Committee of Experts on the Transport of Dangerous Goods
and on the Globally Harmonized System of Classification
and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals   **20 November 2012**

Twenty–fourth session
Geneva, 12 – 14 December 2012
Item 4 (a) of the provisional agenda
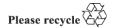**Implementation of the GHS:**
Implementation issues

Classification of carbon nanotubes as hazardous chemicals

Transmitted by the expert from Australia

Background

1.   Australia is implementing the third revised edition of the GHS through the model Work Health and Safety legislation, with a 5-year implementation period until 31 December 2016. Consistent with the principle of self-classification, the Work Health and Safety regulations require manufacturers and importers to classify chemicals according to the GHS classification criteria.

2.   Australia provided papers on nanomaterials and safety data sheets to the December 2009 and December 2010 meetings of the Sub-Committee (ST/SG/AC.10/C.4/2009/11 and ST/SG/AC.10/C.4/2010/19). The issues raised have subsequently been considered by the Correspondence Group on the revision of Section 9 of Annex 4 to the GHS.

3.   The potential for carbon nanotubes (CNTs) to be hazardous to health if inhaled has been extensively reported. In December 2010 the United States National Institute for Occupational Safety and Health (NIOSH) proposed a Recommended Exposure Limit of $7\mu g/m^3$ for carbon nanofibres, including CNTs, determined as elemental carbon by NIOSH Method 5040[1].

4.   To help manufacturers and importers classify CNTs, Safe Work Australia commissioned the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to assemble and review the available toxicological data and to undertake a formal human health hazard assessment. NICNAS provided a recommended classification of CNTs under the GHS criteria. NICNAS is an authoritative government body for hazard assessment of chemicals in Australia.

5.   **This study demonstrates how a classification may be performed for emerging materials where not all hazards are fully known or established, using a precautionary approach.**

---

[1] Draft Document for Public Review and Comment. NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers, December 2010.

Classification

6.   NICNAS predominantly used reviews and journal articles on CNTs published in the international research literature from January 2007 to the end of June 2010 to determine the health hazards. In addition, a few key articles post June 2010 were included during document review and revision.

7.   The findings and a recommended classification of CNTs are reported in *Human Health Hazard Assessment and Classification of Carbon Nanotubes,* published by Safe Work Australia with an associated Information Sheet *Classification of Carbon Nanotubes as Hazardous Chemicals.*[2]

8.   Classification was undertaken against all health hazard endpoints according to both the third revised edition of the GHS and Australia's previous criteria, the *Approved criteria for classifying hazardous substances,* which is being replaced by the GHS criteria but may still be used during the regulatory transition period. The following approach was used to describe the recommended classification based on the information available for each health endpoint:

- **Not classified as hazardous** - OECD test guideline studies and/or other suitable scientific data acceptable for regulatory decision making are available for single-walled carbon nanotubes (SWCNTs)/single-walled carbon nanohorns (SWCNHs) and/or multi-walled carbon nanotubes (MWCNTs), however the data do not meet the criteria for classification;

- **Cannot be classified** - Guideline studies or other suitable scientific data acceptable for regulatory decision making (i.e. administration route relevant for human exposure) are not available for SWCNTs/SWCNHs or MWCNTs, or the available data are not sufficient to make a classification decision;

- **Classified as hazardous** – At least one guideline toxicity study or other suitable data for SWCNTs/SWCNHs and/or MWCNTs are available for which the outcomes meet the criteria for classification.

9.   A summary of the recommended GHS classifications is given in Table 1 below.

Table 1: Summary of recommended classifications - for both MWCNTs and SWCNTs

Classification recommended	Health hazard end point
Classified as hazardous	Carcinogenicity: Category 2 Specific target organ toxicity - repeated exposure: Category 2
Not classified as hazardous	Acute toxicity: Oral, Dermal Serious eye irritation Skin irritation Skin sensitisation Specific target organ toxicity - single exposure
Cannot be classified	Acute toxicity: Inhalation Respiratory sensitisation Germ cell mutagenicity Reproductive toxicity

---

[2] http://www.safeworkaustralia.gov.au/sites/SWA/AboutSafeWorkAustralia/Whatwedo/Publications/Pages/Human-Health-Hazard-Assessment-and-Classification-of-Carbon-Nanotubes.aspx

GHS carcinogenicity classification

10. The hazard assessment noted that MWCNTs have been shown to induce mesothelioma in rodents after a single intraperitoneal or intrascrotal exposure and that the carcinogenic potential of CNTs is not solely determined by the length of the individual carbon nanotubes, but by their ability to present as a fibre with pathogenic dimensions, either as an individual fibre or through aggregation.

11. Based on the limited data available on mesothelioma formation in animal studies and difficulty in conclusively determining whether a specific MWCNT can present as a fibre of pathogenic dimensions, the report recommends that all MWCNTs should be considered as hazardous and classified for carcinogenicity as follows:

   • **Classification**: Carcinogenicity: Category 2

   • **Hazard statement**: H351 Suspected of causing cancer

12. The report notes that there are no studies demonstrating that SWCNTs cause mesothelioma. Neither is there evidence to suggest SWCNTs will behave differently to MWCNTs with respect to the potential to form granulomas or mesotheliomas given they have been shown to be durable and have shown to elicit a fibre pathogenic response through the ability to form rigid fibre-like structures through aggregation inside the body. Hence the report considers it is prudent to take a precautionary approach and also apply the recommended classification for MWCNTs to SWCNTs.

GHS Specific target organ toxicity - repeated exposure classification

13. The NICNAS assessment noted two 90-day repeat dose inhalation toxicity studies in rodents showed that MWCNTs can cause fibrosis and granulomas at very low doses. The adverse effects are likely due to lung overload, but the doses at which these effects were observed are significantly below the classification cut-off concentrations. This can therefore be considered to be an intrinsic property of these particles. Hence, the report considers that inhaling MWCNTs repeatedly, even at very low doses, could be harmful to humans and MWCNTs should be classified for repeated or prolonged inhalation exposure:

   • **Classification**: Specific target organ toxicity - repeated exposure: Category 2

   • **Hazard statement**: H373 May cause damage to lungs/respiratory system through prolonged or repeated inhalation exposure

14. Although there are no supportive data for SWCNTs, given the adverse effects have been postulated due to lung overloading, SWCNTs are not expected to behave differently to MWCNTs. Therefore, the report recommends that the above classification should also be applied on a precautionary basis to SWCNTs until data to the contrary become available, particularly as the applicability of the pathogenic fibre hypothesis to granuloma and fibrosis induction is not clear.

15. The report noted that the toxicological properties of CNTs may vary due to a number of factors; impurities and their concentrations, dimensions, state (agglomerated/aggregated or dispersed) and surface functionality. It recommends that when specific toxicity data are available, a case-by-case hazard assessment of CNTs is undertaken.

Proposal

16. That the Sub-Committee notes the recommended classification of CNTs by the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS).