WHO GUIDELINES ON PROTECTING WORKERS FROM POTENTIAL RISKS OF MANUFACTURED NANOMATERIALS

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Why WHO guidelines for MNM exposure?

- MNMs have new physicochemical properties that are not tested sufficiently for possible health hazards
- Some of the physical properties are more clearly related to toxic effects than others; for example a rigid long fibre structure such as in carbonnanotubes (CNTs)
- It is generally recommended to take a precautionary approach until testing results are available.
- This means that MNMs should be considered as hazardous unless there is clear proof that they are not.

WHO guideline process

- Since 2007 evidence-based to increase transparency
- Starts with key questions; NOT handbook
- Answers based on systematic reviews of the literature
- Recommendations based on evidence, values, feasibility
- Recommendations for policy makers, OSH experts, or employers and employees
- Recommendations can be strong (everybody should do this) or conditional (can be adapted according to local context)

Guiding principles

- Precautionary approach
  - Take measures in absence of good knowledge on magnitude of risks
- Hierarchy of controls
  - Eliminate hazard/Substitute
    - e.g. from powder to granules
  - Engineering controls: ventilation
  - Personal Protective Equipment

Best practices

- Workers should always be educated and trained
- Workers should always be involved in risk assessment and control
- For hazard assessment MNMs can be best grouped:
  - MNMs that are fibres such as CNTs
  - MNMs with specific toxicity such as Cadmium NP releasing Cadmium ions
  - MNMs that are granular biopersistent particles such as carbon black

Recommendations

1. Assess health hazards of MNMs
2. Assess exposure to MNMs
3. Control exposure to MNMs
4. Health surveillance should be in place
5. Training and involvement of workers is needed

1. Assess health hazards

1. Assign hazard classes to all MNMs according to the ***Globally Harmonized System of Classification and Labelling of Chemicals*** (GHS) for use in safety data sheets. For a limited number of MNMs this information is made available in these guidelines.
2. Update ***safety data sheets with MNM-specific hazard information*** or indicate which toxicological end-points did not have adequate testing available.
3. For the respirable fibres and granular biopersistent particles' groups, use the available classification of MNMs for ***provisional classification of nanomaterials of the same group***.

Material Safety Data Sheet

acc. to OSHA and ANSI

1 - Identification of substance:

Chemical Name: Carbon Nanotubes
Formula: Carbon
Chemical Family: Carbon Nanotubes
Synonyms: Single Walled, Double Walled, Thin Walled, M
CNTs, SWNTs, DWNTs, TWNTs, MWNTs
CAS Number:

- **Manufacturer/Supplier:**

Cheap Tubes Inc.
3992 Rte 121 E #3
Cambridgeport, VT 05141

(802) 869-5555

Components with limit values that require monitoring at the workplace:

Graphite

	mg/m3
ACGIH TLV	2
Belgium TWA	2.5
Finland TWA	5
France VME	2
Germany MAK	6
Ireland TWA	5
Korea TLV	2
Netherlands MAC-TGG	2
Poland TWA	2
Sweden NGV	5 (dust)
Switzerland MAK-W	2.5
United Kingdom	5-LTEL
USA PEL	15 mppcf

Additional information: No data

Category	Study Reference	Nanomaterials and specifications	OEL Name	Mass concentration µg/m^3
Carbon	Pauluhn (2010)	Multi-walled carbon nanotubes, MWCNT Baytubes®	nano-OEL, inhalable fraction	50
Carbon	Stone (2009)	MWCNT	DNEL chronic inhalation, systemic immune effect	0.67
Carbon	NIOSH (2013)	All carbon nanotubes and nanofibers	REL respirable elemental carbon	<1

TABLE 2. CLASSIFICATION OF HAZARDOUS PROPERTIES OF NANOMATERIALS (MNMS) THAT HAVE AN EXISTING OECD DOSSIER

MNM	Acute toxicity	Skin corrosion/ irritation	Serious eye damage/eye irritation	Respiratory or skin sensitization	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Specific target organ toxicity (single exposure)	Specific target organ toxicity (repeated exposure)
Fullerene (C_{60})	No[a]	No	No	No	No	No data[b]	No data	No data	No
SWCNT	No	No	No	No	Cat 2B[c] (L)[d]	No data IARC[e] 3	No data	No data	Cat 1 (L)
MWCNT	No	No	Cat 2A (H)[g]	No	Cat 2 (H)	MWCNT–7: Cat 2 (M)[f], IARC 2B Other MWCNTs: IARC 3	No	No data	Cat 1 (M)
AgNP	No	No	No	Cat 1B (M)	No	No data	No	No data	Cat 1 inhalation (H) Cat 2 oral (H)
AuNP	No data	No data	No data	No data	No data	No data	No data	No data	Cat 1 inhalation (H)
SiO_2	No	No	No	No	No	No data	No	No data	Cat 2 inhalation (H)
TiO_2	No	No	No	No	No	No data; IARC 2B	Cat 2 (L)	No data	Cat 1 inhalation (H)
CeO_2	No	No data	No data	No data	No data	No data	No data	No data	Cat 1 inhalation (M)
Dendrimer	No data	No data	No data	No data	No data	No data	No data	No data	No data
Nanoclay	No data	No data	No data	No data	No data	No data	No data	No data	No data
ZnO	No	No	No	No data	No	No data	No	No data	Cat 1 inhalation (M)

