemical Data

Properties	Unit	Typical Value
Specific surface area (BET)	m²/g	200 ± 25
Average primary particle size1	nm	12
Tapped density (approx. value)* acc. to DIN EN ISO 787/11, Aug. 1983	g/l	approx. 50
Moisture* 2 hours at 105 °C	wt.%	≤ 1.5
ignition loss 2 hours at 1000 °C based on material dried for 2 hours at 105 °C	w <b>t.</b> %	<u>≺</u> 1.0
pH n 4% dispersion		3.7 • 4.7
SIO <sub>2</sub> - content based on ignited material	wt%	≥ 99.8

<sup>^</sup> em plami.

The data represents typical values and not production parameters.

# **Technical and safety information publicly available**

AEROS La Turned Silica - EHAS

Loxicology and Industrial Hygiene

Synthetic emergine relation on type AFPOSI. <sup>16</sup> mortufactures by dome hydrolysis is converted to a kits amorphics street. The determination in church and on typical samples is enromment of the drystaline that for followed by Xinay D. Yradion. The detection initiation inlines to easily have a possible. The detection initiation in this relation of this celebration of this celebration is the sample of the s

Synthetic an orphicus sitical is used in a wide variety of products and processes. The administration of synthetic aniciphocals it is results in no adult tusis symptons when rathin is erad either orably or defined y. Shot es for assessing busicity with skin or aya contact allow that synthetic aniciphocal sitical contract of the ayes or skin. It is known that synthetic aniciphocal contract the contract of the synthetic principhocal contract of the contract of the synthetic principhocal contract of the synthetic principho

In inhabitor studies, not a of the investigated symmetrically amorphous situal coused permanent braniges in the onglor progressive injuries comparable to situatis. In many apidemiological studies on other ideally expressive models are investigated to see the order of the permanent map that containing the activation of the permanent map products are containing to a towards the data, say medicinal reducts either are appropriately in the individual product containing to a containing to a form and the other containing the data and the permanent of the other containing the data and the permanent of the other containing the data and the other containing the permanent and the containing the con

#### http://www.evonik.com → products → chemicals

<sup>&</sup>lt;sup>1</sup>The primary partice size is mentioned to indicate the application properties of a given product. It does not represent the effective particle size in the supplied product, as the primary particles form larger aggregates and agglomerates during production

#### **Materials Safety Data Sheet publicly available**



SAFETY DATA SHEET	(EC 1907/2006)
-------------------	----------------

AEROSIL® 200

 Material no.
 Version
 1.17 / REG\_EU

 Specification
 132138
 Revision date
 14.08.2007

 Print Date
 20.06.2008

VA-Nr Page 1/6



safety data sheet publicly available

safety data sheets for non hazardous material issued

#### 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

#### 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.

Mahad: literature

Abute inhalation toxicity LC0 Rat: 0,139 mg/l / 4 h

Method: litterature

(maximum concentration attainable in experiments)

No deaths occurred.

Abute dermal toxicity LD50 Rabbit: > 5000 mg/kg.

Nethod: 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.

Vulagenicity assessment In vitro and in vivo experiments, no evidence of mutagenic effects,

literature.

Cardinogenially 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

Toxidiy to fish LC50 (Brachydanio rerio): > 10000 mg/l / 96 h

Metro: OECD 203

Toxicity to daplinia EC50 Dachmia magna. > 10000 mg/l / 24 h

Metros: 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, TiO<sub>2</sub>, Al<sub>2</sub>O<sub>3</sub>, ZnO, SiO<sub>2</sub>
- Volume estimated >> 10 t: CeO<sub>2</sub>

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

## **Summary**



- 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.