AgNP: silver nanoparticles; AuNP: gold nanoparticles; CeO_2: cerium dioxide; MWCNT: multi-walled carbon nanotubes; SiO_2: silicon dioxide; SWCNT: single-walled carbon nanotubes; TiO_2: titanium dioxide; ZnO: zinc oxide.

[a] No: no hazard class assigned based on data.

[b] No data: no studies available in OECD dossier.

[c] GHS categories: Cat 1 usually implies serious and/or irreversible damage; Cat 2 milder or reversible damage. Within a category A implies more serious and B milder damage.

[d] L: low level of evidence.

[e] IARC refers to the International Agency for Research on Cancer categories of confidence in carcinogenicity: IARC Cat 2B = possibly carcinogenic; IARC Cat 3 = not enough evidence to draw conclusion.

[f] M: moderate level of evidence.

[g] H: high level of evidence.

2. Assess exposure

1. Assess workers' exposure in workplaces with methods similar to those used for the proposed specific occupational exposure limit (OEL) value of the MNM.
2. Assess whether workplace exposure exceeds a proposed OEL value for the MNM. A list of proposed OEL values is provided in Annex 1 of these guidelines.
3. If specific OELs for MNMs are not available in workplaces, use a stepwise approach for inhalation exposure. For dermal exposure assessment, there was insufficient evidence to recommend one method of dermal exposure assessment over another.

OELs

Category	Study reference	MNM and specs	OEL name	Mass concentr. µg/m³	Particle concentr. (particle/ml, fibres/cm³)	Surface concentr. (nm²/cm³)	Derivation approach
Inhalation exposure: general MNM approach							
MNM	Guidotti 2010	Particles ≤ 2500 nm	BOEL	30	ND	ND	Environmental
MNM	McGarry 2013	Airborne particles from NT processes	PCVs	ND	3 times LBPC for more than 30 minutes	ND	Environmental
Inhalation exposure: categorical MNM approach							
CMAR	BSI 2007	CMAR nanomaterials, NM	BEL	0.1 × bulk WEL	ND	ND	Bridging
Fibres	AGS 2013	Non-entangled fibrous NM	Acceptance level, respirable fraction	ND	0.01	ND	Bridging/ grouping
Fibres	BSI 2007	Fibrous NM	BEL	ND	0.01	ND	Bridging/ grouping
Fibres	Stockmann-Juvala 2014	Carbon nanofibres	OEL	ND	0.01	ND	Bridging/ grouping

3. Control exposure

1. Focus control of exposure on preventing inhalation exposure with the aim of reducing it as much as possible
   - especially during cleaning and maintenance, collecting material from reaction vessels and feeding MNMs into the production process.
   - In the absence of toxicological information, implement the highest level of controls to prevent workers from any exposure. When more information is available, take a more tailored approach.
2. Use the principle of hierarchy of controls

3. Control exposure

1. Prevent ***dermal exposure*** by occupational hygiene measures such as surface cleaning and the use of appropriate gloves.

2. When assessment and measurement by a workplace safety expert is not available, ***use control banding*** for nanomaterials to select exposure control measures in the workplace.

4. Other recommendations

1. Health surveillance: no nano-specific recommendations

2. Worker training and involvement: no nano-specific recommendations. Good training materials available for MNMs. (e.g Kulinowski NIHS US 2011)

Questions for breakouts

1 Can you provide examples of how you can implement these guidelines in your organization?

2 Which recommendations do you consider most important to be implemented?

3 What is needed most for implementation? (e.g information, expert training, financial support, local OEL)

4 Is the current occupational health infrastructure sufficient to deal with MNM problems?

5 Should there be additional regulation specifically aimed at containment of potential risks of MNMs?

Implementation Objectives

1) Improving accessibility to the guidelines (translation)

2) Providing instruments for policy-makers (OELs)

3) Providing practical guidance for occupational safety and health experts (Safety Data Sheets)

4) Providing examples of good practices for employers and employees (Guidance)

5) Joining efforts to achieve these objectives with other international bodies such as OECD and UNITAR (Guidance and training sessions)

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